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Agency

Prevention, Pesticides  
and Toxic Substances  
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# Interim Reregistration Eligibility Decision (IRED)

## Fenamiphos



# Fenamiphos Facts

EPA has assessed the risks of fenamiphos and prepared an Interim Reregistration Eligibility Decision (IREED) document for this organophosphate (OP) pesticide. The IRED identifies risk mitigation measures needed to reduce risk, as well as data needed to better characterize risks. The sole registrant, Bayer Corporation, has requested voluntary cancellation of all existing fenamiphos registrations rather than committing to develop additional data.

Used on variety of vegetables and fruits, fenamiphos residues in food do not pose risk concerns. However, exposure to drinking water sources from shallow water tables (less than 50 feet deep) and extremely vulnerable soils do pose risk concerns. Extremely vulnerable soils are defined as, "hydrologic soil group A soils that are excessively drained and predominantly sand or loamy sand such as soils in the suborder psamments." These classifications and soil taxonomy refer to USDA definitions. Therefore, all use of fenamiphos in areas with extremely vulnerable soils and shallow water tables will be phased out by May 31, 2005. Use on all other soils will cease effective as of May 31, 2007.

Fenamiphos is not used in a residential setting. There is, however, use on turf including golf course turf, which could lead to golfer exposure from residues on treated courses. Nevertheless, the Agency believes that the watering-in of fenamiphos adequately protects golfers. Implementation of risk mitigation during the phase out, negotiated between the registrant and the Agency, is expected to decrease the risks associated with fenamiphos.

EPA's next step under the Food Quality Protection Act (FQPA) is to consider available information on the cumulative risk of the OP

## The OP Pilot Public Participation Process

The organophosphates (OPs) are a group of related pesticides that affect the functioning of the nervous system. They are among EPA's highest priority for review in implementing provisions of the Food Quality Protection Act (FQPA) of 1996.

EPA encourages the public to participate in the review of the OP pesticides. Through a six-phased pilot public participation process, the Agency has released 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](http://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. (Please see [www.epa.gov/pesticides/cumulative.htm](http://www.epa.gov/pesticides/cumulative.htm).)

pesticides, which share a common mechanism of toxicity. The tolerance reassessment decision for fenamiphos cannot be considered final until the cumulative risks of the OPs are considered.

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. OPs require decisions about their eligibility for reregistration under FIFRA. OPs with food, drinking water, residential, and any other non-occupational exposures must be reassessed to make sure they meet the new FFDCSA safety standard, brought about by the Food Quality Protection Act (FQPA) of 1996.

The fenamiphos interim decision was made through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in EPA's development of risk assessments and risk management decisions. EPA worked extensively with affected parties to reach the decisions presented in the IRED document. The agreement on the voluntary cancellation, based on the registrant's decision not to develop data that were an essential part of the risk mitigation proposal, concludes the OP pilot process for fenamiphos.

### **Uses**

- A nematicide and an insecticide, fenamiphos is used primarily to control nematodes and thrips on various agricultural crops (i.e., citrus, grapes, peanuts, pineapples, tobacco, etc.) and non-agricultural (i.e., turf and ornamentals) sites. Additionally, all uses are soil incorporated, except for the pineapple use. There are no residential uses for fenamiphos.
- Annual domestic use is low-- approximately 780,000 pounds of active ingredient per year.
- Fenamiphos is a Restricted Use Pesticide (RUP) due to high acute toxicity and toxicity to wildlife.

### **Health Effects**

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

### **Risks**

- Dietary (acute and chronic) exposures from eating commodities treated with fenamiphos are below the Agency's level of concern for the entire U.S. population, including infants and children.
- Dietary (drinking water) exposures are generally not of concern for surface and ground water sources in soils that are not extremely vulnerable. However, exposure to shallow ground water sources of drinking water associated with soils that are extremely vulnerable exceed the Agency's level of concern.

- EPA has risk concerns for workers who mix, load, and/or apply fenamiphos to agricultural sites and golf courses.
- Acute and chronic risks exceed the Agency's level of concern for terrestrial, aquatic, and endangered species.

### **Risk Mitigation**

The registrant has requested voluntary cancellation of existing fenamiphos product registrations.

- The registrant has agreed to cancel use, and formulation for use, of all of its existing fenamiphos registrations in areas with extremely vulnerable soils and shallow water tables effective as of May 31, 2005. Cancellation for use on all other soils will be effective as of May 31, 2007.
- All sale, distribution and use of existing stocks shall be prohibited for manufacturing and end-use products, effective as of May 31, 2007.
- Sale and distribution of existing stocks by persons other than the registrant may continue until May 31, 2008.
- Revised labels for all fenamiphos products have been submitted to the Agency in accordance with the registrant's request for an amendment of all of its existing registrations. Use of stocks in the channels of trade may continue until depleted, except where prohibited by the revised labels.
- The registrant has also agreed to produce no more than 500,000 pounds of fenamiphos manufacturing use products for use in the United States the first year of the phase out which ends May 31, 2003. Each subsequent year of the 5 year phase out, production will be reduced by 20% of the previous year's production.

### **Next Steps**

- Numerous opportunities for public comment were offered as this decision was being developed. The fenamiphos IRED is being issued in final (see [www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op) or [www.epa.gov/pesticides/reregistration/status.htm](http://www.epa.gov/pesticides/reregistration/status.htm)), without a formal public comment period. However, the docket remains open, and any comments submitted in the future will be placed in this public docket.
- A Notice of Availability for this interim RED for fenamiphos will be published in the *Federal Register*. A copy of the interim RED and all supporting documents are available on the Agency's website at <http://www.epa.gov/pesticides/op/fenamiphos.htm>.
- A 6(f) Notice for fenamiphos will be published in the *Federal Register* announcing receipt of request from the registrant to voluntarily cancel fenamiphos.



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 (OP) fenamiphos. 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 September 14, 1999. Additionally, the Agency held a Technical Briefing on September 2, 1999, where the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee, and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on September 10, 1999 and closed on November 15, 1999.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of fenamiphos. The EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of fenamiphos and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for fenamiphos will be finalized once the cumulative risks for all of the organophosphate pesticides are considered. The enclosed "Interim Reregistration Eligibility Decision for Fenamiphos," which was approved on March 31, 2002, contains the Agency's decision on the individual chemical fenamiphos.

A Notice of Availability for this Interim Reregistration Eligibility Decision (interim RED) for fenamiphos is being published in the *Federal Register*. To obtain a copy of the interim RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 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 at <http://www.epa.gov/pesticides/op/fenamiphos.htm>.

The interim RED is based on the updated technical information found in the fenamiphos 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 fenamiphos (revised as of September 2, 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 fenamiphos, a proposal was submitted by Bayer Corporation, the only registrant. Comments on mitigation or mitigation suggestions were submitted by the registrant, academia, various industry stakeholders and the public.

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 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 fenamiphos risk assessment and the attached interim RED concern only this particular organophosphate. This interim RED presents the Agency's conclusions on the dietary risks posed by exposure to fenamiphos alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of fenamiphos. 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 considering the risks for the individual organophosphates. The Agency is working towards completion of a methodology to assess cumulative risk and the individual risk assessments for each organophosphate are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks associated with the current uses of fenamiphos. The Agency will issue the final tolerance reassessment decision for fenamiphos and finalize decisions on reregistration eligibility once the cumulative risks for all of the organophosphates are considered.

For reference purposes, this document contains a description of further generic and/or product-specific data requirements for fenamiphos. EPA will collect these data via a Data Call-In (DCI), which is being sent to registrants under separate cover. Additionally, 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.

In this interim RED, the Agency has determined that fenamiphos will be eligible for reregistration provided all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of fenamiphos may pose unreasonable adverse effects to human health and

the environment, and that such effects can be mitigated with the risk mitigation measures identified in this interim RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this interim RED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this interim RED.

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

The Agency understands that the technical registrant, Bayer Corporation, intends to request voluntarily cancellation of all fenamiphos registrations consistent with a phase out schedule amenable to the Agency. Once the request for voluntary cancellation is received by the Agency, the terms and conditions of the cancellation will be established in a separate document. If Bayer Corporation does not submit a request for voluntary cancellation, Bayer will need to satisfy the measures described in this interim RED in order for fenamiphos to be eligible for reregistration.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Tawanda M. Spears at (703) 308-8050. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Bonnie Adler at (703) 308-8523.

Sincerely,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

Attachment

**Interim Reregistration Eligibility Decision  
for  
Fenamiphos**

**Case No. 0333**



## TABLE OF CONTENTS

Executive Summary .....	1
<b>I. Introduction .....</b>	<b>6</b>
<b>II. Chemical Overview .....</b>	<b>8</b>
<b>A. Regulatory History .....</b>	<b>8</b>
<b>B. Chemical Identification .....</b>	<b>8</b>
<b>C. Use Profile .....</b>	<b>9</b>
<b>D. Estimated Usage of Pesticide .....</b>	<b>11</b>
<b>III. Summary of Fenamiphos Risk Assessment .....</b>	<b>12</b>
<b>A. Human Health Risk Assessment .....</b>	<b>12</b>
<b>1. Dietary Risk from Food .....</b>	<b>13</b>
<b>a. Toxicity .....</b>	<b>13</b>
<b>b. FQPA Safety Factor .....</b>	<b>13</b>
<b>c. Population Adjusted Dose (PAD) .....</b>	<b>14</b>
<b>d. Toxicological Endpoints .....</b>	<b>14</b>
<b>e. Exposure Assumptions .....</b>	<b>14</b>
<b>f. Food Risk Characterization .....</b>	<b>15</b>
<b>2. Dietary Risk from Drinking Water .....</b>	<b>15</b>
<b>a. Surface Water .....</b>	<b>16</b>
<b>1) Surface Water Modeling .....</b>	<b>17</b>
<b>2) Surface Water Monitoring .....</b>	<b>17</b>
<b>b. Ground Water .....</b>	<b>18</b>
<b>1) Ground Water Monitoring .....</b>	<b>18</b>
<b>3. Drinking Water Levels of Comparison (DWLOCs) .....</b>	<b>21</b>
<b>4. Residential/Recreational (Golfer) Risk .....</b>	<b>22</b>
<b>5. Aggregate Risks .....</b>	<b>23</b>
<b>6. Occupational Risk .....</b>	<b>23</b>
<b>a. Toxicity .....</b>	<b>24</b>
<b>b. Exposure .....</b>	<b>25</b>
<b>c. Occupational Handler Risk Summary .....</b>	<b>26</b>
<b>1) Agricultural Handler Risk .....</b>	<b>27</b>
<b>2) Hand-held Equipment Golf Course Assessment .....</b>	<b>29</b>
<b>3) Post-Application Worker Risk .....</b>	<b>29</b>
<b>7. Human Incident Reports .....</b>	<b>30</b>
<b>B. Environmental Risk Assessment .....</b>	<b>31</b>
<b>1. Environmental Fate and Transport .....</b>	<b>32</b>
<b>2. Risk to Birds and Mammals .....</b>	<b>32</b>
<b>a. Toxicity (Hazard) Assessment .....</b>	<b>32</b>
<b>b. Exposure and Risk .....</b>	<b>33</b>
<b>3. Risk to Aquatic Species .....</b>	<b>35</b>
<b>a. Toxicity (Hazard) Assessment .....</b>	<b>35</b>

b.	Exposure and Risk .....	36
4.	Risks to Plants and Insects .....	37
a.	Toxicity and Exposure to Terrestrial Plants .....	37
b.	Toxicity and Exposure to Beneficial Insects .....	37
5.	Incident Reports .....	38
6.	Endangered Species .....	38
<b>IV.</b>	<b>Interim Risk Management and Reregistration Decision .....</b>	<b>39</b>
<b>A.</b>	<b>Determination of Interim Reregistration Eligibility .....</b>	<b>39</b>
<b>B.</b>	<b>Summary of Phase 5 Comments and Responses .....</b>	<b>40</b>
<b>C.</b>	<b>Regulatory Position .....</b>	<b>42</b>
1.	FQPA Assessment .....	42
a.	“Risk Cup” Determination .....	42
b.	Tolerance Summary .....	42
c.	Codex Harmonization .....	46
d.	Residue Analytical Methods .....	47
2.	Endocrine Disruptor Effects .....	48
3.	Benefits .....	48
4.	Labels .....	50
<b>D.</b>	<b>Regulatory Rationale .....</b>	<b>51</b>
1.	Human Health Risk Mitigation .....	51
a.	Dietary Mitigation .....	51
1)	Acute Dietary (Food) .....	51
2)	Chronic Dietary (Food) .....	51
3)	Drinking Water .....	51
4)	Residential/Recreational (Golfer) .....	54
5)	Aggregate .....	54
b.	Occupational Risk Mitigation .....	54
1)	Agricultural Uses .....	54
2)	Postapplication Risk Mitigation .....	56
2.	Environmental Risk Mitigation .....	56
a.	Avian and Mammalian Species Mitigation .....	56
b.	Aquatic Species Mitigation .....	57
<b>E.</b>	<b>Other Labeling .....</b>	<b>57</b>
1.	Endangered Species Statement .....	57
2.	Spray Drift Management .....	57
<b>V.</b>	<b>What Registrants Need to Do .....</b>	<b>59</b>
<b>A.</b>	<b>Manufacturing Use Products .....</b>	<b>60</b>
1.	Additional Generic Data Requirements .....	60
2.	Labeling for Manufacturing Use Products .....	61
<b>B.</b>	<b>End-Use Products .....</b>	<b>61</b>
1.	Additional Product-Specific Data Requirements .....	61
2.	Labeling for End-Use Products .....	61
<b>C.</b>	<b>Existing Stocks .....</b>	<b>61</b>

<b>D. Required Labeling Changes Summary Table</b> .....	62
<b>VI. Related Documents and How to Access Them</b> .....	71
<b>VII. Appendices</b> .....	72
<b>Appendix A. Table of Use Pattern Eligible for Reregistration</b> .....	73
<b>Appendix B. Table of Generic Data Requirements and Data Supporting Guideline Requirements for the Reregistration Decision</b> .....	82
<b>Appendix C. List of Available Technical Support Documents</b> .....	88
<b>Appendix D. Bibliography</b> .....	90

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## GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWEL	Drinking Water Equivalent Level. The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory. The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir

LC <sub>50</sub>	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 <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal. The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	(USGS) National Water Quality Assessment
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	(EPA) Office of Pesticide Programs
OPPTS(EPA)	Office of Prevention, Pesticides and Toxic Substances
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	(USDA) Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million

PRN	Pesticide Registration Notice
PRZM/ EXAMS	Pesticide Root Zone Model and Exposure Analysis Modeling System, which is a Tier II Surface Water Computer Model
Q <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. Concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

## Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decision for fenamiphos. Although the Agency has not yet considered cumulative risks for the organophosphates, the Agency has determined that fenamiphos is eligible for reregistration provided: (i) the use of fenamiphos on extremely vulnerable soils is phased out by May 31, 2005 (continued use on such soils would result in acute and chronic dietary risks, due to drinking water, which are inconsistent with the Food Quality Protection Act of 1996); (ii) current data gaps for use on other soils are addressed; (iii) the risk mitigation measures outlined in this document are adopted to reduce risk from other uses and label amendments are made to reflect these measures; and (iv) cumulative risks considered for the organophosphates support a final reregistration eligibility decision.

The decisions outlined in this document do not include the final tolerance reassessment decision for fenamiphos, however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment (see below). The final tolerance reassessment decision for this chemical will be issued once the cumulative risks for all of the organophosphates are considered. The Agency may need to pursue further risk management measures for fenamiphos once cumulative risks are considered.

The revised human health and environmental risk assessments are based on review of the database supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on fenamiphos. After considering the revised risks, as well as mitigation proposed by Bayer Corporation, and comments and mitigation suggestions from other interested parties (such as the State of Florida, the National Golf Course Superintendents Association, several independent golf courses, and a number of grower groups), EPA developed its risk management decision that is discussed fully in this document.

Fenamiphos is an organophosphate nematicide/insecticide used on a variety of nematodes, thrips, aphids, beetles, root weevils, and root borers. It was first registered in 1972 for at-plant control of nematodes in annual field and vegetable crops or in established perennial, deciduous and tropical fruit crops. In 1994, the Agency provided preliminary risk assessments to the registrant and discussed its concerns about numerous wildlife incident reports. After these discussions, the registrant voluntarily implemented various risk mitigation measures, including use restrictions and rate reductions, to reduce certain risks identified in the risk assessments.

The revised risk assessments discussed in this decision document are based on current product labels, which reflect the various changes made to the labels from 1994 to 1996. Use data from 1990 to 1998 indicate an average domestic use of approximately 780,000 lbs a.i. per year.



## Dietary Risk

The acute dietary (food) risk estimate is below the Agency's level of concern for the general U.S. population and all population subgroups. Infants (younger than one year of age), the most highly exposed subpopulation, are expected to be exposed to fenamiphos at a level less than or equal to 1% of the aPAD. The chronic dietary risk estimate is also below the Agency's level of concern for the general population and all population subgroups. The exposure is estimated to be equal to or less than 1% of the cPAD for all population subgroups including infants and children (from 1 to 6 years of age), the most highly exposed subpopulation.

In calculating risks to populations drinking ground water, the Agency's assessment found that the expected concentrations of fenamiphos in drinking water will vary depending on the type of soil and depth to ground water. When soils are extremely vulnerable and the groundwater is shallow, fenamiphos is expected to rapidly leach into ground water. As the soils become less vulnerable, the expected concentrations drop. For the purposes of this assessment the Agency has established two distinct categories of soil types: extremely vulnerable and vulnerable. The vulnerable category is expected to portray worst-case exposure for all soil types that are not extremely vulnerable. The extremely vulnerable category contains those soils classified as hydrologic soil group A soils that are excessively drained and predominately sand or loamy sand and where the ground water table is less than 50 feet deep. The Central Ridge of Florida is an example of an area where the soil would be classified extremely vulnerable.

Dietary risks from residues on food combined with residues in drinking water are a concern for people who rely on ground water sources of drinking water in areas where fenamiphos is used on extremely vulnerable soils. In these areas, for both acute and chronic risk, the expected environmental concentrations (EECs) in drinking water are substantially higher than the drinking water levels of concern. Using turf as an example, the Agency found that the acute EEC is 425 ppb and the chronic EEC is 45 ppb, while the acute drinking water level of concern (DWLOC) is 12 ppb and the chronic DWLOC is 1 ppb. The Agency believes that the potential risk to the public from the use of fenamiphos on extremely vulnerable soils is unreasonable and inconsistent with the Food Quality Protection Act (FQPA). Therefore, these uses will be phased out by May 31, 2005.

The Agency believes risks are not of concern for those drinking groundwater in areas with soils that are not extremely vulnerable or those drinking from surface water sources. In these areas, for both acute and chronic risk, the EECs in drinking water are lower than the DWLOCs. Because there is some uncertainty in the database, the Agency will be issuing a DCI to require additional data to confirm its exposure conclusions for vulnerable soils.

## Residential (Golfer) Risk

Although fenamiphos is not used in a residential setting, golfers may be exposed to fenamiphos while playing on courses that have been treated with fenamiphos. Because fenamiphos is watered-in on golf courses, the Agency believes any residual pesticide does not pose an exposure or

risk concern for golfers and that no additional mitigation is needed at this time. The Agency will be issuing a DCI requiring additional data to confirm these conclusions.

### Aggregate Risk

An aggregate risk assessment looks at combined exposure from dietary (food and drinking water routes) and residential or non-occupational sources, when appropriate. For fenamiphos, an aggregate assessment would include dietary and golfer exposure. As discussed in the Dietary Risk section above, the risk estimates are below the Agency's level of concern for all populations exposed to combined fenamiphos residues from food and drinking water, provided the population is not drinking water obtained from ground water sources in areas with extremely vulnerable soils. The risks to golfers cannot be quantitatively included in the aggregate risk assessment at this time as the data are not sufficient or robust enough to allow this calculation. The Agency believes that this exposure is not significant and that its inclusion in the aggregate risk assessment would not change the conclusions of the aggregate risk assessment.

### Occupational Risk

The Agency's occupational risk findings show that many fenamiphos uses do not pose risks of concern (i.e., MOEs are greater than 100). Some uses, however, pose occupational risks exceeding the Agency's level of concern for certain handlers and workers. The Agency has worked with the registrant and user community to explore ways of reducing occupational risks in general and believes many of the measures agreed to by the registrant will reduce the occupational risk to levels not of concern. In some cases, however, the Agency's risk estimates show that certain handlers remain at risk levels higher than the Agency's risk reduction objectives.

The Agency assessment shows that, after mitigation, the use of the granular product does not pose a risk of concern to workers for any crop other than loading and applying by push spreader on turf. For workers using a push spreaders, the MOE is 28. All granular MOEs were calculated assuming that the worker was wearing an organic vapor-removing respirator. To mitigate risks to these levels, the following measures are necessary: limiting the amount of active ingredient a single worker can handle to 50 lb ai/day for turf uses and prohibiting body-mounted or hand-held application equipment.

For mixer/loaders and applicators using liquid fenamiphos, MOEs are of concern (less than 100) for several different crops. Of the MOEs of concern for agricultural products, all are above 50, with the majority between 65 and 75. For turf, the MOEs are 37 for mixer/loaders and 53 for applicators using groundboom equipment with closed systems and enclosed cabs. To mitigate risks to workers using the liquid formulation, the following measures are necessary: closed mixing/loading systems and application by enclosed cab, reduced application rates for various crops, and limit the amount of active ingredient a single worker can handle to 200 lbs ai/day for turf uses.

Although these measures lessen the exposure for workers using fenamiphos products, the MOEs for some mixer/loader and applicators are still less than 100. Because there are significant

benefits from the uses of fenamiphos on turf, as discussed below, the Agency has determined that additional mitigation of occupational risk is not necessary at this time.

### Environmental Risk

The fenamiphos ecological assessment indicates that virtually all uses at maximum application rates result in risks that exceed both the high acute and chronic risk levels of concern for terrestrial, aquatic, and endangered species. Fenamiphos is either soil incorporated or watered-in, which may reduce potential exposures to wildlife; however, because of its high toxicity, small amounts pose a high risk to sensitive species. Incident data support this conclusion, as fish and bird kill incident reports indicate losses of wildlife directly attributable to fenamiphos. The implementation of earlier mitigation measures, such as lowering application rates to minimize runoff potential, may be helping to reduce these types of incidents.

Research shows that fenamiphos must be applied at application rates outlined in this interim RED for the pesticide to be efficacious. Therefore, the Agency is unable to further reduce these rates to be more protective of avian and mammalian species. In addition to rate reductions on other crops proposed in this document, the Agency is also proposing additional label changes to reduce exposure, including: cancellation of cotton use and granular use on pineapples; reducing maximum seasonal application rates for several crops; requiring more rapid watering in when irrigation is used to incorporate fenamiphos; and restrictions on time of day applied during thunderstorm season to limit the potential for runoff. Some of these measures are already on existing labels, but they must be expanded to additional uses (as specified below) in order for fenamiphos to be eligible for reregistration.

Although these measures may somewhat reduce fenamiphos exposure to aquatic and terrestrial species, they are not expected to reduce it to levels that are not of concern to the Agency. However, because there are significant benefits from the use of fenamiphos (see below), the Agency is not proposing additional action at this time.

### Benefits

Fenamiphos is one of only a handful of effective nematicides left for use in agriculture. It provides effective control of many important plant parasitic nematodes and several important insect pests, which can cause severe crop damage and significant yield losses if left unchecked. Fenamiphos is effective for use both pre-plant and post-plant. As a post-plant application, fenamiphos is often the only effective nematicide available. The post-plant application is critical for perennial crops, such as pineapple, kiwifruit, tree fruits, grapes and raspberries, which must rely solely on a post-plant control of nematodes after the first growing season. For most of these crops fenamiphos is the only effective post-plant control. Fenamiphos is also important for the control of nematodes in a number of annual crops as well, particularly in California (the state with the highest agricultural usage), where effective nematode controls include several soil fumigants and fenamiphos. California has imposed use restrictions on the soil fumigants, which limit the availability of these nematicide alternatives (e.g., Telone, methyl bromide, metam-sodium).

Fenamiphos is also critical for the control of nematodes in golf course turf. The types and extent of damage varies with the nematode type(s) present, population levels, types of grass, environmental stress levels (soil temperature, water availability, etc.) and other unknown soil factors. Nematodes are root parasites which cause damage including stunted growth, foliage discoloration, premature wilting and death of plants.

Increased fertilizer and water are often used to treat nematode infestations and fenamiphos is used only when the problem cannot be controlled by these means. Additional application of water is not always an option, due to limits on water usage in some areas and under certain conditions. There are no registered fenamiphos alternatives known to be effective for use on turf, and if fenamiphos is not available on turf, golf courses and turf farms could be adversely impacted.

### Process and Timeframes

This interim RED document for fenamiphos is being announced in a Notice of Availability published in the *Federal Register*. This interim RED document includes guidance and time frames for any necessary label changes for products containing fenamiphos. Note that there is no comment period for this document, and that the time frames for the label changes outlined in this document are shorter than those given in some earlier reregistration eligibility decisions. As part of the public participation process, the Agency's risk assessments for fenamiphos have already been subject to numerous public comment periods, and a further comment period for fenamiphos was deemed unnecessary. Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period, depending on the content of the risk management decision. With regard to the risk mitigation measures outlined in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for fenamiphos can be considered final until the cumulative risks for all organophosphate pesticides are considered. The cumulative assessment may result in further risk mitigation measures for fenamiphos.

The Agency understands that the technical registrant, Bayer Corporation, intends to request voluntarily cancellation of all fenamiphos registrations consistent with a phase out schedule amenable to the Agency. Once the request for voluntary cancellation is received by the Agency, the terms and conditions of the cancellation will be established in a separate document. If Bayer Corporation does not submit a request for voluntary cancellation, Bayer will need to satisfy the measures described in this interim RED in order for fenamiphos to be eligible for reregistration.

## 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. 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" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all existing tolerances. For those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. FQPA also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the Federal Food, Drug and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Fenamiphos belongs to a group of pesticides called organophosphates (OPs), which share a common mechanism of toxicity - they all affect the nervous system by inhibiting cholinesterase. Although the 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 the 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 fenamiphos. It is intended to be only the first phase in the reregistration process for fenamiphos. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision for fenamiphos.

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 an advisory committee, which was composed of representatives from industry, environmental groups, and other interested parties. The committee identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- C Applying the FQPA 10-Fold Safety factor
- C Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments
- C How to Interpret "No Detectable Residues" in Dietary Exposure Assessments
- C Refining Dietary (Food) Exposure Estimates

- C Refining Dietary (Drinking Water) Exposure Estimates
- C Assessing Residential Exposure
- C Aggregating Exposure from all Non-Occupational Sources
- C Conducting a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- C Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- C Whether and How to Use Data Derived from Human Studies

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

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment and describes the process for working with the public 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 risk assessments resulting from public comments and other information. Section IV presents the Agency's interim decision on reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list Data Call-In (DCI) information (requirements that the Agency intends to issue to the registrant). The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page <http://www.epa.gov/oppsrrd1/op/fenamiphos.htm>, and in the Public Docket.

## II. Chemical Overview

### A. Regulatory History

Fenamiphos was first registered in the United States in 1972 by Chemagro Corporation, a Division of Baychem Corporation. Throughout the years, the company changed names, Mobay Chemical Corporation, then Miles, Inc. and, finally, Bayer Corporation. Currently, Bayer Corporation is the only manufacturer of fenamiphos technical and four end-use products.

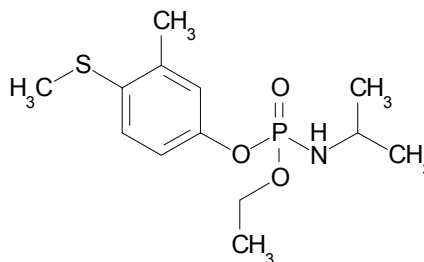
The chemical was formulated as Nemaicur (EPA Reg No 3125-269), a manufacturing use product to be further formulated into end-use products for at-plant control of nematodes in annual field and vegetable crops or in established perennial deciduous and tropical fruit crops. In 1987, the Agency issued a Registration Standard for fenamiphos. As part of the Registration Standard and in a separate Data Call-In Notice in September 1999, the Agency called-in additional data to better understand the risks associated with using fenamiphos.

After the Agency's 1994 draft preliminary human health and ecological risk assessments were provided to the registrant for review, the registrant voluntarily put into place numerous risk mitigation measures, addressing many of the Agency's concerns at that time. These measures included use restrictions and rate reductions to address certain risks identified in the risk assessments.

This Interim Reregistration Eligibility Decision document is the Agency's first reevaluation of fenamiphos since issuance of the Registration Standard in 1987. The revised risk assessments, which are summarized in this document, are based on current product labels and reflect the various changes made to the labels from 1994 to 1996.

### B. Chemical Identification

- **Common Name:** Fenamiphos
- **Chemical Name:** Ethyl 3-methyl-4-(methylthio)phenyl-(1-methyl-ethyl)phosphoramidate



- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 22224-92-6

- **OPP Chemical Code:** 100601
- **Empirical Formula:** C<sub>13</sub>H<sub>22</sub>NO<sub>3</sub>PS
- **Molecular Weight:** 303.4
- **Trade and Other Names:** Nematicur<sup>®</sup>
- **Basic Manufacturer:** Bayer Corporation

Technical fenamiphos is an off-white to tan waxy solid with a melting point of 49°C and a vapor pressure of 4.7 x 10<sup>-5</sup> mmHg at 20°C. Fenamiphos is soluble in dichloromethane, 2-propanol and toluene, only slightly soluble in n-hexane, and insoluble in water.

### C. Use Profile

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

**Type of Pesticide:** Nematicide/Insecticide

#### Summary of Use Sites:

Food: Apple, asparagus, banana, beets (garden), bok choy, Brussels sprouts, cabbage, cherries, citrus (except on kumquat, tangelo, or citrus hybrids in California), eggplant, garlic, grapes, kiwifruit, nectarine, okra, peaches, peanuts, peppers (non-bell), pineapples, raisins, raspberries, strawberries

Residential: None

Public Health: None

Other Nonfood: Commercial, industrial, and ornamental turf, sod farm, golf course turf, ornamental and shade trees, tobacco, and the following ornamental plants: herbaceous plants, nonflowering plants, woody shrubs and vines, and other nonbearing crops

**Target Pests:** The majority of labeled uses are for plant parasitic nematodes and thrips. Additional pests include aphids, cutworms, citrus root weevil, flea beetles, Fuller rose beetle, mole crickets, phylloxera, and wireworms.



**Formulation Types Registered:**

Technical:	Nemacur Concentrate (74.6%)
Granular:	Nemacur 10% G and 15% G (10% and 15% a.i., respectively)
Emulsifiable Concentrate:	Nemacur 3 (35% a.i.)

**Method and Rates of Application:**

Equipment: Drip irrigation, granule applicator, groundboom, low pressure ground sprayer, low pressure irrigation, soil incorporation equipment spreader, sprinkler.

Method and Rate: Broadcast, chemigation, soil band treatment, soil broadcast treatment, soil drench treatment, soil in-furrow treatment, soil incorporated treatment, soil treatment, spray.

Following application, labels instruct that both the emulsifiable concentrate and granular formulations are to be watered-in or mechanically incorporated into soil.

Current application rates vary depending on the commodity or site. Overall, maximum single application rates range from 1 to 10 lbs a.i./acre, with maximum yearly rates ranging from 2 to 20 lbs a.i./acre.

Timing: At planting, bloom through foliar, fall, foliar, post-final harvest, post-harvest, post-plant, post-transplant, pre-bloom through foliar, pre-emergence, pre-plant, pre-transplant, ratoon, transplant, at seedling, pre-seedling.

**Use Classification:** Restricted Use Pesticide (RUP) due to high acute toxicity and toxicity to wildlife.

#### D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of fenamiphos, based on available pesticide usage information for the past eight years. A full listing of all uses of fenamiphos, with the corresponding use and usage data for each site, has been completed and is in the “Quantitative Usage Assessment” document, which is available on the internet at <http://www.epa.gov/pesticides/op/fenamiphos.htm> and in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. On average, approximately 780,000 pounds of fenamiphos active ingredient are used annually, according to Agency and registrant estimates. Table 1 provides estimates for usage of fenamiphos.

**Table 1. Fenamiphos Estimated Usage for Representative Sites**

Crop	Lbs. a.i. Applied (wghtd Avg. in 000 pounds) <sup>1</sup>	Percent Crop Treated (Weighted Avg.)	Percent Crop Treated (Likely Max)
<b>Food Commodities</b>			
Apple	5	<1	1
Banana	Not Available	3	3
Beets, garden	2	<1	2
Bok Choy	1	5	11
Brussels Sprouts	1	13	29
Citrus - Grapefruit	15	1	3
Citrus - Lemons	25	7	13
Citrus - Oranges	45	2	4
Citrus - Other <sup>2</sup>	5	2	6
Cabbage	4	9	11
Cherries	4	1	2
Eggplant, Peppers	1	1	2
Grapes	130	5	10
Kiwifruit	1	9	17
Nectarines	2	3	6
Peaches	10	1	3
Peanuts	74	2	4
Pineapple	14	24	68

Crop	Lbs. a.i. Applied (wghtd Avg. in 000 pounds) <sup>1</sup>	Percent Crop Treated (Weighted Avg.)	Percent Crop Treated (Likely Max)
Raspberries	3	9	21
Strawberries	<1	1	2
Vegetables	6	1	2
<b>Non-Food Sites</b>			
Tobacco	230	11	22
Turf, golf courses and sod	67	Not Available	Not Available
<b>Ornamentals</b>			
Nursery Stock	50	Not Available	Not Available

<sup>1</sup> Data from 1990 - 1998; when percent crop treated is < 1%, the Agency uses 1% for dietary analysis

<sup>2</sup> Includes kumquats, limes, tangelos and tangerines

### III. Summary of Fenamiphos Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide fenamiphos, as fully presented in the documents, "Human Health Risk Assessment, Fenamiphos," dated September 2, 1999 (golfer assessment amended dated July 27, 2001; turf handler amended February 21, 2001; and occupational amended June 25, 2000) and "Fenamiphos Environmental Risk Assessment," dated March 6, 2002. 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 revised risk assessments for fenamiphos were presented at a September 2, 1999 Technical Briefing, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's risk management decision for fenamiphos only; the Agency must consider cumulative risks of all the organophosphate pesticides before any tolerance reassessments can be finalized.

#### A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for fenamiphos on August 12, 1998 (Phase 3 of the public participation process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. These updates and refinements included some minor changes to the dietary consumption estimates, but there were no major changes in the assessments.

## **1. Dietary Risk from Food**

### **a. Toxicity**

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete, and that it supports an interim reregistration eligibility determination for all currently registered uses. Further details on the toxicity of fenamiphos can be found in the September 2, 1999 Human Health Risk Assessment. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2.

The toxicology profile of fenamiphos demonstrates that fenamiphos, like other organophosphates, has anticholinesterase activity in all species tested including mice, rats, rabbits and dogs. Technical fenamiphos has high acute oral toxicity (Toxicity Category I), with an LD<sub>50</sub> of 2.7 mg/kg in male rats and 3.0 mg/kg in female rats (MRID 00033831). Fenamiphos did not cause organophosphate induced delayed neurotoxicity in hens. No treatment-related pathological lesions were seen in the central or peripheral nervous system of rats following a single gavage dose or repeated dietary administration. The principal toxicological effects in rats and dogs following subchronic and chronic oral (dietary) exposure was inhibition of plasma, red blood cell and/or brain cholinesterase activity. Repeated dermal applications to rabbits for 21-days resulted in inhibition of plasma, erythrocyte and brain cholinesterase activity. There was no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in prenatal developmental toxicity studies, no offspring toxicity was seen at the highest dose tested (HDT) in the two-generation reproduction toxicity study, and there was no evidence of abnormalities in the development of the fetal nervous system in these studies.

Fenamiphos is classified as a Group E chemical based on no evidence of carcinogenicity in two adequate studies in mice and rats. Mutagenicity studies show that fenamiphos is not mutagenic either *in vivo* or *in vitro*. Metabolism studies in the rat indicated no major differences between oral and intravenously administered fenamiphos. Fenamiphos is degraded and/or eliminated within 48 hours postdosing and does not accumulate in tissues. The major metabolites are sulfoxides and sulfones.

### **b. FQPA Safety Factor**

The FQPA safety factor was reduced to 1X. In prenatal developmental toxicity studies following *in utero* exposure in rats and rabbits, there was no evidence of developmental effects being produced in fetuses at doses that did not also induce maternal toxicity, nor was there evidence of an increase in severity of effects at or below maternally toxic doses. In the pre/post-natal two-generation reproduction study in rats, there was no evidence of enhanced susceptibility in pups when compared to adults (i.e., effects noted in offspring occurred at maternally toxic doses or higher). There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. The toxicology database is complete and there are no data gaps according to the Subdivision F Guideline requirements. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary (food and water) exposure and to provide a screening level drinking

water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential exposure or risk for infants and children. Therefore, the additional 10X factor as required by FQPA was reduced to 1X.

**c. Population Adjusted Dose (PAD)**

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose (RfD), 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 fenamiphos, the FQPA safety factor is 1X; therefore, both the acute and chronic PADs are identical to the corresponding acute and chronic RfDs. The Agency applied the conventional uncertainty factor of 100X to account for both interspecies extrapolation (10X) and intraspecies variability (10X). These uncertainty factors were applied to the No Observed Adverse Effect Level (NOAEL) selected for risk assessment. For the aPAD, an additional 3X uncertainty factor was applied to the lowest observed adverse effect level (LOAEL) because a NOAEL was not identified in the acute rat neurotoxicity study. The acute PAD (aPAD) is 0.0012 mg/kg/day and the chronic PAD (cPAD) is 0.0001 mg/kg/day. The bases for the aPAD and cPAD are summarized in Table 2 below. A risk estimate that is less than 100% of the acute or chronic PAD is below the Agency’s level of concern.

**d. Toxicological Endpoints**

Table 2 outlines the toxicological endpoints that are used in the dietary risk assessments. These endpoints were established after review of the entire toxicological database including toxicity and reproductive studies for both chronic and acute exposures.

**Table 2. Summary of Toxicological Endpoints for Dietary Risk Assessments**

Assessment	Dose (mg/kg/day)	Endpoint	Study	Uncertainty Factor	FQPA Safety Factor	PAD
Acute Dietary	0.37 (LOAEL)	plasma (male & female), red blood cell (male) cholinesterase inhibition	Acute Rat Neurotox	300, add'l 3X for use of LOAEL	1X	0.0012 mg/kg
Chronic Dietary	0.01 (NOAEL) 0.03 (LOAEL)	plasma cholinesterase inhibition	Chronic tox - dogs	100	1X	0.0001 mg/kg/day

NOAEL = No Observed Adverse Effect Level

LOAEL = Lowest Observed Adverse Effect Level

**e. Exposure Assumptions**

The Agency's dietary risk assessment for fenamiphos uses the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. Percent of crop treated data were also used in this analysis. Both acute and chronic anticipated residues were calculated using residue

monitoring data from USDA's PDP and the FDA Surveillance Monitoring Program data. PDP data were evaluated from 1994-1997, while FDA Monitoring data were evaluated from 1995-1997. The monitoring data analyzed samples for fenamiphos and its regulable metabolites (fenamiphos sulfoxide and fenamiphos sulfone).

Acute dietary risk is calculated considering maximum or high-end single-day exposure to pesticide residues in food. Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods. The Agency uses the estimated maximum percent crop treated for the acute risk and the average estimate percent crop treated for the chronic risk.

#### **f. Food Risk Characterization**

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's level of concern. Both the acute and the chronic dietary risk from food are below the Agency's level of concern; that is, less than 100% of the acute or chronic PAD is utilized. All subgroups, even the most exposed (infants younger than one year), are estimated to consume residues on food that comprise less than 1% of the aPAD at the 99.9th percentile of exposure. Similarly, on a chronic basis the most exposed subgroup (children from one to six years of age) is expected to consume residues on food that comprise less than 1% of the cPAD.

Refinements to the dietary analyses were made using zeros rather than one-half the limit of detection ( $LOD_{1/2}$ ) in the probabilistic analysis. The Agency adopts this approach when a substantial amount of monitoring data are available showing very few to no detectable residues. For fenamiphos, all but three samples (two grape and one strawberry) of the 26,619 samples analyzed by PDP and FDA (for the above noted time periods) detected no residues of either fenamiphos or its regulable metabolites.

## **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 potential exposure. In the case of fenamiphos, monitoring data for ground and surface water were available; however, for surface water these data were not sufficient to estimate expected concentrations in water. For ground water, these data were of higher quality and were used in the risk assessment. Therefore, both modeling and monitoring were used to estimate drinking water risks from these sources.

The GENEEC (Generic Estimated Environmental Concentration) model and PRZM-EXAMS (Pesticide Root Zone Model and Exposure Analysis Modeling System) model using the Index Reservoir scenario were used to estimate surface water concentrations. Both of these models are used for screening, with the PRZM-EXAMS model being somewhat more refined than GENEEC.

For ground water, the Agency reviewed monitoring data from a variety of sources including registrant-conducted studies, USGS monitoring, and state monitoring information to estimate impacts from fenamiphos use on ground water quality. These monitoring data were used to estimate ground water concentrations.

For fenamiphos, the Agency uses the term total fenamiphos residues to indicate that parent fenamiphos plus its two primary degradates (fenamiphos sulfoxide and fenamiphos sulfone) are all considered toxic and thus are all considered in calculating risk from drinking water. Fenamiphos and its degradates are mobile and persistent. Parent fenamiphos is relatively mobile, while laboratory studies show the sulfoxide and sulfone degradates are more mobile than the parent. Parent fenamiphos has the potential to be moderately persistent under certain conditions. Although the aerobic soil metabolism half-life is short (15.7 days), the anaerobic soil metabolism half-life for the parent is approximately 87.9 days (13 weeks) which indicates that fenamiphos will persist after reaching ground water. In water, the hydrolysis half-life of the parent is greater than 234 days. Persistence data are incomplete for the degradates, but in soil they appear to be at least as persistent as the parent.

#### **a. Surface Water**

Fenamiphos has the potential to reach surface water via spray drift and runoff. The typical incorporation of fenamiphos into the soil should limit the fraction available for runoff. However, relatively high application rates coupled with only moderate susceptibility to biodegradation can result in substantial quantities of fenamiphos remaining within approximately the top one centimeter of the soil. The Agency expects these residues to be available for runoff for several weeks post-application (aerobic soil metabolism half-life of 16 days for fenamiphos and 62 days for fenamiphos sulfoxide). Although fenamiphos is susceptible to rapid photodegradation on soil, approximately only the top one millimeter of soil is typically exposed to solar irradiation. The rest of the chemical in the top centimeter and below will not be exposed, and is not expected to be degraded by photolytic processes.

Because surface drinking water monitoring data are limited, estimated environmental concentrations (EECs) in surface drinking water for fenamiphos were based on results of Tier II drinking water modeling (PRZM-EXAMS) using the Index Reservoir scenario. Modeling results for a drinking water reservoir downgradient of a watershed planted in grapes are 141 ppb for the peak concentration, 13.7 ppb for the annual mean, and 7.4 ppb for the overall mean (i.e., 36-year average). Concentrations of degradates were not modeled. However, the model also used conservative assumptions to compensate for key data that are missing, including photodegradation in water and metabolism studies. The conservative assumptions lead to an overestimation in the model results, while lack of consideration of the degradates leads to an underestimation. Overall, the Agency expects the model results to overestimate the expected concentration in surface drinking water sources. Additional fenamiphos-specific data are expected to refine these results.

## **1) Surface Water Modeling**

On turf, fenamiphos concentrations were estimated using a Tier I screening model (GENEEC). For major crops, Tier II PRZM-EXAMS screening model using the Index Reservoir (IR) scenario and a Percent Crop Area (PCA) adjustment were used to estimate upper-bound concentrations in surface water used as a source of drinking water. This model, in general, is based on more refined, less conservative assumptions than the Tier I GENEEC screening model. Refined modeling with the Index Reservoir scenario and the PCA is intended for use as a screen. That is, the estimate should be higher than most values that are seen in areas where a particular crop is grown.

The Index Reservoir represents a watershed that is more vulnerable than most used as drinking water sources. It was developed from a real watershed in western Illinois. The Index Reservoir is used as a standard watershed that is combined with local soils, weather, and cropping practices to represent a vulnerable watershed for each crop that could support a drinking water supply. If a community derives its drinking water from a large river, the estimated exposure would likely be higher than the actual exposure. Conversely, a community that derives its drinking water from smaller bodies of water with minimal outflow would likely get higher drinking water exposure than estimated using the Index Reservoir. Areas with a more humid climate that use a similar reservoir and cropping patterns would likely have higher pesticide residues in their drinking water than predicted by the model. For fenamiphos, the modeling is expected to overestimate expected concentrations in surface water.

In addition, maximum application rates were used in the model. Also, when soil incorporation was allowed for a specific use, that agronomic practice was simulated in the modeling using the minimum depth of incorporation. Based on fenamiphos use on grapes, peanuts, peaches, and tobacco, the models provide very conservative, upper-bound concentrations for drinking water reservoirs ranging from 19 ppb (peanuts) to 141 ppb (grapes).

## **2) Surface Water Monitoring**

Surface water monitoring data are limited for fenamiphos, fenamiphos sulfoxide, and fenamiphos sulfone, in part because they are not currently regulated under the Safe Drinking Water Act. The Agency has analyzed monitoring data from three sources: a study in Florida, STORET (EPA's STOrage and RETrieval system for water and biological monitoring data), and a pilot reservoir study. In none of these studies was sampling conducted with adequate frequency to capture peak concentrations, which is to be expected as it is virtually impossible to determine peak concentrations from non-targeted monitoring studies.

Miles and Pfeuffer (1994) summarized the results of monitoring by 27 sites in the South Florida Water Management District (SFWMD). A total of 28 sampling events were documented over a 4.5-year period. Sampling was quarterly from June 1989 through October 1990, which subsequently increased to six times per year through November 1993. The study only analyzed samples for parent fenamiphos and no detections were reported. Since peak concentrations are expected to be of short duration, it is highly unlikely, given the nature of these monitoring data, that a



peak concentration of fenamiphos would have been detected even if the degradates had been included as analytes. Therefore, these data do not provide much useful information about the impact of fenamiphos use on surface-water quality.

STORET lists 37 samples analyzed for fenamiphos from more than 20 sites in three states. Fenamiphos was not detected in any of the samples. No information is provided about whether samples were taken from fenamiphos use areas. As such, it is not possible to draw reliable conclusions about fenamiphos from this monitoring data set.

From 1999 through 2000, EPA and USGS jointly sponsored a program to monitor twelve drinking water reservoirs across the United States. Samples were analyzed for a number of pesticides, including fenamiphos and its sulfoxide and sulfone degradates. Degradates of fenamiphos were detected in three out of the twelve reservoirs at concentrations ranging from 0.005 to 0.033 ppb. Degradates were also detected in the finished water (i.e., water that has been processed for use as drinking water) at all three reservoirs at concentrations ranging from 0.007 to 0.022 ppb. One reservoir, where fenamiphos sulfone had been detected in finished water for two consecutive months during the first year of sampling, was not sampled during the second year of the program. Because the pilot study was not designed to directly correlate fenamiphos use areas and loading in a watershed with concentrations in downgradient reservoirs, predictions about the magnitude of fenamiphos and its degradates in drinking water for reservoirs across the nation can not be made. However, the results support the conclusion that fenamiphos and/or its degradates can migrate to surface waters and then to community water systems that are in close proximity to use areas.

## **b. Ground Water**

Because of its chemical characteristics, fenamiphos and its major degradates have the potential to leach to ground water in vulnerable areas. Persistence data are incomplete for the degradates, but they appear to be at least as persistent in soil as the parent. Both fenamiphos sulfoxide and sulfone have been detected in ground water in Florida and elsewhere, indicating that they are sufficiently persistent to leach in some environments.

Although ground water monitoring data for fenamiphos are not extensive, they are sufficient to estimate concentrations in drinking water derived from ground water. Because expected fenamiphos concentrations in ground water vary significantly, the Agency has calculated EECs from a variety of uses on both vulnerable and extremely vulnerable use areas. Extremely vulnerable areas are hydrologic soil group (HSG) A soils that are excessively drained and predominately sand or loamy sand, such as soils in the suborder psamments. EECs for both types of soils are presented in Table 4, following the ground water monitoring discussion.

### **1) Ground Water Monitoring**

The Agency reviewed monitoring data from a variety of sources including registrant-conducted studies, USGS monitoring, and state monitoring information to estimate impacts from fenamiphos use on ground water quality. Because a maximum contaminant level has not been

established for fenamiphos and its degradates, no monitoring is being conducted under the Safe Drinking Water Act. The two major fenamiphos use states, California and Florida, have monitored for this pesticide, but fenamiphos is also used in 27 other states where no reliable monitoring has been conducted. Table 3 outlines the results of several fenamiphos monitoring studies.

**Table 3. Ground Water Monitoring Data for Fenamiphos and its Degradates**

Study	Well Type	# of Wells Sampled	# Wells w/ Detections	Concentration Range (ppb)
California prospective study on grapes (1997-2000)	monitoring	16	5	0.05 (parent) 0.06 - 2.13 (sulfoxide) 0.53 (sulfone)
Georgia prospective study on tobacco (1996-1998)	monitoring	16	2	0.0 (parent) 0.04 - 0.05 (sulfoxide) 0.0 (sulfone)
Florida prospective (1995-1996) – citrus use site (4.1 lbs a.i./A) on the Central Ridge	monitoring	16	9	0.10 - 0.58 (parent) 0.13 - 83 (sulfoxide) 0.14 - 3.3 (sulfone)
USGS Florida golf course study (1992-1994)	monitoring/ irrigation	41	8	0.03 - 0.71 (parent) 0.2 - 0.75 (sulfoxide) 0.1 (sulfone)
Florida retrospective (1989-1992)	monitoring	12	12	0.1 - 24 (parent) 0.2 - 218 (sulfoxide) 0.1 - 27 (sulfone)
California monitoring program (1985-1994)	drinking water	803	0	not detected
Mississippi monitoring program (1989-1995) <sup>1</sup>	drinking water	348	0	not detected
Oregon monitoring program (1986-1995) <sup>1</sup>	drinking water	1000 samples	0	not detected
Texas monitoring program (1987-1988) <sup>1</sup>	drinking water	188	0	not detected
Washington monitoring program (1988-1995) <sup>1</sup>	drinking water	248	0	not detected

<sup>1</sup> Study only analyzed for parent fenamiphos

The prospective and retrospective studies conducted by the registrant, and other studies conducted by the USGS, and the State of California are of high quality. The other monitoring studies did not necessarily coincide with use areas, making it difficult to interpret and use study results.

The most extensive ground water monitoring studies for fenamiphos were conducted in Florida by the registrant at the request of USEPA and the State of Florida. The data from the Georgia prospective ground water study do not show a pattern of movement to ground water. The data in

Georgia suggest fenamiphos and its degradates may not leach in some soils. However, until the factors limiting the movement at this site are defined, it is not possible to extrapolate these results to other specific soils and geographical areas.

While not all of the monitoring data were collected from drinking water wells, these studies provide solid evidence that fenamiphos and its degradates leach to ground water. Moreover, available ground water monitoring data are sufficient to show that significant ground water contamination may occur in areas with sandy soils. Prospective and retrospective studies have found concentrations of total fenamiphos residues (parent and its degradates) of up to several hundred ppb.

Because available data indicate fenamiphos leaches much more readily in extremely vulnerable soils than in other soils, the Agency has developed two separate sets of EECs to more accurately portray risk. Expected concentrations in extremely vulnerable ground water are based on a prospective ground water study conducted in Florida. Although a prospective ground water study from California was used to estimate concentrations in other vulnerable soils, there are weaknesses in this study. Therefore, the Agency intends to issue a DCI to require additional data to confirm the conclusions of this assessment.

The EECs in the Table 4 are expected to occur in ground water as a result of normal agricultural and non-agricultural uses. In extremely vulnerable areas, such as the Central Ridge region of Florida, acute ground water EECs range from 43 to 425 ppb and chronic EECs range from 4 to 45 ppb. In other vulnerable soils, acute EECs range from 1 to 7 ppb and chronic EECs range from 0.1 to 0.93 ppb. Since fenamiphos may be used on a particular crop on similar soils but in areas where climatic conditions vary, these EECs may not be conservative. For example, the study on grapes in Fresno County, California, was conducted under drier conditions than other grape growing areas; therefore, greater leaching and higher fenamiphos concentrations would be expected in areas with higher rainfall. The Agency believes the expected concentrations outlined in Table 4 represent use sites in the two different soil types.

**Table 4. Drinking Water EECs For Ground Water Resources**

Crop	Maximum Application Allowed on Label (lbs a.i./A/year)	Extremely Vulnerable Soils		Other Vulnerable Soils	
		Acute (ppb)	Chronic (ppb)	Acute (ppb)	Chronic (ppb)
Citrus (FL PGW)	4.1	87.2	9.2	NA	NA
Grapes (CA PGW)	6	NA	NA	2.1	0.28
Citrus	7.5	160	17	2.63	0.35
Citrus (FL)	10	213	22	3.50	0.47
Grapes/Raspberry	6	128	13	2.10	0.28
Peanuts	7.5	160	17	2.63	0.35

Crop	Maximum Application Allowed on Label (lbs a.i./A/year)	Extremely Vulnerable Soils		Other Vulnerable Soils	
		Acute (ppb)	Chronic (ppb)	Acute (ppb)	Chronic (ppb)
Pineapple <sup>2</sup>	24	510	54	8.40	1.12
Protea/Anthurium/nursery stock <sup>3</sup>	20	425	45	7.00	0.93
Iris/Lily/Narcissus/leather leaf fern	10	213	22	3.50	0.47
Bananas and plantains	6.7	142	15	2.35	0.31
Beets	3.1	66	7	1.09	0.14
Eggplant/nonbell pepper/asparagus	2	43	4	0.70	0.09
Cabbage and Brussels sprouts	4.5	96	10	1.58	0.21
Strawberries	7.5	160	17	2.63	0.35
Garlic/okra	4.5	96	10	1.58	0.21
Tobacco	7.5	160	17	2.63	0.35
Apples/Cherries/Peaches	7.5	160	17	2.63	0.35
Turf/Golf courses	20	425	45	7.00	0.93

<sup>1</sup> NA = Not Applicable

<sup>2</sup> Proposed application rate reduction is expected to reduce the EECs for pineapple by almost two-thirds

<sup>3</sup> Proposed application rate reduction is expected to reduce the EECs for protea by approximately one-half

### 3. 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). 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 the Agency’s level of concern.

The results of the Agency’s acute drinking water analysis, which used screening models and actual monitoring data to develop expected concentrations in water, are summarized in Table 5. For surface water, the modeled concentrations exceed the DWLOC by a relatively substantial margin. The Agency believes that uncertainties in the assessment, as discussed earlier, cause the model to overestimate the expected concentrations in surface water.

For groundwater, the potential exposure derived from drinking water is not greater than the Agency’s DWLOC, provided fenamiphos is not used in areas with extremely vulnerable soils, as

described earlier in the ground water section. In areas with extremely vulnerable soils, the potential drinking water exposure derived from ground water is greater than the DWLOC. Table 5 summarizes the DWLOCs and EECs for acute exposure.

**Table 5. Summary of DWLOC Calculations for Acute Risk**

Population Subgroup	Acute PAD (mg/kg/day)	Exposure (mg/kg/day)		EECs in Water (ppb)			DWLOC (ppb)
		Expected Food	Allowable Water	Extremely Vulner. Ground	Vulner. Ground	Surface	
Adult Females	0.0012	0	0.0012	425	7	141	36
Adult Males		0	0.0012				42
Infants (younger than 1 year)		0	0.0012				12

For chronic risk, the potential drinking water exposure derived from ground water does not exceed the DWLOC for any population, provided fenamiphos is not used in areas with extremely vulnerable soils. In areas with extremely vulnerable soils, the potential drinking water exposure derived from ground water exceeds the DWLOC by a large margin.

The potential drinking water exposure derived from surface water exceeds the chronic DWLOC for all populations. However, the Agency believes that uncertainties in the assessment as discussed earlier cause the model to significantly overestimate the expected concentrations in surface water. Table 6 summarizes the DWLOCs and EECs for chronic exposure.

**Table 6. Summary of DWLOC Calculations for Chronic Risk**

Population Subgroup	Acute PAD (mg/kg/day)	Exposure (mg/kg/day)		EECs in Water (ppb)			DWLOC (ppb)
		Food	Allowable Water	Extremely Vulner. Ground	Vulner. Ground	Surface <sup>1</sup>	
U.S. Population	0.0001	0	0.0001	22	0.47	13.7	4
Children (aged 1 - 6)		0	0.0001				1

<sup>1</sup> Estimate is believed to be conservative because key environmental fate data are not available.

#### 4. Residential/Recreational (Golfer) Risk

Fenamiphos is not used in a residential setting. However, because fenamiphos is used on golf course turf, golfers may be exposed to its residues when playing on a treated course. In evaluating the risk to golfers, the assessment considered exposure to be short-term, and assumes that no protective

clothing is used. To evaluate these risks, the Agency initially conducted a post-application assessment that showed the MOE is not greater than 100 until 18 days after treatment. However, a recently published study (R.H. Snyder, et al., 1999) indicates that watering-in, as required by fenamiphos labels, reduces dislodgeable residues of a liquid formulation of fenamiphos to less than 1% less than 24 hours after application. Data for granular formulations are not available, however, the Agency believes that residues will also be significantly reduced from watering-in of these products. Provided fenamiphos is watered-in after applications, the Agency believes that golfers will be adequately protected. Additional data are being called-in for the granular formulation to confirm this conclusion.

## **5. Aggregate Risks**

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and residential or non-occupational risk, when appropriate. Generally, combined risks from these exposures must have MOEs of 100 or greater to not be of concern to the Agency. Although fenamiphos is not used in a home residential setting, it is used on golf course turf. Therefore, golfers may be exposed to fenamiphos while playing on courses after treatment. The risks to golfers is not included in the Agency's quantitative assessment of the aggregate risks at this time as the data are not sufficient or robust enough to allow its inclusion in this calculation. However, the Agency has qualitatively evaluated such risk and believes that this exposure is not significant and that its inclusion in the aggregate risk assessment will not change its conclusions.

The Agency believes that the results of the drinking water and food aggregate assessment discussed above describes total aggregate risk from exposure to fenamiphos residues. As discussed in the drinking water section above, the Agency is not concerned about the risk to any population exposed to combined fenamiphos residues from food and drinking water, provided the population is not drinking ground water in areas with extremely vulnerable soils. In areas with extremely vulnerable soils, the potential drinking water exposure derived from ground water is of concern. For surface water, the Agency expects that additional chemical-specific environmental fate data will show that concentrations are not of concern.

## **6. Occupational Risk**

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

The Agency considered the tasks (*e.g.*, mixing/loading, applying), fenamiphos formulation (*e.g.*, liquid, granular), application method (*e.g.*, groundboom, soil-band or broadcast or in-furrow treatment, chemigation, soil injection), application rate and similar parameters in assessing worker

exposure. The Agency considered both direct and indirect or secondary exposure and risks that may result from the use of fenamiphos, such as handlers not directly involved in mixing/loading or applying the chemical. The Agency also reviewed human incident data that may pertain to the occupational assessment.

**a. Toxicity**

The toxicity of fenamiphos is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for fenamiphos, including a 21-day dermal toxicity study and a 21-day inhalation toxicity study. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for fenamiphos are listed in Table 7 below. As this table indicates, all of the endpoints are based on route specific studies. Therefore, additional factors are not necessary. Because fenamiphos is used in limited amounts, even by custom applicators, chronic exposure is not expected.

**Table 7. Summary of Toxicological Endpoints Used to Assess Worker and Golfer Risk**

Assessment	Dose (mg/kg/day)	Endpoint	Study
Short- and intermediate-term dermal	NOAEL <sup>1</sup> = 2.5 LOAEL = 10	Plasma, blood and brain cholinesterase inhibition	21-day dermal toxicity in rabbits
Short- and intermediate-term inhalation	NOAEL = 0.061 LOAEL = 0.85	Plasma cholinesterase inhibition	21-day inhalation toxicity in rats

<sup>1</sup> Marginal effects seen at the NOAEL in only female rabbits in this study (plasma cholinesterase decreased 30% on day 10; brain cholinesterase decreased 11% on day 15)

According to the results of available acute toxicity studies, fenamiphos is in Toxicity Category I for oral and dermal toxicity and in Toxicity Category II for inhalation toxicity. Because fenamiphos causes mild eye irritation, it is in Toxicity Category III. Fenamiphos is not irritating to the skin (Toxicity Category IV) and is not a dermal sensitizer. Table 8 provides toxicity categories for each of the routes of exposure.

**Table 8. Acute Toxicity Profile for Occupational Exposure for Fenamiphos**

Route of Exposure	Results	Toxicity Category	MRID
Oral	LD <sub>50</sub> = males: 2.7 mg/kg LD <sub>50</sub> = females: 3.0 mg/kg	I	00033831
Dermal	LD <sub>50</sub> = males: 225 mg/kg LD <sub>50</sub> = females: 178.8 mg/kg	I	00037962
Inhalation	LC <sub>50</sub> = >0.1 mg/L	II	00154492
Eye Irritation	mild	III	00082111
Dermal Irritation	not irritating	IV	00082111

Route of Exposure	Results	Toxicity Category	MRID
Dermal Sensitizer	negative	N/A	00148464

**b. Exposure**

Chemical-specific exposure data were not available for fenamiphos, so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED). PHED is a comprehensive generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposures for pesticide handlers (*e.g.*, mixers, loaders, and applicators) involved in the handling or application of pesticides. The database currently contains data for over 2000 monitored exposure events. The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments; the application rates are derived directly from fenamiphos labels. The exposure factors (*e.g.*, body weight, protection factors, etc.) are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but are the best available data. The quality of the data for each scenario assessed is discussed in the Human Health Assessment document for fenamiphos, which is available in the public docket and on the internet at <http://www.epa.gov/pesticides/op/fenamiphos.htm>.

Anticipated use patterns, application methods, and range of application rates were derived from current labeling. Application rates specified on fenamiphos labels range from 1 to 10 pounds of active ingredient per acre in agricultural settings, and 10 pounds of active ingredient per acre on turf. The Agency typically uses acres treated per day values that are thought to represent eight hours of work. For fenamiphos, refined values were provided by the registrant indicating the number of acres that are typically treated for each site.

The Agency performed its own analysis of the maximum number of acres that are generally treated with fenamiphos on one day. Based on this analysis, the Agency agreed to use maximum acres treated values in the occupational risk assessment. The Agency's analysis also revealed that, for low acreages, a single handler may perform the mixer/loader and applicator tasks on the same day. Because PHED is largely setup to measure mixer/loader exposure separately from applicator exposure, most of the Agency's calculations to assess these combined exposures are not robust enough for regulatory use. The Agency's assessment does, however, provide additional information that can be used to qualitatively assess risks.

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. If required (*i.e.*, MOEs are less than 100), increasing levels of risk mitigation and PPE are added. 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 fenamiphos activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Label: Chemical-resistant suit, gloves, and footwear; socks; protective eyewear; chemical-resistant headgear for overhead exposures; dust/mist filtering respirator (outdoors); respirator with either organic vapor-removing cartridge with prefilter approved for pesticides, or canister approved for pesticides (enclosed areas)
- Minimum PPE: Baseline plus chemical-resistant gloves.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, and an organic vapor-removing respirator
- Engineering controls: Closed mixing/loading system and thereafter an enclosed cab during application.

Finally, post-application exposure to workers entering treated agricultural fields was also considered. Because the majority of labeled uses require that the applications are soil incorporated and/or watered-in via irrigation or natural rainfall, and the timing is at or near planting or during the dormant stage for most of the pest targets, post-application exposure to workers is not expected for most crops.

### **c. Occupational Handler Risk Summary**

The Agency initially identified seven major handler exposure scenarios for users of fenamiphos: 1) loading granular formulations; 2) mixing liquid formulations for groundboom applications; 3) mixing the liquid formulation for chemigation; 4) groundboom application; 5) soil injection; 6) tractor-drawn granular application; and 7) loading and applying by push spreader. At a later date, the Agency performed an additional analysis that combines scenarios 1 and 6, 2 and 4, to account for low acreage situations where the mixer, loader and applicator are the same person (chemigation is already assumed to be performed by the same individual). The data were inadequate for conducting an assessment on the soil injection use; though it is assumed exposure would be no greater than for the groundboom use.

As mentioned earlier, the occupational assessment uses acreage-treated information provided by the registrant. These numbers, which are lower than Agency default values, are intended to more closely reflect current practice. The Agency has validated this information through contacts with growers and State representatives.

## 1) Agricultural Handler Risk

In an effort to characterize the risk to agricultural workers, the occupational assessment addressed the risk to workers on each crop for which fenamiphos is registered. For each scenario, at least one crop has MOEs that are below 100 and of concern. MOEs of concern range from 28 to 86, as outlined in Table 9, when mixing/loading and applying are performed by different people.

As mentioned earlier, occupational risks for handlers that mix, load and/or apply fenamiphos were estimated using refined acres treated assumptions rather than Agency defaults, the maximum application rate, and other standard assumptions on a crop-by-crop, site-by-site basis. The MOE ranges presented in the Table 9 show the lowest and highest MOEs for each specific activity (i.e., load granulars), application equipment used (i.e., tractor drawn spreader), and crop-specific parameters applicable to that scenario. As such, numerical relationships do not follow the typical linear progression and may not correspond exactly. However, these MOEs reflect the actual estimates for the parameters that were assessed. See the Human Health risk assessment dated September 1999 for a detailed discussion of the MOEs and their derivation.

**Table 9. Agricultural Uses: Risk Concerns (combined dermal & inhalation MOEs)**

Scenario	Crops	Max. Acre	Max. Rate	Base-line	Short-term and Intermediate-Term MOE					
					Max PPE <sup>1</sup>			Engineering Controls <sup>2</sup>		
					Dermal	Inhalation	Combined	Dermal	Inhalation	Combined
Load Granulars (I)	Turf	40	10	4.6	119	50	35	NA	NA	NA
	Other (peanut/eggplant) <sup>3</sup>	50/2	3/10	14 - 136	389 - 2,917	150 - 1,526	108 - 1,002	NA	NA	NA
Mix Liquids Ground-boom (II)	Turf	40	10	0.2	18	90	15	49	153	37
	Tobacco, pome/stone/citrus/ grape	55/40	6/6	0.2 - 0.3	21 - 57	100 - 310	17 - 48	60 - 81	153 - 203	43 - 58
	Other (peanut/eggplant) <sup>3</sup>	50/10	3/2	0.5 - 3.0	57 - 357	310 - 2,034	48 - 304	156 - 972	432 - 2,669	115 - 713
Mix Liquids Chem-igation (III)	(Pome/stone/citrus/ grapes/kiwi)/ornam.	80/20	3/10	0.3	29 - 35	150 - 180	24 - 29	80 - 96	203 - 244	57 - 69
	Fern/Banana	9/5	5/10	1.3	156	760 - 870	129 - 132	432	1186	317
Apply Ground-boom (IV)	Turf	40	10	10	44	150	34	64	305	53
	Tobacco/grapes (incl. Pome/stone/citrus)	55/40	6/6	13 - 19	53 - 96	100 - 310	42 - 73	81 - 109	301 - 414	64 - 86
	Other (peanut/eggplant) <sup>3</sup>	50/10	3/2	21 - 309	147 - 875	610 - 6,100	118 - 765	211 - 1,306	804 - 4,965	167 - 1,034
Soil Inj. (V)	Cotton	10	3	no data	no data	no data	no data	no data	no data	no data
Apply Gran. Tractor-Drawn (VI)	Turf	40	10	6.8	93	70	40	NA	NA	NA
	Other (Peanut/eggplant) <sup>3</sup>	50/10	3/2	20 - 163	307 - 2,303	230 - 2,034	131 - 1,080	NA	NA	NA

<sup>1</sup> MOE for label rates are the same as in Max PPE column. Label requires chemical-resistant coveralls, which have same protection as canvas coveralls.

<sup>2</sup> NA = Not Available

<sup>3</sup> Two crops with the lowest and highest MOEs that are greater than 100 with mitigation. Crops not listed have MOEs between these two values.

Typically, the Agency assumes that mixing/loading and applying are two separate tasks performed by two separate individuals. Because the acreage-treated values used in the fenamiphos assessment are less than the default values, the Agency believes that these activities may be performed by a single person. Consequently, the risks to workers who mix/load/apply fenamiphos would be higher than portrayed in Table 9. To help characterize these risks, the Agency performed a separate risk analysis, which showed that the MOEs for all scenarios were less than 100 when all tasks were conducted by a single worker. The MOEs ranged from 14 - 75, with the majority being less than 40. Unlike the separate mixer/loader and applicator assessment, the acres treated and application rates were reported as ranges in the combined assessment.

## 2) Hand-held Equipment Golf Course Assessment

In addition to the MOEs discussed above for turf, the Agency conducted an assessment for the application of granular fenamiphos to golf courses via hand-held or operator equipment, such as a drop spreader or belly grinder. While the extent of the use of this equipment is somewhat uncertain, these methods were examined for their potential use on turf. The following estimates are for a single individual loading and applying the granular formulation on a golf course.

The drop spreader assessment was conducted using a draft review of the Occupational and Residential Exposure Task Force study (MRID 44972201). Table 10 provides MOEs for hand application methods on turf.

**Table 10. Occupational Exposure Scenarios for Hand Application Methods on Turf**

Mixer/Loader/Applicator MOEs for Granular Application on Turf			
Hand Application Method	Acres Treated	Max Rate (lb ai/A)	Max PPE
Drop Spreader	1	10	140
Drop Spreader	5	10	28
Belly Grinder	1	10	3
Belly Grinder	5	10	0.6

## 3) Post-Application Worker Risk

The post-application occupational risk assessment considered exposures to workers entering treated agricultural sites, as well as exposures that can occur as a result of turf management activities. Post-application exposure is primarily a concern for human activities which may involve contact with the soil after treatment (e.g., transplanting strawberries) or contact with plants after a foliar treatment.

There are no chemical-specific exposure data for handling fenamiphos-treated soil; therefore, the Agency will be issuing a DCI to require post-application exposure data and to clarify the use patterns and worker activities or practices which may result in postapplication exposure. These uses

are on strawberries, asparagus, ornamental nonflowering plants, ornamental herbaceous plants, ornamental woody shrubs and vines, and all nursery stock.

Pineapple is the only crop that is treated with a foliar application of fenamiphos. For pineapples, the Agency reviewed a study that used Nemacur 3 (EC) at a rate of 10 lb ai/acre (MRID 41901701). Using this study, the short/intermediate term MOE does not reach 100 until day 17. The pineapple growers are proposing to reduce the application rate from 10 lb ai/acre to 2 lb ai/A, which the Agency expects would reduce the average dislodgeable foliar residue. While it is widely recognized that foliar residues are not directly proportional to application rate, the Agency believes this technique is adequate to estimate foliar residues from the application to pineapples. Based on the label rate reduction to 2 lb ai/acre, the Agency believes that the MOE for harvesting pineapples would be greater than 100 in less than 48 hours. The current WPS REI for pineapples of 48 hours is based on multiple factors, including acute toxicity, and should be continued for post-application reentry.

## **7. Human Incident Reports**

In evaluating incidents to humans, the Agency reviewed reports from the Incident Data System (IDS), Poison Control Centers (PCC), California Pesticide Illness Surveillance Program and National Pesticide Telecommunications Network (NPTN). Overall, relatively few incidents of illness are associated with fenamiphos. From cases in the Incident Data System (IS) and the California data, it appears that equipment malfunction and failure to adhere to protective equipment requirements are significant factors leading to poisoning. Poison Control Center data are relatively sparse but suggest that fenamiphos poisonings are similar to other cholinesterase inhibitors in terms of severity of symptoms and requirements for health care.

The IS contains over 17,000 pesticide-related reports of incidents involving adverse effects to humans and approximately 9,000 reports involving domestic animals since 1992. From 1996 to 1999, fenamiphos was identified in only five human cases. Of these, one case may have been due to coincidental exposure to poison oak and not fenamiphos. Of the remaining four cases, two resulted in complications requiring hospitalization.

The PCC data contains reports of 16 occupational cases and 27 non-occupational cases of fenamiphos exposure from 1985 through 1992. Twenty-one of these cases were reported from 1993 through 1996. Six of the 21 PCC cases may be associated with unrelated effects and the remaining cases were associated with various effects including nausea, vomiting, and abdominal pain. Eleven of the 21 exposures were considered occupational and four were reported to be due to environmental exposures, suggesting exposure to residues (*e.g.*, spray from a hose leak to bystander or exposure to irrigation water). Two of the environmental cases exhibited minor effects and two exhibited potentially toxic effects.

The California Pesticide Illness Surveillance Program reported 26 illnesses that are possibly, probably, or definitely related to fenamiphos exposure or fenamiphos in combination with other pesticides. Of the 26 cases, fenamiphos was determined to be the primary pesticide associated with

10 cases. Five of the 10 cases involved pesticide handlers, including three applicators and two mixer/loaders.

Fenamiphos was not reported to be involved in human incidents on the list of the top 200 chemicals for which National Pesticide Telecommunications Network (NPTN) received calls from 1984 to 1991.

## **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 March 6, 2002, available on the internet at <http://www.epa.gov/oppsrrd1/op/fenamiphos.htm> and in the public docket.

Whether or not terrestrial and aquatic animals will be adversely affected is dependent on the fate, distribution, and magnitude of fenamiphos in their habitat. Environmental factors can greatly modify the fate and distribution of fenamiphos. Like other chemicals, fenamiphos can be biotransformed by microbial communities or other environmental fate processes, which influences the degree of exposure to ecological components.

Fenamiphos is generally applied in the spring as a single band or broadcast soil application for most crop uses. Spring is also the season when plants and animals reappear and reproduce. Many terrestrial species traverse home ranges from several acres to several square miles in size, increasing the likelihood of exposure to pesticides during and after treatment. In addition, bird banding studies reveal that many birds return to nest in exactly the same locations every year, increasing the likelihood of recurrent exposure if fenamiphos is used on the same treatment areas in subsequent years.

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

Based on estimated environmental concentrations (EECs) from modeling and toxicity data for aquatic organisms, the Agency's levels of concern are exceeded for acute and chronic effects to fish and invertebrates. On avian and mammalian food items, risk estimates exceed levels of concern for potential acute and chronic effects to both birds and mammals.

## **1. Environmental Fate and Transport**

The environmental fate database is sufficient to identify the risks associated with fenamiphos use. However, EPA intends to issue a DCI to require additional data for the parent and two major degradates (fenamiphos sulfoxide and sulfone) to address areas of concern and uncertainty. These data are expected to confirm the conclusions of this risk assessment.

Fenamiphos and its degradates are mobile and have a high potential for leaching into ground water and contaminating runoff into surface waters. Moreover, evidence from laboratory studies indicate the sulfoxide and sulfone degradates are more mobile than the parent fenamiphos. Fenamiphos is relatively resistant to hydrolysis in sterile buffered systems with calculated half-lives of 245 days at pH 5.0, 301 days at pH 7.0, and 235 days at pH 9.0. (MRID 42149302)

Although an aqueous photolysis study was conducted, it does not conform to Agency guidelines and is expected to overestimate photolysis rates. Therefore, the photodegradation study in water was not suitable for use in this assessment. A new study is being required to refine the risk assessment.

When exposed to natural light on the soil surface, fenamiphos readily photodegrades, with a half-life of 3.23 hours. Fenamiphos dissipates in soil by microbial degradation to fenamiphos sulfoxide and sulfone. Eventually, further degradation of parent fenamiphos occurs via aerobic and anaerobic soil metabolism, with respective degradation half-lives of 15.7 and 87.9 days. The half-life for the degradates were determined to be 62 days for fenamiphos sulfoxide and 29 days for fenamiphos sulfone. An additional ancillary study demonstrated that the rate of fenamiphos degradation increases with temperature from 16° to 28° C. Persistence data are incomplete for the degradates, but they appear to be at least as persistent as the parent in soil. (MRIDs 40524601, 40608001, 42149303, 41064302, 40933701, 41286901 and 40524601)

## **2. Risk to Birds and Mammals**

### **a. Toxicity (Hazard) Assessment**

Fenamiphos is classified as very highly toxic to birds and mammals. Due to the potency of fenamiphos and its degradates (fenamiphos sulfoxide and sulfone), exposure to extremely small quantities can result in the impairment of reproductive capability or the death of wildlife. Terrestrial wildlife can be exposed to fenamiphos applied to the ground by deliberate or incidental ingestion of soil and/or granules while feeding or preening, ingestion of residues on soil invertebrates and plants, dermal contact, and inhalation. The Agency's risk assessment considers exposure to fenamiphos from the oral route only.

Although label directions require soil incorporation by mechanical methods or by irrigation to move fenamiphos down into the soil profile, a portion of the applied fenamiphos will be available as (1) granules at the soil surface or (2) in solution as moist fenamiphos-laden soil. In addition to

adverse effects resulting from exposure to parent fenamiphos, terrestrial organisms may be exposed to the major environmental degradates (fenamiphos sulfone and sulfoxide).

Acute toxicity data on the major degradates are limited, however, data for fenamiphos sulfone show that it is very highly toxic to mammals ( $LD_{50} = 2.6$  ppm). It is likely that fenamiphos sulfoxide is equally as toxic as the parent. Additional data being required on the environmental degradates are expected to confirm the conclusions of this risk assessment. Table 11 summarizes the data that support the toxicity endpoints used in assessing the risks of terrestrial animals. (MRID 00040215)

**Table 11. Acute Toxicity Endpoints for Birds and Mammals**

Toxicity Study	Test Species	% a.i.	Endpoint	Toxicity Category	MRID
<b>Acute (Single dose by gavage)</b>					
Avian Oral	Bobwhite quail	90.0	$LD_{50} = 1.6$ mg/kg	Very highly toxic	00121289
Mammalian Oral	Laboratory rat	99.7	$LD_{50} = 2.38$ mg/kg (female) 3.15 mg/kg (male)	Very highly toxic	06F1693
<b>Subacute (Five days of treated feed)</b>					
Avian Dietary	Bobwhite quail	88.0	$LC_{50} = 38$ ppm	Very highly toxic	00025959

Chronic effects to birds and mammals measured by reproduction studies show reproductive effects occur at low concentrations. A statistically significant decrease in normal hatchlings and survivors was observed when Bobwhite quail mated pairs were fed diets containing 8 ppm or more of fenamiphos. The lowest NOAEL of 2 ppm was selected for calculating avian chronic risks. Table 12 discusses the reproductive endpoints for terrestrial animals that were used in the risk assessment.

**Table 12. Reproductive Toxicity Endpoints for Birds and Mammals**

Test Species	% a.i.	NOAEL (ppm)	LOAEL (ppm)	Effects at LOAEL	MRID
Bobwhite quail	90.0	2.0	8.0	Reduced hatchling survival at 14 days	Accession 00121291
Laboratory rat	89.0	2.5	10.0	Reduced body weight, cholinesterase depression in parents and offspring	42491701

### **b. Exposure and Risk**

For avian and mammalian species, the acute and chronic levels of concern (LOCs) are exceeded for all uses of fenamiphos based on current application rates and methods. Even when fenamiphos is soil incorporated to reduce exposures, estimated acute and chronic RQs are significantly higher than the LOCs for both mammalian and avian species. The results of the risk assessment, incident reports and field tests support the conclusion that all current uses of fenamiphos



are likely to cause mortality as well as sublethal effects to terrestrial wildlife. The risk quotients are presented below in Table 13 for the avian risk due to fenamiphos residues on plants and insects or on/in soil from the liquid formulation and from ingestion of granules applied to the ground. The table does not list chronic RQs for the granular formulation because the granules will dissolve over time. Watering-in, as required by fenamiphos labels, was not accounted for in the exposure models for either liquid or granular applications. Watering-in would be expected to reduce calculated risks. For exposure to granules the RQs are expected to be reduced by less than 10% when one-half inch of irrigation water is applied.

Fenamiphos applied in irrigation water and uses with high application rates result in the highest expected risks. High risk is expected as a result of exposure from the chemigation use with low-pressure irrigation equipment using the emulsifiable fenamiphos formulation (Nemacur 3) in grape vineyards, citrus and kiwi groves and stone fruit orchards. Water used to apply fenamiphos can attract terrestrial organisms increasing the potential for exposure.

**Table 13. Avian Acute/Chronic RQs from Fenamiphos Application**

Crop	Application Rate (lbs a.i./A)	Acute RQs			Chronic RQs	
		Residues (liquid product)		Granules <sup>2</sup> (granular product)	Residues (liquid product)	
		Fruits, pods, seeds, & large insects <sup>1</sup>	Short grass <sup>1</sup>		Fruits, pods, seeds, & large insects <sup>1</sup>	Short grass <sup>1</sup>
Citrus (FL)	5	2.0	32	NA	38	600
Citrus (non FL)	7.5	3.0	47	NA	56	900
Peanuts	2.5	1.0	16	7 to 373	20	312
Pineapple	9.0	3.6	>57	9 to 439	68	>1,080
Tobacco/Grape	6.0	2.4	38	NA	45	720
Turf	10	3.9	63	65 to 3254	74	1,188

NA = not applicable

<sup>1</sup> Represents exposure pathway from ingestion of residues on given food items. Watering-in was not accounted for in the exposure model, but would be expected to reduce these risks.

<sup>2</sup> RQs were calculated for a range of body sizes from large (1000 grams) to small (20 grams). Watering-in was not accounted for in the exposure model, however, RQs are expected to be reduced by less than 10% when one-half inch of irrigation water is applied.

Mammalian acute and chronic LOCs are exceeded for all crop uses at current rates and application methods. The mammalian risks are presented in Table 14 as calculated risk quotients based on exposure to fenamiphos residues.

**Table 14. Mammalian Acute/Chronic RQs from Fenamiphos Application**

Crop	Application Rate (lbs a.i./A)	Acute RQs			Chronic RQs	
		Residues (liquid product)		Granules <sup>2</sup> (granular product)	Residues (liquid product)	
		Fruits, pods, seeds, large insects <sup>1</sup>	Short grass <sup>1</sup>		Fruits, pods, seeds, large insects <sup>1</sup>	Short grass <sup>1</sup>
Citrus (FL)	5	0.9 to 30	76 to 479	not applicable	30	480
Citrus (non FL)	7.5	1.4 to 45	>113 to >718	not applicable	45	720
Peanuts	2.5	0.5 to 16	39 to 249	5 to 334	16	250
Pineapple	9.0	1.7 to > 77	>136 to >862	6 to 394	54	>864
Tobacco/Grape	6.0	1.1 to 36	91 to 575	not applicable	36	576
Turf	10	1.9 to 59	150 to 948	44 to 2917	59.4	950

<sup>1</sup> Range of RQs for four categories of food items and three consumption rates (15, 66, 95% of body weight). Watering-in was not accounted for in the exposure model, but would be expected to reduce these risks.

<sup>2</sup> RQs were calculated for a range of body sizes from large (1000 grams) to small (20 grams). Watering-in was not accounted for in the exposure model, however, RQs are expected to be reduced by less than 10% when one-half inch of irrigation water is applied.

The acute and chronic RQs are based solely on dietary exposure via contaminated food sources and/or pesticide granules. Since, fenamiphos is highly to very highly toxic to terrestrial vertebrates, low level exposures by dermal, inhalation or oral routes considered singly or in combination, can result in significant impairment or death of exposed organisms. Furthermore, organisms which survive acute exposure and predation may still experience reproductive impairment.

### **3. Risk to Aquatic Species**

#### **a. Toxicity (Hazard) Assessment**

The available acute toxicity data on technical fenamiphos, outlined in Table 15, indicate that it is very highly toxic to aquatic species. Fenamiphos applied to the ground at use sites may reach surface water bodies through runoff from the site, spray drift, and contaminated groundwater/surface water interactions. The degradates, fenamiphos sulfoxide and sulfone, are equally toxic to aquatic invertebrates but are expected to be slightly less toxic to fish than fenamiphos. Because of the high toxicity of fenamiphos and its degradates, small quantities reaching surface water may kill aquatic organisms.

**Table 15. Acute Toxicity Endpoints for Aquatic Species**

Toxicity Study	Test Species	% a.i.	LC <sub>50</sub> (ppb)	Toxicity Category	MRID
Freshwater Fish	Bluegill Sunfish	88.0	9.5	Very highly toxic	00025962
Freshwater Invertebrate	Daphnid	88.7	1.9	Very highly toxic	40799706
Estuarine/Marine	Mysid Shrimp	88.7	6.2	Very highly toxic	40799708

Chronic data for freshwater organisms show that growth and development was the most sensitive endpoint to fenamiphos. The no observed effect concentrations (NOECs) and the lowest observed effect concentrations (LOECs) for freshwater fish and invertebrates are outlined in Table 16. EPA intends to issue a DCI to require estuarine and marine data for chronic effects from fenamiphos and its degradates.

**Table 16. Reproductive Toxicity Endpoints for Aquatic Species**

Toxicity Study	Test Species	% a.i.	NOEC <sup>1</sup> (ppb)	LOEC <sup>2</sup> (ppb)	Endpoints	MRID
Freshwater Invertebrate Life-Cycle	Water flea	99.6	0.12	0.24	Reproduction (# of neonates/reproductive day and mean body lengths)	43121401 40922201
Freshwater Fish Early Life-Stage	Rainbow trout	88.7	3.8	7.4	Larval length and weight	41064301

<sup>1</sup> No observed effect concentration

<sup>2</sup> Lowest observed effect concentration

### **b. Exposure and Risk**

In all acute and nearly every chronic case examined, the risk to nontarget aquatic organisms exceeds the LOC for all fenamiphos use sites. RQs for the aquatic risk in relation to fenamiphos residues range from 0.8 to 464 for acute and from 1.2 to 6,375 for chronic risk.

Acute RQs for estuarine/marine invertebrates exposed to runoff from large acreage crops, turf, high-end application rate ornamentals, and non-bell peppers are provided in Table 17. For non-turf and non-ornamental uses, the acute RQs for estuarine/marine invertebrates range from 1.3 to 11. Acute RQs for high-end ornamental applications is 132 and is 142 for turf use. RQs from all evaluated uses and rates exceed all LOCs for estuarine/marine invertebrates. Although required, chronic data have not been submitted and therefore chronic estuarine RQ values cannot be determined at this time.

**Table 17. Acute/Chronic RQs for Aquatic Species from Fenamiphos Application**

Crop	Maximum single application rate (lbs a.i./A) <sup>1</sup>	Freshwater				Estuarine/Marine
		Acute RQ		Chronic RQ		Acute RQ
		Fish	Invert.	Fish	Invert.	Invert.
Peaches	7.5	3.1	16	5.1	212	4.8
Peanuts	2.6	0.8	4.2	1.2	55	1.3
Tobacco	6.0	1.7	8.6	2.6	116	2.6
Grapes	6.0	7.1	35	11	482	11
Ornamentals <sup>2</sup>	10	86	432	103	5,183	132
Turf <sup>2</sup>	10	93	464	156	6,375	142

<sup>1</sup> Although application rates may be the same for some crops, typical field conditions may differ leading to different estimated surface water concentrations.

<sup>2</sup> For ornamentals and turf, the expected concentrations in water were estimated using GENEEC, a Tier I, screening model, which is expected to overestimate risk.

The Agency has limited monitoring data on the concentrations of fenamiphos and its degradates in surface water; therefore, no reliable conclusions can be made from empirical monitoring data to characterize the fate of fenamiphos in surface water in use areas. Based on the screening-level model results, fenamiphos use near surface water is expected to result in concentrations well above the median lethal concentration (LC<sub>50</sub>) for the more sensitive freshwater fish and invertebrates tested.

#### **4. Risks to Plants and Insects**

##### **a. Toxicity and Exposure to Terrestrial Plants**

Available information suggest that fenamiphos is toxic to plants. RQs could not be calculated because toxicity data for plants are not available. The potential for acute risks to non-endangered, endangered or threatened terrestrial, semi-aquatic and aquatic plants exposed to fenamiphos at use sites is unknown. EPA intends to issue a DCI to require plant data to assess the risks to terrestrial, semi-aquatic and aquatic plants. Currently, the Agency does not perform chronic risk assessments for terrestrial and semi-aquatic plants.

##### **b. Toxicity and Exposure to Beneficial Insects**

Parent fenamiphos is rated as highly toxic to honey bees (with an LD<sub>50</sub> of 1.87 µg/bee). Fenamiphos is a systemic nematicide; after application it is readily absorbed by plant roots and translocated throughout the target plant. Honey bees and other beneficial insects may have a greater potential for extended exposures via the nectar and pollen of blooming plants growing in and around treated areas. (MRID 00036935)

## 5. Incident Reports

Incident reports submitted to EPA involving fenamiphos have been tracked in the Incident Data System (IDS), microfiched, and then entered into a second database, the Ecological Incident Information System (EIIS). Incidents have to labeled use and misuse of both liquid and granular formulations of fenamiphos have been reported.

Prior to 1994, the EPA received a report in February of 1990 from Martin County, Florida, about American Robins (*Turdus migratorius*) and Cedar Waxwings (*Bombycilla cedrorum*) killed by a fenamiphos application to turf. Tissue sample analyses confirmed that their poisoning was the result of the fenamiphos application.

From 1994 to 1996, EPA received several reports of incidents. In June of 1995, an accidental poisoning of a Great Blue Heron (*Ardea herodias*) was associated with an application of fenamiphos to a golf course. Then, in November of 1996, EPA again received a report from Bay County, Florida, that 28 American Coot (*Fulica americana*) were killed by a fenamiphos application to a golf course.

In 1998, 28 birds and 1000 fish were killed as a result of wrongful use of fenamiphos on a kiwifruit orchard in Fresno, California. Then, in November of 2000, the Agency received a report from Sonoma County, California, on a bird kill (320 birds mainly robins and bluebirds) associated with chemigation of a grape vineyard with fenamiphos. Fenamiphos was detected in the gullets and on feathers and feet of dead birds. The investigation was instigated by neighbors to the vineyard reporting birds dying on their lawns. After the findings in the November 2000 case, a similar grape vineyard incident of 17 dead birds reported in Mendocino County was revisited where fenamiphos had been analyzed for in the gullets but not found. An analysis of feet and feathers confirmed exposure to fenamiphos.

As a result of 1994-1996 incidents, mitigation measures were implemented to reduce the risks resulting from fenamiphos use. Labels were subsequently amended to incorporate new rate reductions and restrictions for many uses including turf. While these measures have not totally eliminated incidents, the Agency believes that they may have reduced the severity and frequency of wildlife incidents.

## 6. Endangered Species

Based upon the environmental risk assessment, fenamiphos exceeds the endangered species levels of concern for birds, mammals, fish, invertebrates, insects, reptiles, and amphibians at the current label application rates and methods.

Fenamiphos was included in the formal Section 7 consultation with the US Fish and Wildlife Service (USFWS) for the corn cluster review in 1984. The Biological Opinion stated that this use of fenamiphos would jeopardize the continued existence of the Attwater's greater prairie chicken and the Aleutian Canada goose.

Fenamiphos was also included in the reinitiated Biological Opinion of 1989 from the USFWS. In this opinion, the Service found jeopardy to one species of amphibians, 17 species of freshwater fish, 22 species of mussels, two species of freshwater crustaceans and four bird species for its uses on various crops. Reasonable and Prudent Alternatives were given for each jeopardized species. Reasonable and Prudent Measures were also given for twelve non-jeopardized species to minimize incidental take of these species. These consultations and the findings expressed in the Opinions, however, are based on old labels and application methods, less refined risk assessment procedures and an older approach to consultation which is currently being revised through interagency collaboration.

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

#### **IV. Interim Risk Management and Reregistration Decision**

##### **A. Determination of Interim Reregistration Eligibility**

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

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient fenamiphos, as well as a fenamiphos-specific dietary risk assessment that has not considered the cumulative effects of the organophosphates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient fenamiphos, EPA has sufficient information on the human health and ecological effects of fenamiphos to make interim decisions as part of the tolerance reassessment process under FFDCFA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that fenamiphos is eligible for reregistration provided that: (i) current data gaps and additional data needs specified below are addressed and the resultant data do not demonstrate unreasonable adverse effects on the environment; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; (iii) cumulative risks considered for the organophosphates support a final reregistration eligibility decision; and (iv) the use of fenamiphos on extremely vulnerable soils is phased out by May 31, 2005, (because its continued use on such soils would result in acute and chronic dietary risks, due to drinking water, which are inconsistent with the Food Quality Protection Act of 1996). Label changes are described in Section V. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of fenamiphos, and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet considered cumulative risks for the organophosphates, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to support the continued use of fenamiphos. Based on its current evaluation of fenamiphos alone, the Agency has determined that fenamiphos products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of fenamiphos.

At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For fenamiphos, if all changes outlined in this document are incorporated into the labels and the use on extremely vulnerable soils is phased-out by May 31, 2005, then all current dietary risks will be mitigated. But, because this is an interim RED, the Agency may take further actions, if warranted, after considering the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

Because the Agency has not yet considered cumulative risks for the organophosphates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing fenamiphos food residue tolerances as called for by the FQPA. When the Agency has considered cumulative risks, fenamiphos tolerances will be reassessed in that light. At that time, the Agency will reassess fenamiphos along with the other organophosphate pesticides to complete the FQPA requirements and make a final reregistration eligibility determination. By publishing this interim decision on reregistration eligibility and requesting mitigation measures now for the individual chemical fenamiphos, the Agency is not deferring or postponing FQPA requirements. Rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending completion of the cumulative assessment required under the FQPA. This interim decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

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

## **B. Summary of Phase 5 Comments and Responses**

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. Overall, most people who submitted comments supported the continued use of fenamiphos on one or more use sites and, in some cases, provided information that helped the Agency refine the risk assessment. The registrant's comments focused mostly on specific studies and related issues that the registrant believed were important to improving the risk assessment. Generally speaking, there was limited information provided that addressed risk mitigation measures for reducing risk to humans or the environment. These comments in their

entirety are available in the docket. A brief summary of the comments and the Agency response is noted here.

*Comment: A number of comments focused on the value of fenamiphos and the need for continued availability. Comments of this type were received from academic scholars (representing universities in Louisiana, Georgia, and Florida), a state extension agent (from Georgia), nursery operators (in Michigan and Texas), and representatives from the American Nursery and Landscape Association, the Georgia Farm Bureau Federation, and the Georgia Agricultural Commodity Commission for Tobacco.*

EPA Response: These comments provided valuable information on the use of fenamiphos, and showed the pesticide's recognized and widespread role in nematode control for a number of different commodities and use sites.

*Comment: The International Banana Association submitted information on the use pattern and pest control alternatives for banana production, including estimates for the percent of banana crop treated by fenamiphos and other chemicals.*

EPA Response: This comment provided useful commodity specific information. Because the most recent dietary risk (food) assessment showed little risks of concern, the assessment has not been updated with the new information. If, however, it becomes necessary to refine the dietary risk assessment values in the future, the Agency will incorporate this new information at that time.

*Comment: Information submitted by the Pineapple Growers of Hawaii indicated the current application rates used in Hawaii are lower than the maximum application rate specified on the Nemacur 3 label. The pineapple growers also submitted an extensive document in support of continued use of fenamiphos on pineapples.*

EPA Response: This information informed the Agency's understanding of the current use practice on pineapples, leading to revision of the occupational risk assessment for workers involved with pineapple cultivation. After considering this information and consulting with the registrant, the registrant has agreed to lower the maximum application rate to the level currently used and recognized by the Pineapple Growers of Hawaii. The current human health risk assessment now reflects a lower application rate for calculating post-application residues, which dramatically reduced the restricted entry interval originally under consideration by the Agency.

*Comment: The registrant, Bayer Corporation, submitted comments addressing primarily the Agency's risk assessment findings and the methods employed by the Agency to reach those findings.*

EPA Response: Although these written comments by the registrant did not include measures to reduce the risk of fenamiphos, they helped the Agency to better characterize the risk assessment and to frame the mitigation measures which were needed.



## **C. Regulatory Position**

### **1. FQPA Assessment**

#### **a. “Risk Cup” Determination**

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment is 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 fenamiphos is within its own “risk cup,” provided that the risk mitigation measures identified in the IRED are implemented, including the termination of all uses on extremely vulnerable soils. In other words, if fenamiphos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for fenamiphos meet the FQPA safety standards, provided the mitigation measures outlined in this document are adopted and the use on extremely vulnerable soils is discontinued. 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, golfing, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to fenamiphos would fit within the individual risk cup if proposed mitigation were adopted, including the phasing out of the use on extremely vulnerable soils by May 31, 2005. Therefore, the fenamiphos tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is considered.

#### **b. Tolerance Summary**

In the individual assessment, tolerances for residues of fenamiphos in/on plant commodities [40 CFR §180.349] are presently expressed in terms of the combined residues of fenamiphos and its cholinesterase-inhibiting metabolites.

#### **Tolerances Listed Under 40 CFR §180.349 (a)(1):**

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.349(a) for the following commodities: apples; bananas; Brussels sprouts; cabbage; cherries; citrus, oil; citrus pulp, dried; cottonseed; eggplant; garlic; grapefruit; grapes; lemons; limes; okra; oranges; peaches; peanuts; pineapples; pineapples, bran; raisins; raspberries; strawberries; and

tangerines. Table 18 summarizes fenamiphos tolerances, provides modifications in commodity definitions and summarizes the recommendations for harmonizing U.S. tolerances with Codex MRLs.

The Agency proposes revoking the tolerance for pineapple bran since it is no longer considered to be a major animal feed item (see Residue Chemistry Guidelines 860, August 1996). In addition, the Agency proposes that the established tolerance for cottonseed be revoked because this use is being canceled. The revocation will allow sufficient time for legally treated commodities to clear the channels of trade.

A crop group tolerance of 0.5 ppm will be proposed for the citrus fruits group concomitant with the reassignment of the established tolerances for grapefruits, lemons, limes, oranges, and tangerines of 0.6 ppm. EPA also intends to propose that the tolerance for peanuts will be increased to 1.0 ppm.

**Tolerances Listed Under 40 CFR §180.349 (a)(2):**

Tolerances for milk, eggs and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep are no longer required due to the elimination of several feed items from Table 1 in Residue Chemistry Guidelines Series 860 dated August 1996. Section 180.349(a) (2) should be deleted from the CFR. See section 180.6(a)(3) for additional explanation.

**Tolerances Listed Under 40 CFR §180.349(b) - Reserved**

This section should be deleted from the CFR.

**Tolerances Listed Under 40 CFR §180.349(c):**

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.349(c) (i.e., tolerances with regional registrations, as defined in 180.1(n), for the combined residues of fenamiphos and its cholinesterase-inhibiting metabolites fenamiphos sulfoxide and fenamiphos sulfone) for the following commodities: asparagus; beets, garden, roots; beets, garden, tops; cabbage, Chinese; kiwifruits; and peppers, non-bell.

**Table 18. Tolerance Summary for Fenamiphos and its Metabolites.**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment* (ppm)	Comment
<b>Tolerances Listed Under 40 CFR §349(a)(1)</b>			
Apples	0.25	0.25	[Apple]
Bananas	0.10	0.10	[Banana]
Brussels sprouts	0.10	0.05	Codex harmonization
Cabbage	0.10	0.10	

<b>Commodity</b>	<b>Current Tolerance (ppm)</b>	<b>Tolerance Reassessment* (ppm)</b>	<b>Comment</b>
Cherries	0.25	0.25	<i>[Cherry, sweet and cherry, tart]</i>
Citrus, oil	25.0	25.00	<i>[Citrus, oil, refined]</i>
Citrus pulp, dried	2.5	2.50	<i>[Citrus, dried pulp]</i>
Cottonseed	0.05	Revoke	Use on cotton is no longer supported
Eggplant	0.1	0.05	Lower level sufficiently accounts for residues from current use practices
Garlic	0.50	0.50	
Grapefruit	0.60	Reassign	Reassign, concomitant with establishing group tolerance for <i>[fruit, citrus, group]</i> of 0.5 ppm to harmonize with Codex
Grapes	0.10	0.10	<i>[Grape]</i>
Lemons	0.60	Reassign	Reassign, concomitant with establishing group tolerance for <i>[fruit, citrus, group]</i> of 0.5 ppm to harmonize with Codex
Limes	0.60	Reassign	Reassign, concomitant with establishing group tolerance for <i>[fruit, citrus, group]</i> of 0.5 ppm to harmonize with Codex
Okra	0.30	0.30	
Oranges	0.60	Reassign	Reassign, concomitant with establishing group tolerance for <i>[fruit, citrus, group]</i> of 0.5 ppm to harmonize with Codex
Peaches	0.25	0.25	<i>[Peach]</i>
Peanuts	0.02	1.00	<i>[Peanut]</i>
Pineapples	0.30	0.30	<i>[Pineapple]</i>
Pineapples, bran	10.0	Revoke	No longer considered a feed item
Raisins	0.3	0.30	<i>[Grape, raisin]</i>
Raspberries	0.1	0.10	<i>[Raspberry]</i>
Strawberries	0.6	0.60	<i>[Strawberry]</i>
Tangerines	0.60	Reassign	Reassign, concomitant with establishing group tolerance for <i>[fruit, citrus, group]</i> of 0.5 ppm to harmonize with Codex

Commodity	Current Tolerance (ppm)	Tolerance Reassessment* (ppm)	Comment
<b>Tolerances Listed Under 40 CFR §349(a)(2)</b>			
Cattle, fat	0.05	Revoke	Based on revisions of the Series 860 Residue Guidelines (August 1996) (Table 1) meat and milk tolerances are no longer required due to elimination of several animal feed items used to estimate secondary residues in livestock commodities there is no reasonable expectation of finite residues in meat or milk. See 40 CFR 180.6(a)(3).  Delete Section 40 CFR Section 180.349(b).
Cattle, meat	0.05		
Cattle (mbyp)	0.05		
Goats, fat	0.05		
Goats, meat	0.05		
Goats (mbyp)	0.05		
Hogs, fat	0.05		
Hogs, meat	0.05		
Hogs (mbyp)	0.05		
Horses, fat	0.05		
Horses, meat	0.05		
Horses (mbyp)	0.05		
Milk	0.01		
Sheep, fat	0.05		
Sheep, meat	0.05		
Sheep (mbyp)	0.05		
<b>Tolerances Listed Under 40 CFR §349(c)</b>			
Asparagus	0.02	0.02	
Beets, garden, roots	1.5	1.50	<i>[Beet, garden, roots]</i>
Beets, garden, tops	1.0	1.00	<i>[Beet, garden, tops]</i>
Bok choy	0.5	0.50	<i>[Cabbage, Chinese, Bok choy]</i>
Kiwifruit	0.1	0.10	<i>[Kiwifruit]</i>
Peppers, non-bell	0.6	0.60	<i>[Pepper, nonbell]</i>

\* The term "reassessed" here is not meant to imply that the tolerance has been reassessed as required by FQPA, since this tolerance may be reassessed only upon completion of the cumulative risk assessment of all organophosphates, as required by this law. Rather, it provides a tolerance level for this single chemical, if no cumulative assessment was required, that is supported by all of the submitted residue data.

The Agency intends to commence proceedings to revoke, modify the existing tolerances, and correct commodity definitions in accordance with the table above. The establishment of a new tolerance or raising tolerances will be deferred, pending the outcome of the cumulative assessment. If the registrant elects not to support its domestic fenamiphos registrations, then the Agency will work to identify which tolerances are being requested to be kept as import tolerances, whether the above levels are appropriate, and whether additional data are necessary.

### **c. Codex Harmonization**

Several maximum residue limits (MRLs) for fenamiphos have been established in various commodities by the Codex Alimentarius Commission. The fenamiphos residues regulated by Codex and the U.S. are equivalent. The recommended changes to U.S. tolerances are based on a reassessment of existing tolerances and may or may not be compatible with Codex.

The Agency has reached a number of conclusions on efforts to harmonize U.S. tolerances with Codex MRLs. These conclusions are outlined in Table 19. No questions of compatibility exist with respect to commodities where: (i) no Codex MRLs have been established but U.S. tolerances exist; and (ii) Codex MRLs have been established but U.S. tolerances do not exist. Compatibility between the U.S. tolerances and Codex MRLs exists for bananas, cottonseed, and grapes. The recommended increase in the level of the U.S. tolerance for peanuts to 1.0 ppm will not be compatible with the Codex MRL of 0.05 ppm, but is necessary to allow for potential residues from use practices in the United States.

The level of the U.S. tolerances should be decreased to achieve compatibility with the Codex MRLs for Brussels sprouts (from 0.10 to 0.05 ppm) and oranges (from 0.6 for oranges to 0.5 ppm for citrus fruits group). The available residue data support these decreased tolerance levels.

The U.S. tolerances for the following commodities are based on registered use patterns in the U.S. and cannot be lowered to achieve compatibility with the Codex MRLs: cabbage, kiwifruits, and pineapples. If the registrant elects not to support its domestic fenamiphos registrations and these tolerances are still needed for imported commodities, then the import-only tolerances will be established at the Codex MRLs.

**Table 19. Codex MRLs with Applicable U.S. Tolerances**

Commodity	MRL (mg/kg) <sup>1</sup>	U.S. Tolerance (ppm)	Recommendation
Bananas	0.1	0.10	
Broccoli	0.05 <sup>2</sup>	0.1 (proposed)	Deferred comparison
Brussels sprouts	0.05 <sup>2</sup>	0.10	Decrease U.S. tolerance
Cabbages, head	0.05 <sup>2</sup>	0.10	Retain U.S. tolerance
Cauliflower	0.05 <sup>2</sup>	0.1 (proposed)	Deferred comparison
Coffee beans	0.1	0.2 (proposed)	Decrease U.S. tolerance proposal
Cotton seed	0.05 <sup>2</sup>	0.05	U.S. tolerance to be revoked
Grapes	0.1	0.10	
Kiwifruit	0.05 <sup>2</sup>	0.10	Retain U.S. tolerance
Melons, except watermelon	0.05 <sup>2</sup>	0.05 (proposed for cantaloupes)	
Oranges, sweet, sour	0.5	0.6	Decrease U.S. tolerance for citrus fruits group
Peanut	0.05 <sup>2</sup>	0.02	Increase U.S. tolerance from 0.02 to 1.0 ppm
Pineapple	0.05 <sup>2</sup>	0.30	Retain U.S. tolerance

<sup>1</sup> All fenamiphos MRLs are final (CXL).

<sup>2</sup> At or about the limit of detection.

#### **d. Residue Analytical Methods**

Adequate enforcement methods are available for determining residues of fenamiphos and its cholinesterase-inhibiting metabolites in/on plant and animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists two GLC methods, each with thermionic detection (TD) and a limit of detection of 0.01 ppm. Method I (Bayer, Inc. Method 25402) is available for the determination of the combined residues of fenamiphos and its sulfoxide and sulfone metabolites, measured as sulfone, in/on plant commodities and Method II is available for the determination of the combined residues of fenamiphos, its sulfoxide and sulfone metabolites, des-isopropyl fenamiphos, des-isopropyl fenamiphos sulfoxide, and des-isopropyl fenamiphos sulfone in animal tissues and milk.

Residue data submitted in response to the Guidance Document and in support of petitions for the establishment of new tolerances were collected using modifications of the available PAM Vol. II

methods. These modified methods, along with other methods listed in PAM Vol. II, are adequate for fenamiphos data collection and tolerance enforcement.

## **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, fenamiphos may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

## **3. Benefits**

Fenamiphos is one of only a handful of effective nematicides available for use in agriculture. It provides effective control of many important plant parasitic nematodes and several important insect pests, which can cause severe crop damage and significant yield losses if left unchecked. Fenamiphos is effective for use both pre-plant and post-plant. As a post-plant application, fenamiphos is often the only effective nematicide available. The post-plant application is critical for perennial crops, such as pineapple, kiwifruit, tree fruits, grapes and raspberries, which must rely solely on a post-plant control of nematodes after the first growing season. For most of these crops fenamiphos is the only effective post-plant control. Fenamiphos is also important for the control of nematodes in a number of annual crops as well, particularly in California (the state with the highest agricultural usage), where effective nematode controls include several soil fumigants and fenamiphos. California has imposed use restrictions on the soil fumigants, which limits the availability of these nematicide alternatives (e.g., telone, methyl bromide, metam-sodium).

Fenamiphos is also critical for the control of nematodes in golf course turf. The two predominant target pests in the major usage states are sting and lance nematodes. Other damaging but less frequently encountered pests are awl, cyst, ring, root-knot, sheath, and sheathoid nematodes. The types and extent of damage varies with the nematode type(s) present, population levels, types of grass, environmental stress levels (soil temperature, water availability, etc.) and other unknown soil factors. Nematodes are root parasites and cause damage including stunted growth, foliage discoloration, premature wilting of plants, and death of plants.

There are more than 2 million acres of golf course turf in the U.S. Private golf courses account for nearly 85% of the approximately 17,000 golf courses in the U.S. and municipal/county golf courses account for the remaining 15% of courses. The Southern U.S. accounts for nearly 35% of the total number of golf courses in the U.S., followed by the North Central (32%), Northeast (17%), and the West (16%). The average size of a golf course in the U.S., though it varies widely, is 122 acres. Approximately 2% of this acreage is greens, another 2% tees, 23% fairways, 70% roughs, and the remaining 3% is miscellaneous grounds. Information supplied by golf course superintendents in Florida suggests that fenamiphos is used mainly on tees and greens (90% of the time), with the remaining use as the spot treatment of fairways. It appears that there is very little complete golf course application of fenamiphos.

Limited data suggests that 80,000 to 100,000 pounds of fenamiphos are applied to turf annually, of which 95% is used on golf courses. Between 1996 and 1999, estimates show that fenamiphos usage on turf increased more than 25%. Although data limit estimates by region, the majority of the fenamiphos usage on turf appears to occur in the Southern U.S., with Florida accounting for more than 75% of the usage on turf. California is the only state with significant turf usage outside of the Southern U.S. Fenamiphos is relatively expensive to apply (costing as much as \$300 per acre) and, as a result, more than 75% of the use is on private golf courses.

Estimates of the number of courses in Florida using fenamiphos range from 50 to 90% in a given year, and those not using fenamiphos probably do not have severe nematode problems. It is also estimated that in Florida, on average, 33% of the golf courses use none or very little fenamiphos per year, 33% apply fenamiphos once per year, and 33% apply fenamiphos twice per year.

Increased fertilizer and water are often used to treat nematode infestations and fenamiphos is used only when the problem cannot be controlled by these means. Water is not always an option, due to limits on water usage in some areas and under certain conditions. There are no registered fenamiphos alternatives known to be effective for use on turf, and if fenamiphos is not available on turf, golf courses and turf farms could be adversely impacted.

Without fenamiphos, golf courses would likely face significant cost increases associated with the replacement of nematode damaged turf. Depending on the method chosen by a golf course to repair damaged turf, costs would range from \$4,000 per green for renovation to \$25,000 per green for reconstruction. Additional economic costs would likely occur due to the closing of the affected areas of a course for significant periods of time, and a decline in their customer base as a result of diminished playing conditions. The replacement of turf is a worst-case scenario, but is a likely result from uncontrolled nematode infestations. Nematode damage is most severe on tees, greens and fairways, which golfers expect to be in good playing condition. It is not clear how much more often turf damage would result in diminished playing conditions or turf would need to be replaced on golf courses, but given that as many as 90% of the Florida golf courses (there are more than 1,600 courses and the majority of fenamiphos used on turf is in Florida) use fenamiphos in a given year, damage could be severe and widespread if fenamiphos were not available.



#### 4. Labels

A number of label changes are necessary in order for fenamiphos products to be eligible for reregistration. Provided the following risk mitigation measures are incorporated in their entirety into labels for fenamiphos-containing products, the Agency finds that all currently registered uses of fenamiphos, except for the use in areas with extremely vulnerable soils, are eligible for reregistration, pending consideration of cumulative risks of the organophosphates. The use in areas with extremely vulnerable soils is ineligible for reregistration and will be phased out no later than May 31, 2005.

The risks of concern warranting label changes include dietary (ground water and surface water sources of drinking water); occupational (many handler types and certain post-application workers); and ecological (non-target terrestrial and aquatic organisms).

Mitigation measures include:

- Phase-out the use of fenamiphos on extremely vulnerable soils by May 31, 2005 (soils that are hydrologic soil group A, excessively drained and predominately sand or loamy sand, such as soils in the suborder psamments, and where ground water is less than 50 feet deep)
- Closed mixing/loading systems and application by enclosed cab for liquid products
- Organic vapor-removing respirators and double-layer clothing for mixers, loaders and applicators of the granular formulation
- Cancellation of the use on cotton and the granular formulation on pineapples (already in process)
- Reduce the application rate on protea (evergreen shrubs) to 10 lb ai/A, pineapples to 2 lb ai/A, and grapes to 4.5 lb ai/A
- Revise use directions for all agricultural crops to indicate minimum row spacing (derived from proposed maximum lbs per acre) in addition to application by row length (per 1000' of row)
- Establish or lower the maximum amount of fenamiphos that can be applied per season on: pineapples (reduced to 9 lb, ratoon crop; 12 lb plant crop), Brussel sprouts (4.5 lb), eggplant (2 lb), peanuts (2.55 lb), peppers (non-bell) (2 lb), Bok Choy (4.5 lb), tobacco (6 lb), citrus (5 lb in FL, 7.5 lb elsewhere), strawberries (4.5 lb), asparagus (2 lb), garden beets (3 lb), ornamentals (10 lb), leatherleaf fern (9 lb), garlic (4.5 lb)
- Prohibit use of any body-mounted or hand-held application equipment

- For turf, limit the amount of product handled to that needed to treat 5 acres/person/day (maximum of 50 pounds active ingredient) for granular products and to 20 acres/person/day (200 pounds ai/day) for liquid products
- Prohibit the use between noon and sunset during the heavy thunderstorm season (June through September) for all applications that require overhead irrigation for incorporation
- When overhead sprinkler irrigation is used to incorporate fenamiphos, irrigation must occur within 6 hours of the application

**D. Regulatory Rationale**

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

**1. Human Health Risk Mitigation**

**a. Dietary Mitigation**

**1) Acute Dietary (Food)**

Dietary risk from food alone does not pose an acute risk of concern. The acute dietary estimate is below the Agency's level of concern for the general U.S. population and all population subgroups. Nursing infants (younger than 1 year of age), the most highly exposed subpopulation, are exposed to fenamiphos at a level of less than 1% of the aPAD. No mitigation measures for acute dietary food risk are necessary at this time.

**2) Chronic Dietary (Food)**

The chronic dietary risk estimate is also below the Agency's level of concern for the general population and all population subgroups. The risk is estimated to be less than 1% of the cPAD for all population subgroups, including the most highly exposed subgroup of infants and children (from 1 to 6 years of age). No mitigation measures for chronic dietary food risks are necessary at this time.

**3) Drinking Water**

In calculating risks to populations drinking ground water, the Agency's assessment found that the expected concentrations in drinking water varied significantly depending on the type of soil and depth to ground water. When soils are extremely vulnerable and the groundwater is shallow, fenamiphos is expected to rapidly leach into ground water. As the soils become less vulnerable, the expected concentrations drop dramatically. For the purposes of this assessment the Agency established two distinct categories of soil types: extremely vulnerable and vulnerable. The vulnerable

category is expected to portray worst-case exposure for all soil types that are not extremely vulnerable. The extremely vulnerable category contains those soils classified as hydrologic soil group A soils that are excessively drained and predominately sand or loamy sand and where the ground water table is less than 50 feet deep. The Central Ridge of Florida is an example of an area where the soil would be classified extremely vulnerable.

#### Groundwater in areas with vulnerable soils

The Agency is not concerned about people drinking ground water when fenamiphos is used in areas with soils that are not extremely vulnerable. In these areas, for both acute and chronic risk, the expected environmental concentrations (EECs) in drinking water are lower than the drinking water levels of concern (DWLOCs). For turf, the crop with the highest application rate, the Agency found that the acute EEC is 7 and the chronic EEC is 0.93 ppb, while the acute DWLOC is 12 ppb and the chronic DWLOC is 1 ppb.

Although the EECs from use in areas that do not have extremely vulnerable soil are below the DWLOCs, these estimates are based on results from the prospective ground water study that was conducted in California. The Agency has concerns that deficiencies in this study make it difficult to unequivocally conclude that higher concentrations will not occur in vulnerable soils. Therefore, the Agency will be issuing a DCI requiring additional monitoring in these soils to confirm that concentrations in ground water in such soils are not of concern.

#### Groundwater in areas with extremely vulnerable soils

The Agency is concerned about people drinking ground water in areas where fenamiphos is used on extremely vulnerable soils. In these areas, for both acute and chronic risk, the expected environmental concentrations (EECs) in drinking water are substantially higher than the drinking water levels of concern (DWLOCs). Using turf as an example, the Agency found that the acute EEC is 425 and the chronic EEC is 45 ppb, while the acute DWLOC is 12 ppb and the chronic DWLOC is 1 ppb.

Based on this analysis, the Agency believes that the potential risk to the public from the use of fenamiphos on extremely vulnerable soils is of concern and inconsistent with the Food Quality Protection Act (FQPA). Therefore, this use is ineligible for reregistration and will be phased out by May 31, 2005.

The Agency's concern for groundwater is based on monitoring data associated with agricultural crops grown in extremely vulnerable soils and leaching studies conducted on turf. These studies provide solid evidence that fenamiphos and its degradates can leach to ground water. Although available ground water monitoring data are limited in some aspects, they are sufficient to show that significant ground water contamination would be expected in areas with sandy soils.

During the public comment period and subsequent mitigation discussions, the technical registrant for fenamiphos, Bayer Corporation, and the State of Florida expressed a concern that the

Agency's conclusions are based on data from agricultural scenarios, which may not directly translate to turf. They have requested the opportunity to develop additional monitoring data supporting the use on golf courses in extremely vulnerable soils. If the registrant elects to develop monitoring data, Florida has agreed to participate in the study design/development, conduct and oversight in cooperation with the Agency. Several other states have also expressed a preliminary interest.

The importance of fenamiphos to the golf course industry, particularly in Florida, is well understood by the Agency. Nevertheless, the Agency believes existing data demonstrate that the use on extremely vulnerable soils will result in ground water contamination at levels that pose dietary risk concerns, particularly given the magnitude of the detections above the acute and chronic DWLOCs and Bayer Corporation's earlier voluntary cancellation of the use of fenamiphos on citrus on the Central Ridge of Florida based on these same monitoring data. Therefore, the use on extremely vulnerable soils are ineligible for reregistration and will be phased out by May 31, 2005. However, because these data are not irrefutable, the Agency will consider any data that are submitted during the three-year phase-out period and, if appropriate, reconsider its decision before the final date of cancellation for this use.

### Surface Water

Modeling results for a drinking water reservoir downgradient of a watershed planted in grapes are 141 ppb for the peak concentration, 13.7 ppb for the annual mean, and 7.4 ppb for the overall mean (i.e., 36-year average). Although these estimates are substantially higher than the DWLOCs of 12 ppb for acute exposure and 1 ppb for chronic exposure, the Agency believes that these values significantly overestimate risk to people who drink water from surface water sources.

In making this determination, the Agency considered the fact that PRZM-EXAMS is a Tier II model, and is considered to be a screening-level assessment. Also, as discussed earlier, the model used conservative assumptions because key data are missing but also did not consider the degradates. Overall, the Agency expects the model results to be higher than those actually found in surface water used as a drinking water source. EPA will issue a Data Call-In for environmental fate data for fenamiphos and its degradates to refine the assessment. In addition, the Index Reservoir scenario is undergoing revision of several assumptions that are expected to lower the predicted concentrations for fenamiphos. The Agency believes that, were complete environmental fate data available and model updates and refinements implemented, the results would show that surface water in areas where fenamiphos is used would contain total fenamiphos residues at concentrations that are less than the DWLOC.

For fenamiphos to be eligible for reregistration (except for the use on extremely vulnerable soils), a prohibition on its use between noon and sunset during the heavy thunderstorm season (June through September) is necessary for all applications that require overhead irrigation for incorporation. In addition, in cases when overhead sprinkler irrigation is used to incorporate fenamiphos, irrigation will need to occur within 6 hours of the application.

#### **4) Residential/Recreational (Golfer)**

Fenamiphos is not used in a residential setting. However, because fenamiphos is used on golf course turf, golfers may be exposed to its residues when playing on a treated course. As discussed in Section III, the Agency believes that exposure to golfers is not of concern, provided fenamiphos is watered in after application to golf course turf. Additional data are being called-in for the granular formulation to confirm this conclusion

#### **5) Aggregate**

An aggregate risk assessment looks at combined exposure from dietary (food and drinking water routes) and residential or non-occupational sources, when appropriate. For fenamiphos, an aggregate assessment would include dietary and golfer exposure. The risks to golfers cannot be included in the aggregate risk assessment at this time as the data are not sufficient or robust enough to allow this calculation. However, the Agency believes golfer exposure is not significant and that its inclusion in the aggregate risk assessment will not change the conclusions of the aggregate risk assessment. To confirm this determination, the Agency is requiring additional data.

As discussed in the drinking water section above, the Agency is not concerned about the risk to any population exposed to combined fenamiphos residues from food and drinking water, provided the population is not drinking ground water in areas with extremely vulnerable soils. Therefore, the Agency believes that the results of the drinking water and food aggregate assessment also describes total aggregate risk from exposure to fenamiphos residues. Also, as mentioned earlier, in areas with extremely vulnerable soils, the potential drinking water exposure derived from ground water is of concern and these uses are not eligible for reregistration.

### **b. Occupational Risk Mitigation**

#### **1) Agricultural Uses**

The Agency's occupational risk findings show that many fenamiphos uses do not pose risks of concern. Some uses, however, pose occupational risks exceeding the Agency's level of concern for certain handlers and workers. The Agency has worked with the registrant and user community to explore ways of reducing occupational risks in general and believes many of the measures agreed to by the registrant will reduce the occupational risk to levels not of concern. In some cases, however, the Agency's risk estimates show that certain handlers remain at risk levels higher than the Agency's risk reduction objectives. To limit exposure to fenamiphos, the PPE and engineering controls outlined in Table 20 are necessary.

**Table 20. PPE Summary for all Agricultural Scenarios**

Scenario	PPE (in addition to long-sleeved shirt, long pants, socks, shoes)	Engineering Controls
Loading Granulars (Scenario I)	Coveralls, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant headgear for overhead exposures, and an organic vapor-removing respirator	not available
Mixing Liquids Groundboom (Scenario II)	Chemical-resistant gloves and chemical-resistant apron	closed system
Mixing Liquids Chemigation (Scenario III)	Chemical-resistant gloves and chemical-resistant apron	closed system
Groundboom Applications (Scenario IV)	none	enclosed cab
Soil Injection (Scenario V)	not applicable	not applicable
Granular, Tractor-Drawn Application (Scenario VI)	Coveralls, chemical-resistant gloves, chemical-resistant footwear plus socks, and an organic vapor-removing respirator	none
Loading/Applying Push Spreader (Scenario VII)	Coveralls, chemical-resistant gloves, chemical-resistant footwear plus socks, and an organic vapor-removing respirator	not available

### Granular Product

The Agency assessment shows that, after mitigation, the use of the granular product does not pose a risk of concern to workers for any crop other than for workers using a push spreader. For workers using a push spreader, the MOE is 28. Mitigation that is necessary to reduce the risk from the granular product include:

- using an organic vapor-removing respirator and a double layer of clothing
- limiting the amount of active ingredient a single worker can handle to 50 lb ai/day for turf uses
- prohibiting use of any body-mounted or hand-held application equipment

### Liquid Products

For mixer/loaders and applicators using liquid fenamiphos, MOEs are of concern (less than 100) for several different crops. Of the MOEs of concern for agricultural products, all are above 50, with the majority from 65 - 75. For turf, the MOEs are 37 for mixer/loaders and 53 for applicators using groundboom equipment. To mitigate these risks, the following measures are necessary:

- Closed mixing/loading systems and application by enclosed cab
- Reduced application rates for various crops

- Limit the amount of active ingredient a single worker can handle to 200 lbs ai/day for turf uses

In light of the significant benefits that are derived from the use of fenamiphos, the Agency believes that the products are eligible for reregistration provided that these mitigation measures are implemented.

## **2) Postapplication Risk Mitigation**

The Agency requires data and/or further clarification of the use patterns involving workers handling or working with or in fenamiphos-treated soil which may result in postapplication exposure. These uses are on strawberries, asparagus, ornamental nonflowering plants, ornamental herbaceous plants, sod farm turf, ornamental woody shrubs and vines, and all nursery stock. For these sites the 48-hour REI will be required, until receipt and evaluation of the additional data. The Agency also requires confirmation that the golf course use does not result in postapplication exposure as a result of handling treated grass clippings.

Pineapple is the only crop that is treated with a foliar application of fenamiphos. Based on chemical-specific data and a proposed label rate reduction to 2 lb ai/acre from 9 lb ai/acre, the Agency believes that the MOE for harvesting pineapples would be greater than 100 in less than 48 hours. The current WPS REI for pineapples of 48 hours is based on multiple factors, including acute toxicity, and should be continued for post-application reentry.

## **2. Environmental Risk Mitigation**

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

The fenamiphos ecological assessment indicates that virtually all uses at all maximum labeled rates result in risks that exceed both the high acute and chronic risk levels of concern for terrestrial, aquatic, and endangered species. Even though fenamiphos is either soil incorporated or watered-in, which may reduce potential exposures to wildlife, it is highly toxic causing small amounts to pose a high risk to sensitive species. Incident data, as outlined in Section III(B)(5) support this conclusion, as fish and bird kill incident reports indicate losses of wildlife directly attributable to fenamiphos. The implementation of earlier mitigation measures, such as lowering application rates and minimizing runoff potential, may help in reducing these types of incidents.

### **a. Avian and Mammalian Species Mitigation**

The Agency's risk assessment for avian and mammalian species exceeds the level of concern for both acute and chronic exposure.

Because research shows that fenamiphos must be applied at current application rates for the pesticide to be efficacious, the Agency is unable to reduce these rates to be more protective of avian

and mammalian species that may be exposed on an acute basis. The Agency is, however, proposing additional label changes to reduce exposure, including: cancellation of cotton use and granular use on pineapples; reducing maximum seasonal application rates for several crops; and requiring more rapid watering in, when irrigation is used to incorporate fenamiphos.

Although these measures may somewhat reduce fenamiphos exposure to wildlife, they are not expected to reduce it to levels that are not of concern to the Agency. However, because there are significant benefits from these uses of fenamiphos, as outlined above, the Agency is not proposing additional action at this time.

#### **b. Aquatic Species Mitigation**

In all acute and nearly all chronic cases examined, the risk to nontarget aquatic organisms exceeds the LOC for all fenamiphos use sites. RQs for the aquatic risk in relation to fenamiphos residues range from 1.6 to 464 for acute and from 1.2 to 6,375 for chronic risk. The higher RQ values are based on a less refined, Tier I, model that is expected to overestimate actual risk. The Agency is requiring additional acute and chronic data on the degradates and additional chronic data on the parents to refine the risks. These data are expected to confirm the conclusions reached in this assessment.

To mitigate these risks, the Agency is proposing the following measures: cancellation of cotton use and granular use on pineapples; reduction of the maximum seasonal application rates for several crops; requiring more rapid watering in, when irrigation is used to incorporate fenamiphos; and restrictions on time of day applied during thunderstorm season to limit the potential for runoff.

Although these measures may somewhat reduce fenamiphos exposure to aquatic species, they are not expected to reduce it to levels that are not of concern to the Agency. However, because there are significant benefits from these uses of fenamiphos, as outlined above, the Agency is not proposing additional action at this time.

#### **E. 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 fenamiphos. For the specific labeling statements, refer to Section V of this document

##### **1. Endangered Species Statement**

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires Federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, EPA puts basic toxicity and exposure data developed for interim REDs into



context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticides uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will include consideration of the regulatory changes recommended in this interim RED. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service, or other measures to mitigate any potential impact, as necessary.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at [www.epa.gov/espp](http://www.epa.gov/espp). A final Endangered Species Protection Program, which may be altered from the interim program, is scheduled to be proposed for public comment in the Federal Register in 2002.

## **2. Spray Drift Management**

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

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

For purposes of complying with the deadlines for label submission outlined in this document, registrants (and applicants) may elect to adopt the appropriate sections of the proposed language in Table 21, or a version that is equally protective, for their end-use product labeling. The Agency recognizes that the proposed language does not address application types other than liquids. Registrants may therefore wish to adapt some variation of the old, and proposed new language for their particular products, depending on their application methods.

## V. What Registrants Need to Do

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

- A. For fenamiphos technical grade active ingredient products,

**Within 90 days from receipt of the generic data call-in (DCI):**

- completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
- submit any time extension and/or waiver requests with a full written justification.

**Within the time limit specified in the generic DCI:**

- cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

- B. For products containing the active ingredient fenamiphos,

**Within 90 days from the receipt of the product-specific data call-in (PDCI):**

- completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
- submit any time extension or waiver requests with a full written justification.

**Within eight months from the receipt of the PDCI:**

- two copies of the confidential statement of formula (EPA Form 8570-4);
- a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
  - (1) five copies of the draft label incorporating all label amendments outlined in Table 21 of this document;
  - (2) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

- (3) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
- (1) the product-specific data responding to the PDCI.

**A. Manufacturing Use Products**

**1. Additional Generic Data Requirements**

The generic data base supporting the reregistration of fenamiphos for the above eligible uses has been reviewed and determined to be substantially complete. If the registrant elects to continue supporting its domestic registrations for fenamiphos, then the following data will be required.

875.2100	Foliar dislodgeable residue dissipation study for granular formulation on golf course turf
875.2200	Soil residue dissipation (to evaluate exposures to workers transplanting strawberries)
835.2240	Photodegradation in water (using parent fenamiphos and degradates) <sup>1</sup>
835.4100	Aerobic Soil Metabolism (parent and degradates) <sup>2</sup>
835.4200	Anaerobic Soil Metabolism <sup>2</sup>
835.4300	Aerobic Aquatic Metabolism (parent and degradates) <sup>2</sup>
850.2100	Acute avian oral with one species <sup>2</sup>
850.2200	Avian sub-acute dietary with bobwhite <sup>2</sup>
850.1010	Acute aquatic invertebrate, Daphnia <sup>2</sup>
850.1025	Acute estuarine-marine with oyster <sup>2</sup>
850.1035	Acute estuarine-marine with mysid shrimp <sup>2</sup>
850.1035	Acute estuarine-marine with sheepshead minnow <sup>2</sup>
850.1350	Fish ELS for estuarine-marine (parent fenamiphos and degradates) <sup>2</sup>
850.1400	Fish early life stage (ELS), freshwater <sup>2</sup>
850.1500	Invertebrates life cycle for estuarine-marine (parent fenamiphos and degradates) <sup>2</sup>

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; for fenamiphos, these data are due in 2003.

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<sup>1</sup> Conducted using fenamiphos sulfoxide and fenamiphos sulfone

<sup>2</sup> A total of six studies, three (one each for parent, fenamiphos sulfoxide, fenamiphos sulfone) using subsoil (i.e., deep horizon material) and aquifer solid material, rather than topsoil. Another three (one each for parent, fenamiphos sulfoxide, fenamiphos sulfone) using topsoil. All six studies should measure the pH and Eh of the soil.

## **2. Labeling for Manufacturing Use Products**

To remain in compliance with FIFRA, manufacturing use product labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The labeling should bear the labeling contained in Table 21 at the end of this section.

### **B. End-Use Products**

#### **1. Additional Product-Specific Data Requirements**

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

#### **2. Labeling for End-Use Products**

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 21 at the end of this section.

### **C. Existing Stocks**

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

The Agency has determined that registrant may distribute and sell fenamiphos products bearing old labels/labeling upon approval of new labels. Persons other than the registrant may distribute or sell such products for 24 months from the date of the issuance of this interim RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

#### **D. Required Labeling Changes Summary Table**

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The Table 21 describes how language on the labels should be amended. Label language in Table 21 enclosed in quotation marks represents exact language that should appear on the label. Instructions that are not enclosed in quotation marks represent actions that the registrant must take to amend their labels or product registrations in order for the product to be eligible for reregistration.

**Table 21: Required Labeling Changes Summary Table**

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	“Only for formulation into an nematicide/insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant].”	Directions for Use
	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
All End Use Products		
Handler PPE guidance (all formulations)	Note: Any conflicting PPE requirements on the current label must be removed. PPE that is established on the basis of Acute Toxicity testing with the end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.	Not on label

Description	Amended Labeling Language	Placement on Label
<p>PPE requirements established by the IRED for liquid products</p>	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are” <i>[registrant insert correct chemical-resistant material]</i>. “If you want more options, follow the instructions for category” <i>[registrant inserts A,B,C,D,E,F,G, or H]</i> “on an EPA chemical-resistance category selection chart.”</p> <p>Mixers, loaders, and applicators using engineering controls must wear:</p> <ul style="list-style-type: none"> <li>-- long-sleeved shirt and long pants,</li> <li>-- shoes plus socks.</li> </ul> <p>In addition, mixers and loaders must wear:</p> <ul style="list-style-type: none"> <li>-- chemical-resistant gloves,</li> <li>-- chemical-resistant apron.</li> </ul> <p>Handlers performing tasks such as equipment or spill clean-up, for which engineering controls are not feasible must wear:</p> <ul style="list-style-type: none"> <li>-- coveralls over long-sleeved shirt and long pants,</li> <li>-- chemical-resistant gloves,</li> <li>-- chemical-resistant footwear plus socks,</li> <li>-- chemical-resistant headgear if overhead exposure,</li> <li>-- chemical-resistant apron.</li> <li>-- A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N*, R or P or He prefilter.”</li> </ul> <p>Note: N type filter must be dropped from respirator statement if product contains or is used with oil.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Description	Amended Labeling Language	Placement on Label
Engineering Controls for liquid products	<p>“Engineering Controls</p> <p>Mixers and loaders must use a closed loading system providing dermal and inhalation protection and all loaders must use and maintain this system in a manner consistent with the Worker Protection Standard (WPS) for Agricultural Pesticides [40 CFR 170.240(d)(4)]. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to no more than 2 ml per disconnect. In addition, mixers and loaders must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required above for mixers/loaders;</li> <li>-- wear protective eyewear if the system operates under pressure;</li> <li>-- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown the PPE specified above for handlers performing tasks for which engineering controls are not feasible.”</li> </ul> <p>“Applicators using motorized ground equipment must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required in the PPE section of this labeling for applicators using engineering controls;</li> <li>-- <i>either</i> wear the type of respirator specified in the PPE section of this labeling <i>or</i> use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling;</li> <li>-- must be provided and have immediately available for emergency use if exiting the cab in the treated area becomes necessary the PPE specified above for handlers performing tasks for which engineering controls are not feasible;</li> <li>-- before reentering the cab, the applicators must take off any PPE that was worn in the treated area and store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.” </li></ul>	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately after PPE and User Safety Requirements.)



Description	Amended Labeling Language	Placement on Label
PPE requirements established by the IRED for granular products	<p>“Personal Protective Equipment (PPE)</p> <p>Some materials that are chemical-resistant to this product are” <i>[registrant inserts correct chemical-resistant material]</i>. “If you want more options, follow the instructions for category” <i>[registrant inserts A,B,C,D,E,F,G, or H]</i> “on an EPA chemical-resistance category selection chart.”</p> <p>Mixers, loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>-- coveralls over long-sleeved shirt and long pants,</li> <li>-- chemical-resistant gloves,</li> <li>-- chemical resistant footwear plus socks,</li> <li>-- chemical-resistant headgear (if overhead exposure).</li> <li>-- A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N<sup>2</sup>, R or P or He prefilter.”</li> </ul> <p>“In addition, mixers, loaders and cleaners of equipment must wear a chemical-resistant apron”</p> <p>Note: N type filter must be dropped from respirator statement if product contains or is used with oil.”</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls for granular products	“When handlers use closed systems, enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately after PPE and User Safety Requirements.)
User Safety Requirements	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> <p>“Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	Immediately following Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	<p>“User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following applicator and handler statements in PPE section</p> <p>(Must place in box.)</p>
Restricted-Entry Interval Liquid and Granular Formulations	<p>“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours.”</p> <p>“Exception: if the product is soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated areas without the 48-hour restriction if there will be no contact with anything that has been treated.”</p> <p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> <li>-- coveralls worn over long-sleeve shirt and long pants,</li> <li>-- chemical-resistant gloves made of any waterproof material,</li> <li>-- chemical-resistant footwear plus socks, and</li> <li>-- chemical-resistant headgear (if overhead exposure)”</li> </ul> <p>“Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area.”</p>	<p>Agricultural Use Requirements Box for agricultural crops</p> <p>or</p> <p>Directions for Use directly above Agricultural Use Requirement Box for other crops</p>
General Application Restrictions	<p>“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulations.”</p>	<p>Direction for Use immediately after the misuse statement</p>

Description	Amended Labeling Language	Placement on Label
Spray Drift Restrictions for Liquid Products	<p>“Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals.”</p> <p>“For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy, and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles.”</p> <p>For overhead chemigation:</p> <p>“Apply only when wind speed is 10 mph or less.”</p> <p>On all product labels:</p> <p>“The applicator also must use all other measures necessary to control drift.”</p>	Directions for Use
Restricted Use Classification Required for all Products	<p>“Restricted Use Pesticide</p> <p>Due to high acute toxicity and toxicity to wildlife</p> <p>For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.”</p>	Top of the Label

Description	Amended Labeling Language	Placement on Label
Application Rate Restrictions	<p>See Appendix A for a detailed listing of methods, and other restrictions.</p> <p>The following reduced application rates are being proposed:  pineapple: 2 lb ai/A  protea: 10 lb ai/A  grapes: 4.5 lb ai/A</p> <p>The following maximum applications per season are being proposed:</p> pumpkin: 2 lb ai/A/season asparagus: 2 lb ai/A/season Bok Choy: 4.5 lb ai/A/season Brussels sprouts: 4.5 lb ai/A/season citrus: 5 lb ai/A/season in Florida 7.5 lb ai/A/season elsewhere eggplant: 2 lb ai/A/season garden beets: 3 lb ai/A/season garlic: 4.5 lb ai/A/season leatherleaf fern: 9 lb ai/A/season ornamentals: 10 lb ai/A/season peanuts: 2.55 lb ai/A/season peppers (non-bell): 2 lb ai/A/season pineapples: 9 lb ai/A/season, ratoon crop 12 lb ai/A/season, plant crop strawberries: 4.5 lb ai/A/season tobacco: 6 lb ai/A/season <p>Labels should be amended to specify minimum row spacing (which corresponds to maximum lb per acre) in addition to application by 1000' of row length.</p> <p>“Do not apply to hydrologic soil group A soils that are excessively drained and predominately sand or loamy sand such as soils in the suborder psammets. These classifications and soil taxonomy refer to USDA definitions. If you are unsure of the type of soil you are treating, please consult with you county’s extension agent or the product manufacturer.”</p>	Directions For Use under General Precautions and Restrictions

Description	Amended Labeling Language	Placement on Label
Application Equipment Restrictions (granular products)	“Apply this product with a tractor-drawn or push spreader only.”	Direction for Use under General Precautions and Restrictions
Application Timing Restrictions	<p>For all applications that require overhead irrigation for incorporation:</p> <p>“Do not apply between noon and sunset during the heavy thunderstorm season (June through September).”</p> <p>For all applications that require sprinkler irrigation for incorporation:</p> <p>“irrigation must occur with 6 hours of the application.”</p>	Direction for Use under General Precautions and Restrictions

## **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 September 2, 1999. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the internet at <http://www.epa.gov/pesticides/op/fenamiphos.htm>.

## VII. APPENDICES

# **APPENDIX A. Table of Use Patterns Eligible for Reregistration**



**Appendix A: FENAMIPHOS (CASE 0333) : USE PATTERNS ELIGIBLE FOR REREGISTRATION**

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A/yr)	Minimum Retreatment Interval (days)	Pre- harvest Interval (days)	Restrictions/Comments
<b>Apple, Cherry, Nectarine, Peach</b>						
Band Post-plant Ground	3EC [3125-283]	7.5	7.5	Not Specified	Apples = 72 Cherry, Nectarine, Peach = 45	Center the treated band on the tree row using a band width of 50% of the row spacing and covering the feeder root system of the plant. Mechanically soil incorporate immediately.
Low-pressure Irrigation Post-plant Sprinkler	3EC [3125-283]	3	6	30	Apples = 72 Cherry, Nectarine, Peach = 45	Soil incorporate.
<b>Asparagus (CT, DE, ME, MD, MA, NH, NJ, NY, PA, RI only)</b>						
Band Nursery, Post-Harvest, Plant Crown Ground	3EC [3125-283]	2	2	Not Specified	270	Center the treated band on the tree row using a band width of 50% of the row spacing. Soil incorporate.
<b>Banana (Hawaii only)</b>						
Band Post-plant Ground	3EC [3125-283]	5	10	90	15	Do not apply product with less than a 4-foot total band width. Immediately incorporate the product into the soil with mechanical equipment.

**Appendix A: FENAMIPHOS (CASE 0333) : USE PATTERNS ELIGIBLE FOR REREGISTRATION**

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A/yr)	Minimum Retreatment Interval (days)	Pre- harvest Interval (days)	Restrictions/Comments
<b>Banana, Plantains (Puerto Rico only)</b>						
Low Pressure Irrigation Post-plant Drip Tape	3EC [3125-283]	4.5	13.5	120	Not Specified	Soil incorporate.
<b>Boy Choy (California only)</b>						
Band Pre- or at- planting Ground	15G [3125-236]	4.5	4.5	Not Specified	Not Specified	Direct seeded only. Mechanically incorporate immediately after application and prior to planting.
<b>Brussels Sprouts</b>						
Band Pre-, at-, or post-plant Post-transplant Ground	15G [3125-236]	4.5	4.5	Not Specified	Not Specified	Except brussels sprouts grown for seed. Soil incorporate.
<b>Cabbage</b>						
Band Pre-, at-, or post-plant, Pre-emergence Ground	15G [3125-236]	4.5	4.5	Not Specified	Not Specified	Includes tight-heading varieties of cabbage direct seeded and transplanted. Except cabbage grown for seeds. Soil incorporate.

**Appendix A: FENAMIPHOS (CASE 0333) : USE PATTERNS ELIGIBLE FOR REREGISTRATION**

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A/yr)	Minimum Retreatment Interval (days)	Pre- harvest Interval (days)	Restrictions/Comments
<b>Citrus (Except Florida)</b>						
Band Post-plant Ground	3EC [3125-283]	7.5	7.5	Not Specified	30	In California do not apply to Kumquat, Tangelo, or Citrus Hybrids. Center the treated band on the tree row using a band width of 50% of the row spacing and covering the feeder root system of the plant. Mechanically soil incorporate immediately.
Low pressure irrigation Post-plant Sprinkler	3EC [3125-283]	3	6	30	30	Soil incorporate.
<b>Citrus (Florida only)</b>						
Band Post-plant Ground	3EC [3125-283]	5	5	Not Specified	30	Center the treated band on the tree row using a band width of 50% of the row spacing and covering the feeder root system of the plant. Mechanically soil incorporate immediately. Do not apply within 300 feet of a drinking well.
Low pressure irrigation Post-plant Ground	3EC [3125-283]	3	4.5	30	30	Soil incorporate.

**Appendix A: FENAMIPHOS (CASE 0333) : USE PATTERNS ELIGIBLE FOR REREGISTRATION**

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A/yr)	Minimum Retreatment Interval (days)	Pre- harvest Interval (days)	Restrictions/Comments
<b>Eggplant</b>						
Band At transplant Ground	3EC [3125-283]	2	2	Not Specified	Not Specified	Mechanically soil incorporate immediately.
Band At transplant Ground	15G [3125-236]	2	2	Not Specified	Not Specified	Immediately incorporate the granules mechanically into the soil.
<b>Garlic</b>						
In furrow At planting Ground	15G [3125-236]	4.5	4.5	Not Specified	Not Specified	40" beds with two rows per bed. Soil incorporate.
<b>Grape</b>						
Band Bearing Ground	3EC [3125-283]	4.5	4.5	Not Specified	2	Center the treated band on the vine row using a band width of 50% of the row spacing. Mechanically soil incorporate immediately.
Low pressure irrigation Bearing Sprinkler	3EC [3125-283]	4.5	4.5	30	2	Soil incorporate.

**Appendix A: FENAMIPHOS (CASE 0333) : USE PATTERNS ELIGIBLE FOR REREGISTRATION**

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A/yr)	Minimum Retreatment Interval (days)	Pre- harvest Interval (days)	Restrictions/Comments
<b>Kiwi fruit (California only)</b>						
Low pressure irrigation Foliar Sprinkler	3EC [3125-283]	3	6	30	31	Soil incorporate.
<b>Non-Bell Peppers (California, Georgia, and Puerto Rico only)</b>						
Band At plant Ground	15G [3125-236]	2	2	Not Specified	Not Specified	Mechanically incorporate the granules into the soil.
<b>Okra (Except California)</b>						
Band At planting Ground	15G [3125-236]	2.25	2.25	Not Specified	Not Specified	Mechanically incorporate the granules into the soil.
<b>Ornamental Bulbs (Iris, Narcissus, Lily) Except California</b>						
In-furrow or Band At- or Post- plant Tractor-drawn or Push Spreader	10G [3125-237]	10	10	Not Specified	Not Specified	Irrigate immediately after treatment using a minimum of ½ inch of water.
<b>Ornamentals (Leatherleaf Fern)</b>						
Irrigation Sprinkler Ground	3ECTurf [3125-283]	9	9	Not Specified	Not Specified	Apply in fall or early spring. Irrigation must occur within 6 hours of the application. Do not treat crop grown in the greenhouse.

**Appendix A: FENAMIPHOS (CASE 0333) : USE PATTERNS ELIGIBLE FOR REREGISTRATION**

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A/yr)	Minimum Retreatment Interval (days)	Pre- harvest Interval (days)	Restrictions/Comments
In-furrow or Band At- or Post- plant Tractor-drawn or Push Spreader	10G [3125-237]	9	9	Not Specified	Not Specified	Irrigate immediately after treatment using a minimum of ½ inch of water.
<b>Ornamentals (Protea, Anthurium, Nursery Stock)</b>						
In-furrow or Band At- or Post- plant Ground	10G [3125-237]	10	10	Not Specified	Not Specified	Use on Protea is limited to Hawaii only. Irrigate immediately after treatment using a minimum of ½ inch of water.
<b>Peanuts</b>						
Band At plant Ground	3EC [3125-283]	2.55	2.55	Not Specified	Not Specified	Mechanically soil incorporate immediately.
Band At plant Ground	15G [3125-236]	2.55	2.55	Not Specified	Not Specified	Mechanically soil incorporate immediately.
<b>Pineapple</b>						
Foliar Spray or Drip Irrigation Post-plant Ground	3EC [3125-283]	2	12	30	60	Applications may begin immediately after planting.

**Appendix A: FENAMIPHOS (CASE 0333) : USE PATTERNS ELIGIBLE FOR REREGISTRATION**

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A/yr)	Minimum Retreatment Interval (days)	Pre- harvest Interval (days)	Restrictions/Comments
Foliar Spray or Drip Irrigation Ratoon Ground	3EC [3125-283]	2	9	30	60	First application may be made immediately following crop harvest.
<b>Raspberry (Except California)</b>						
Band Ground	3EC [3125-283]	6	6	Not Specified	180	Apply during the period of October 1 to December 31. Center the treated band on the tree row using a band width of 50% of the row spacing and covering the feeder root system of the plant. Mechanically soil incorporate immediately.
<b>Strawberries</b>						
Band Pre-transplant Ground	3EC [3125-283]	4.5	4.5	Not Specified	110	Double-row beds spaced 48 inches apart. Soil incorporate immediately by cultivation prior to transplanting.
Band Pre-transplant Ground	15G [3125-236]	4.5	4.5	Not Specified	110	Soil incorporate immediately by cultivation.
<b>Strawberries (Non-Bearing)</b>						
Band Post-transplant Cultivation	15G [3125-236]	3.47	6.93	56	600	Nursery stock only. Soil incorporate immediately by cultivation following application.

**Appendix A: FENAMIPHOS (CASE 0333) : USE PATTERNS ELIGIBLE FOR REREGISTRATION**

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. Seasonal App. Rate (lb ai/A/yr)	Minimum Retreatment Interval (days)	Pre- harvest Interval (days)	Restrictions/Comments
<b>Table Beets (Illinois, Indiana, Michigan, New York, Ohio, and Pennsylvania only)</b>						
Band Pre- or at- seedling Cultivation	3EC [3125-283]	3	3	Not Specified	90	Soil incorporate immediately by shallow cultivation.
<b>Tobacco (Except Shade Type)</b>						
Broadcast Ground	3EC [3125-283]	6	6	Not Specified	Not Specified	Soil incorporate to a depth of 2 to 4 inches by disking or tilling.
<b>Transplant Cabbage (Florida only)</b>						
Drench Post-transplant	3EC [3125-283]	1.7	1.7	Not Specified	Not Specified	Application must be separate from hand transplanting. Soil incorporate.
<b>Turf (Golf courses and sod farms)</b>						
Broadcast Spray	3ECTurf [3125-283]	10	20	3	Sod = 30	Irrigate area immediately following application. Do not treat more 10 acres of turf on any golf course in a single 24-hour period. Not recommended for use on tees and greens.
<b>Turf (Golf courses, cemeteries, sod farms and industrial grounds)</b>						
Broadcast Irrigation	10G [3125-237]	10	20	3	Sod = 30	(In CA use only on golf courses and sod farms.) Soil incorporate. Do not treat more 10 A/ 24 hrs.



**APPENDIX B. Table of the Generic Data Requirements and Data Supporting Guideline Requirements for the Reregistration Decision**

## **Appendix B. Data Supporting Guideline Requirements for the Reregistration of Fenamiphos**

### **GUIDE TO APPENDIX B**

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

The data table is organized in the following formats:

1. Data Requirement (Columns 1, 2 & 3). The data requirements are listed in the order of New Guideline Number and appear in 40 CFR §158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161-0002, (703) 487-4650.
2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.
  1. Terrestrial food
  2. Terrestrial feed
  3. Terrestrial nonfood
  4. Aquatic food
  5. Aquatic nonfood outdoor
  6. Aquatic nonfood industrial
  7. Aquatic nonfood residential
  8. Greenhouse food
  9. Greenhouse nonfood
  10. Forestry
  11. Residential
  12. Indoor food
  13. Indoor nonfood
  14. Indoor medical
  15. Indoor residential
3. Bibliographical Citation (Column 5). If the Agency has acceptable data in its files, this column lists the identification number of each study. Normally, this is the Master Record Identification (MRID) Number, but may be a “GS” number if no MRID number has been assigned. Refer to the Bibliography (Appendix D) for a complete citation of the study.

**Appendix B. Data Supporting Guideline Requirements for the Reregistration of Fenamiphos**

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
<b>PRODUCT USE CHEMISTRY</b>				
830.1600	61-2A	Starting Materials and Manufacturing Process	All	43037101
830.1620	61-2B	Description of Production Process	All	43037101
830.1670	61-2B	Discussion of Formation of Impurities	All	43037101
830.1700	62-1	Preliminary Analysis	All	43682501
830.6302	63-2	Color	All	40499802
830.6303	63-3	Physical State	All	40499802
830.6304	63-4	Odor	All	40499802
830.7200	63-5	Melting Point/Melting Range	All	40499802
830.7220	63-6	Boiling Point/Boiling Range	All	WAIVED
830.7300	63-7	Density, Relative Density, Bulk Density	All	40499802
830.7840 830.7860	63-8	Solubility	All	40499802
830.7950	63-9	Vapor Pressure	All	40499802
830.7370	63-10	Dissociation Constant in Water	All	40499802
830.7550	63-11	Octanol/Water Partition Coefficient	All	40499802
830.7000	63-12	pH of Water Solutions or Suspensions	All	40499802
830.6313	63-13	Stability	All	40499802
<b>ECOLOGICAL EFFECTS</b>				
850.2100	71-1A	Avian Acute Oral Toxicity, Bobwhite Quail	A, B, C	00121289
850.2100	71-1B	Avian Acute Oral Toxicity, Mallard Duck	A, B, C	DATA GAP
850.2200	71-2A	Avian Subacute Dietary Toxicity, Bobwhite Quail	A, B, C	00025959, DATA GAP
850.2200	71-2B	Avian Subacute Dietary Toxicity, Mallard Duck	A, B, C	00025958
850.2300	71-4A	Avian Reproduction, Bobwhite Quail	A, B, C	00121291
850.2300	71-4B	Avian Reproduction, Mallard Duck	A, B, C	00121290
850.2500	71-5B	Actual Field Study	A, B, C	43872101, 42029901, 42029902, 42029903, 42029904, 42029905
850.1075	72-1A	Fish Acute Toxicity, Bluegill Sunfish	A, B, C	00025962, 00114012
850.1075	72-1B	Fish Acute Toxicity, Bluegill Sunfish - TEP	A, B, C	40799704

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
850.1075	72-1C	Fish Acute Toxicity, Rainbow Trout	A, B, C	00114012
850.1075	72-1D	Fish Acute Toxicity, Rainbow Trout - TEP	A, B, C	40799701
850.1010	72-2A	Invertebrate Acute Toxicity, Daphnia	A, B, C	40799706, DATA GAP
850.1010	72-2B	Invertebrate Acute Toxicity, Daphnia - TEP	A, B, C	43183501, DATA GAP
None	72-3A	Estuarine/Marine Fish Acute Toxicity	A, B, C	40799710
850.1025	72-3B	Estuarine/Marine Mollusk Acute Toxicity	A, B, C	40799709, DATA GAP
850.1035	72-3C	Estuarine/Marine Invertebrate Acute Toxicity	A, B, C	40799708, DATA GAP
850.1300	72-4A	Fish - Early Life Stage	A, B, C	43157701, 41064301
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	A, B, C	43124101, 40922201
850.1400	72-4C	Early Life Stage, Freshwater Fish	A, B, C	DATA GAP
850.1500	72-5	Life Cycle Fish	A, B, C	DATA GAP
850.1730	72-6B	Fish BCF (Aquatic Organism Accumulation)	A, B, C	40274201, 40274202, 40274203
850.1950	72-7A	Simulated Field Testing for Aquatic Organisms	A, B, C	42029906
850.3020	141-1	Honey Bee Acute Contact Toxicity	A, B, C	00036935
<b>TOXICOLOGY</b>				
870.1100	81-1	Acute Oral Toxicity, Rat	A, B, C	00033831
870.1200	81-2	Acute Dermal Toxicity, Rabbit/Rat	A, B, C	00037962
870.1300	81-3	Acute Inhalation Toxicity, Rat	A, B, C	00154492
870.2400	81-4	Primary Eye Irritation, Rabbit	A, B, C	00111667, 00082111
870.2500	81-5	Primary Skin Irritation	A, B, C	00111667, 00082111
870.2600	81-6	Dermal Sensitization	A, B, C	00148464
870.6100	81-7	Acute Delayed Neurotoxicity, Hen	A, B, C	00057606
870.6200	81-8	Acute Neurotoxicity Screening Battery	A, B, C	44041501, 44041502, 44051401
870.3100	82-1A	90-Day Subchronic Feeding, Rodent	A, B, C	00117403, 00133475
870.3150	82-1B	90-Day Subchronic Feeding, Nonrodent (Dog)	A, B, C	00119238, 00119957, 00154493
870.3200	82-2	21-Day Dermal, Rabbit/Rat	A, B, C	00154497
870.3465	82-4	21-Day Inhalation, Rat	A, B, C	40774809
None	82-5B	90-Day Neurotoxicity, Mammal	A, B, C	44041501, 44051401
870.6200	82-7	Subchronic Neurotoxicity Study	A, B, C	44041501, 44041502, 44051401
870.4100	83-1A	Chronic Feeding Toxicity, Rodent	A, B, C	00161361, 40329601

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
870.4100	83-1B	Chronic Feeding Toxicity, Nonrodent (Dog)	A, B, C	42183601, 42684801
870.4200	83-2A	Chronic Carcinogenicity (Feeding), Rat	A, B, C	00161361,40329601, 00038490
870.4200	83-2B	Chronic Carcinogenicity (Feeding), Mouse	A, B, C	00098614
870.3700	83-3A	Prenatal Developmental Toxicity, Rat	A, B, C	41225401
870.3700	83-3B	Prenatal Developmental Toxicity, Rabbit	A, B, C	40347602
870.3800	83-4	2-Generation Reproduction and Fertility Effects, Rat	A, B, C	41908901,42491701
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity Study, Rat	A, B, C	00161361, 40329601
870.6300	83-6	Developmental Neurotoxicity Study, Rat	A, B, C	44041501, 44041502, 44051401
870.5140	84-2A	Gene Mutation (Ames Test)	A, B, C	00159027, 40319001
870.5375	84-2B	Structural Chromosomal Aberration	A, B, C	00086981
870.5500	84-4	Other Genotoxic Effects	A, B, C	00161367, 40649101
870.7485	85-1	General Metabolism, Rat	A, B, C	41194901, 41194902
<b>OCCUPATIONAL/RESIDENTIAL EXPOSURE</b>				
875.2100	132-1A	Foliar Residue Dissipation	A, B, C	41901701, DATA GAP
875.2200	132-1B	Soil Residue Dissipation	A, B, C	DATA GAP
875.2400	133-3	Dermal Passive Dosimetry Exposure	A, B, C	WAIVED
875.2500	133-4	Inhalation Passive Dosimetry Exposure	A, B, C	WAIVED
<b>ENVIRONMENTAL FATE</b>				
835.2120	161-1	Hydrolysis	A, B, C	42149302
835.2240	161-2	Photodegradation, Water	A, B, C	40608001, DATA GAP
835.2410	161-3	Photodegradation, Soil	A, B, C	40608001
835.2370	161-4	Photodegradation, Air	A, B, C	WAIVED
835.4100	162-1	Aerobic Soil Metabolism Study	A, B, C	42149303, 41064302, 40933701, 40524601, DATA GAP
835.4200	162-2	Anaerobic Soil Metabolism Study	A, B, C	41286901, DATA GAP
835.4300	162-4	Aerobic Aquatic Metabolism Study	A, B, C	DATA GAP
835.1240	163-1	Leaching/Adsorption/Desorption	A, B, C	40547502, 40547501, 40774808, 40774807
835.1410	163-2	Laboratory Volatilization from Soil	A, B, C	40774810
835.6100	164-1	Terrestrial Field Dissipation Study	A, B, C	42149301, 42216201, 42149303
835.1850	165-1	Confined Accumulation in Rotational Crops	A, B, C	41659301

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Citation(s)
835.1900	165-2	Field Accumulation in Rotational Crops	A, B, C	42043601
None	165-3	Accumulation in Irrigated Crops Study	A, B, C	WAIVED
835.1950	165-4	Bioaccumulation in Fish	A, B, C	40274201, 40274202, 40274203
835.7100	166-1	Small Scale Prospective Ground Water	A, B, C	45419701
None	166-2	Small Scale Retrospective Ground Water	A, B, C	44391301
<b>RESIDUE CHEMISTRY</b>				
860.1100	171-2	Chemical Identity	A, B, C	43037101
860.1300	171-4B	Nature of the Residue, Livestock	A, B, C	43055401, 42945701, 40997701
860.1340	171-4C	Residue Analytical Method, Plants	A, B, C	40876001
860.1340	171-4D	Residue Analytical Method, Animals	A, B, C	00105945,00052526
860.1380	171-4E	Storage Stability	A, B	43762801, 43559401
860.1480	171-4J	Magnitude of Residues in Meat, Milk, Poultry and Eggs	A, B	43055401
860.1500	171-4K	Crop Field Trials (Tobacco)	C	42674901, 41258102
860.1520	171-4L	Processed Food (Grapes)	A, B	41194903
860.1520	171-4L	Processed Food (Peanuts)	A, B	41255702
<b>OTHER</b>				
840.1100	201-1	Spray Droplet Size Spectrum	A, B, C	WAIVED
840.1200	202-1	Spray Drift Field Deposition (Evaluation)	A, B, C	WAIVED

# **APPENDIX C. List of Available Technical Support Documents**

## **Appendix C. Technical Support Documents for Fenamiphos**

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding 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 [www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op). Documents that have recently been added include:

### **HED Documents:**

1. Re-analysis of Fenamiphos: Occupational Risk Assessment with Combined Mixer/Loader plus Applicator for Certain Use Sites, June 12, 2000
2. Fenamiphos: Update to Occupational Exposure and Risk Assessment for Mixer/Loader/Applicator on Golf Course Turf, February 21, 2001
3. Fenamiphos: Update to Occupational Exposure and Risk Assessment for Postapplication Exposures, March 29, 2001
4. Review of "Dislodgeable Residues of Fenamiphos Applied to Turfgrass and Implications for Golfer Exposure," Synder R., et al. Published in Soil and Crop Science Society of Florida Proceedings 58; 51-57 (1999); July 27, 2001

### **EFED Documents:**

1. Fenamiphos Environmental Risk Assessment, October 2, 2001
2. Updated RED for Fenamiphos; Fenamiphos Environmental Risk Assessment, March 6, 2002



## **APPENDIX D. Bibliography**

**Appendix D. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE  
SUPPORTING THE INTERIM REREGISTRATION DECISION  
(BIBLIOGRAPHY)**

**GUIDE TO APPENDIX D**

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
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  - (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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