United States Environmental Protection Agency
Office of Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-95-018 July 1995

Reregistration Eligibility Decision (RED)

Fenitrothion

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case fenitrothion. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient(s) to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Moana Appleyard at (703) 308-8175. Address any questions on required generic data to the Special Review and Reregistration Division representative Dennis McNeilly at 308-8066.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

FENITROTHION

LIST A

CASE 0445

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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0445 REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

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Frank Hernandez	Economic Analysis Branch
Margaret Cogdell	LUIS Staff, Biological Analysis Branch

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Carol Stangel	Planning and Reregistration Branch
Moana Appleyard	Planning and Reregistration Branch

Office of Compliance Monitoring:

Rick Colbert	Agriculture and Ecosystems Division

GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/L, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data

GLOSSARY OF TERMS AND ABBREVIATIONS

PPE	Personal Protective Equipment
ppb	Parts Per Billion
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision (RED) document addresses the reregistration eligibility of the pesticide fenitrothion, O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate.

Fenitrothion, an organophosphate, is a cholinesterase inhibiting insecticide/acaricide registered for use on ornamentals, including trees, and in ant and roach baits. Sumitomo Chemical Co. requested voluntary cancellation of the malaria control uses of fenitrothion on February 28, 1995. Annual ornamental usage of fenitrothion is very small and appears to be decreasing. There are no domestic food or feed uses for fenitrothion. The only established U.S. food additive regulation is for the combined residues of fenitrothion and its metabolites O,O-dimethyl O-(4-nitro-m-tolyl)phosphate and 3-methyl-4-nitrophenol in or on wheat gluten imported from Australia arising from the postharvest application of fenitrothion to stored wheat grain in that country. The Agency estimates that the dietary exposure to the U.S. population is 0.000043 mg/kg bwt/day or approximately 3% of the RfD for the general population, and 8% of the RfD for children aged 1 through 6.

Registered end-use formulations of fenitrothion include a wettable powder, four emulsifiable concentrate (EC) formulations, and two bait products. The two products, Sumithion 40 WDP and Sumithion 50 EC (47.5% a.i.), were registered solely for control of Anopheline mosquitoes transmitting malaria, but as stated above, the registrant has requested a voluntary cancellation of these products. Although these products had U.S. registrations, they were never sold or used in this country. Three products are registered for use on ornamentals: Pestroy 4EC, Pestroy 8EC, and Sumithion 8E. Fenitrothion is labeled for greenhouse use and outdoor use on ornamentals, including trees. Two fenitrothion bait products, one for roaches (1.0% active) and one for ants (0.01563% active) were registered on January 9, 1995. These products are labeled for use in and around homes, cabins, apartment buildings, stores, restaurants, trailers, campers, and warehouses. These uses result in considerable less human and environmental exposure than the ornamental uses of fenitrothion. These bait uses for roaches and ants were registered after the human and ecological risk assessments were conducted. These products are used indoors and would have negligible ecological impact. Additionally, these uses would result in considerably less human exposure than the ornamental uses, therefore they are considered eligible for reregistration.

The Agency completed a risk assessment for fenitrothion in September, 1994 that indicated significant risk to human health and a high potential for adverse ecological effects. Consequently, the Agency initiated risk mitigation discussions with the sole technical registrant of fenitrothion, Sumitomo Chemical Company, Limited. This document discusses the Agency's risk estimate for all registered uses as well as the estimated risk after implementation of the proposed risk mitigating label revisions.

Margins of exposure (MOEs), a ratio of the estimated exposure level to the No Observable Effect Level (NOEL), were calculated for all occupational exposure scenarios for which data were available. MOEs for many fenitrothion uses indicate a significant risk to handlers (i.e.,

mixers/loaders/applicators). MOEs, for handlers only, were based on all available exposure data including: (1) chemical specific data submitted by the registrant to support the registration of fenitrothion; (2) data available in the Pesticide Handlers Exposure Database; and (3) data from the open literature.

A significant potential for post-application exposure exists from treatment of ornamentals. The human, non-dietary exposure data used in this risk assessment contain many uncertainties. Five exposure studies submitted to support reregistration were reviewed by the Agency and determined to be unacceptable. Due to the uncertainties in the worker exposure data the Agency is deferring a regulatory decision concerning the low-pressure handwand and knapsack/backpack methods of application until chemical-specific worker exposure studies are submitted. Uncertainties in the existing worker exposure database do not allow the Agency to determine, with confidence, the appropriate MOEs for these exposure scenarios. However, the Agency believes it is in the public's best interest to implement the human health and ecological effect exposure/risk mitigation measures negotiated with the registrant. Therefore, the Agency has decided not to delay issuing the fenitrothion RED until these studies are submitted and reviewed. The Agency is requiring the registrant to submit the worker exposure studies for these two scenarios on an accelerated schedule, i.e., one year.

Due to the acute and subchronic toxicity of fenitrothion, the lack of adequate chemical specific exposure data for all fenitrothion uses, and the low MOEs calculated for mixer/loader/applicators, high-pressure handwand treatment is the only ornamental use eligible for reregistration. While the data base is "substantially complete" for the purposes of making this reregistration eligibility decision, the Agency is requiring the following data as confirmatory*:

71-1	Acute Oral LD50 for Bobwhite Quail with the major degradate: 3-methyl-nitrophenol.
71-4	Chronic Toxicity to Birds with the major degradate: 3-methyl-nitrophenol. (Reserved)
85-4-SS	Six Month Ocular Toxicity Study in Dogs (Reserved)
164-1	Terrestrial Field Dissipation

* NOTE: This list of data requirements is based on the assumption that all risk mitigating label changes proposed by Sumitomo Chemical Company will be implemented.

The following data are required before the Agency can make a regulatory decision regarding reregistration eligibility for the low-pressure handwand and knapsack/backpack methods of application:

132-1(a)	Foliar Dissipation
133-3	Occupational Postapplication Dermal Exposure
133-4	Occupational Postapplication Inhalation Exposure
231	Estimation of Dermal Exposure at Outdoor Sites
232	Estimation of Inhalation Exposure at Outdoor Sites

233	Estimation of Dermal Exposure at Indoor Sites
234	Estimation of Inhalation Exposure at Indoor Sites

These data are considered confirmatory for the high-pressure handwand treatment of ornamentals. The Agency is requiring these studies to be submitted within one year of receipt of this RED.

The Agency is requiring "baseline" personal protective equipment (PPE) for applicators and other handlers for all end-use products containing fenitrothion as follows: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant headgear for overhead exposures, chemical-resistant apron when cleaning equipment, mixing, or loading, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C. The Agency is requiring personal protective equipment for early entry consisting of coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant headgear for overhead exposures, and chemical-resistant eyewear.

To mitigate the risk to workers entering treated areas after application, the Agency is requiring a 48-hour restricted-entry interval (REI) for all uses within the scope of the Worker Protection Standard (WPS). Based on the acute toxicity endpoints for fenitrothion (i.e., category II dermal and inhalation), a 24-hour REI would normally be required. However, because the inhalation NOEL is low (i.e., 0.049 mg/kg/day) and there are no acceptable inhalation data with which to adequately assess the REI, the Agency has decided to require a 48-hour restricted-entry interval and upgrade the personal protective equipment specified for early-entry until acceptable data become available to assess each use pattern of interest. The 48-hour REI is increased to 72 hours when any product containing fenitrothion is used in outdoor areas where the average rainfall is less than 25 inches a year. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses of fenitrothion used to produce agricultural plants (including ornamentals).

Except for the terrestrial field dissipation (164-1) and wildlife toxicity data for fenitrothion degradates, all ecological effects and environmental fate guideline data needed to support the reregistration of fenitrothion on ornamentals in greenhouses and nurseries have been submitted.

Technical grade fenitrothion is highly toxic to birds and aquatic invertebrates, and chronic effects were observed in an avian reproduction study. Fenitrothion is also moderately toxic to mammals. Outdoor uses of fenitrothion exceed the hazard limits established in 40 CFR 152.170 for restricted-use classification. Therefore, the Agency will require all fenitrothion products labeled for outdoor use to be labeled for restricted use only. Of all the registered uses for fenitrothion, the use for Christmas tree plantations and the basal bark treatment result in the greatest potential for exposure to non-target species. The registrant has proposed deleting these uses from the label. For the remaining ornamental uses, the registrant has proposed significant label revisions to reduce ecological risk. The application rate is reduced

on a per acre basis to 0.3125 lb ai/acre, the maximum number of applications is reduced to three per year, and the minimum interval between applications is increased to one month. In addition, all broadcast application will be removed form the label and use will be restricted to spot treatments.

The Agency has determined that outdoor uses of fenitrothion, especially the Christmas tree plantation use, poses a high acute risk to endangered mammals, birds and aquatic invertebrates. In addition, fenitrothion poses a chronic risk to birds and aquatic invertebrates. The Agency has determined that only the high-pressure handwand treatment of ornamentals and bait uses are eligible for reregistration. The Agency is deferring a regulatory decision concerning the low-pressure handwand and knapsack/backpack methods of application until chemical-specific worker exposure studies are submitted. The technical registrant has stated they will cancel voluntarily uses that were assessed by EPA as posing high ecological risk, i.e., Christmas tree farm, basal bark treatments, and ornamental broadcast treatments. Restricted use labeling will ensure that fenitrothion is used only by certified applicators or by applicators under their supervision.

In addition, before reregistering products containing fenitrothion, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base 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.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of fenitrothion. The document consists of six sections. Section I is the introduction. Section II describes fenitrothion, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for fenitrothion. Section V discusses the reregistration requirements for fenitrothion. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

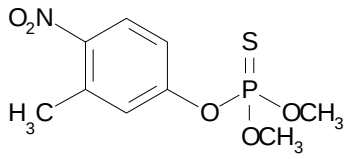
II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Document: Fenitrothion

- **Common Name:** Fenitrothion

- **Chemical Name:** O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate.



- **Chemical Family:** Organophosphate

- **CAS Registry Number:** 122-14-5

- **OPP Chemical Code:** 105901 (OPP: Office of Pesticide Programs)

- **Empirical Formula:** $C_9H_{12}NO_5PS$

- **Trade and Other Names:** Sumithion, Pestroy, Accothion, Agrothion, Bayer 41831, Bayer S 5660, Cytel, Dybar, Fenitox, MEP, Novathion, Nuvanol, Cyfen

- **Basic Manufacturer:** Sumitomo Chemical Co. LTD., Osaka, Japan (Fenitrothion is not manufactured in the U.S.)

B. Use Profile

The following is information on the current registered uses of fenitrothion with an overview of use sites and application methods. A detailed table of these uses of fenitrothion is in Appendix A. Appendix A summarizes current use patterns; it does

not include label revisions proposed by the registrant to mitigate human health or ecological risks. These label revisions are discussed in detail in Sections IV and V.

Type of Pesticide: Nonsystemic organophosphate insecticide and acaricide

Use Sites: Terrestrial and greenhouse non-food crops (ornamentals) including ornamental and/or shade trees. The registrant requested (Feb 28, 1995) voluntary cancellation of the malaria control uses of fenitrothion. This use involved treatment of the interior of domestic, commercial, institutional, and industrial buildings.

Two fenitrothion bait products were recently registered, one for roaches (1.0% active) and one for ants (0.01563% active). These products are labeled for use in and around homes, cabins, apartment buildings, stores, restaurants, trailers, campers, and warehouses. See Appendix A for details on registered uses.

Target Pests: Ants, cockroaches (including waterbugs and palmetto bugs), aphids, bagworm, iris borer, spruce budworm, fall cankerworm, forest and eastern tent caterpillers, Eotetranychus mites, gypsy moth, lacebugs, leaf beetles, azalea and birch leafminers, citrus mealybug and whiteflies, balsam gall midge, eriophyid mites, southern red mite, palmerworm, boxwood and hackberry psyllids, pine tipmoth, sawflies, scale insects, spittlebugs, slugs, fall webworm, black vine weevil, northern pine and pales weevils.

Formulation Types Registered: 0.01563% and 1% baits, 45% EC, 76.8% EC.

Method and Rates of Application:

Equipment - Ground-based and hand-held equipment.

Method and Rate - Applications are made to run-off on various nonfood plants (ornamentals) using up to 100 gallons of spray solution per acre at concentrations ranging from approximately 0.12% up to 2% active ingredient (w/v). Basal bark treatments are to be repeated every 90 days while spot treatments and broadcast applications can be repeated every 7 days. The application rates are the same regardless of whether the site is a greenhouse or a commercial tree lot.

Note: Sumitomo Chemical Company has proposed significant label changes for fenitrothion use, including voluntary cancellation of malaria control uses.

Timing - Principle application times are during late spring and early summer.

C. Estimated Usage of Pesticide

Annual ornamental usage of fenitrothion in the U.S. is very small and appears to be decreasing. The available production figures and information from the registrant both indicate that considerably less than 1% of the nursery land in the U.S. is treated annually with Sumithion 8E, Pestroy 4E or Pestroy 8E (fenitrothion end-use products). Sumithion 40 WDP and 50 EC products for malaria control are not sold in the U.S. and their registrations are being voluntarily cancelled. These products are sold and used in Central America, South America, Asia, Africa and the Caribbean. These estimates are derived from a variety of published and proprietary sources available to the Agency.

D. Data Requirements

Data requested in the July 1987 Registration Standard for Fenitrothion included studies on product chemistry, toxicology, ecological effects, environmental fate, residue chemistry, and occupational/residential exposure. Because fenitrothion is an organophosphate, a DCI was also issued on June 28, 1991 requiring neurotoxicity data to satisfy data requirements for Guidelines: 81-8-SS, 82-5(b), and 85-7-SS. These data were required to support the uses listed in the 1987 Fenitrothion Registration Standard. Appendix B includes all data requirements identified by the Agency for the only registered use remaining after voluntary cancellation, ant and roach baits and use on ornamentals in greenhouses and nurseries.

E. Regulatory History

Fenitrothion was first registered under FIFRA in the United States in 1975. The registration was for control of spruce budworm in forests under the supervision of federal and state officials responsible for insect control programs in forest areas. In November of 1992, at the request of the registrant, all of the fenitrothion products bearing forestry uses were cancelled. Fenitrothion is used in the U.S. for commercial ornamental pest control. The registrant has requested voluntary cancellation of the mosquito control products (i.e., malaria control).

A Data Call-In (DCI) was issued in 1984 requiring additional toxicity data concerning the chronic toxicity of fenitrothion. A Registration Standard for Fenitrothion was issued in July 1987 (NTIS #PB88-191697) which evaluated the studies submitted as a result of the 1984 DCI. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and the June 1991 DCI.

As a result of the Registration Standard review, the Agency determined that certain additional or revised label restrictions were necessary. An interim 24-hour reentry interval was imposed for greenhouse and nursery ornamental uses, until appropriate

reentry data were submitted and evaluated. The Agency also imposed a restricted-use classification on the forestry uses of fenitrothion until receipt and review of comprehensive aquatic and terrestrial studies. Subsequently, in 1992 the forestry uses of fenitrothion were cancelled. Labeling was required to reflect the high toxicity to birds, honeybees, and aquatic invertebrates. Precautions were also imposed to protect potentially exposed endangered species. Two bait products, one for roaches (1.0% active ingredient) and one for ants (0.01563% active ingredient) were registered in January 1995.

Through implementation of the labeling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides (WPS), the 24-hour interim reentry interval (permitted routine entry to perform hand labor tasks if PPE is worn) was converted to a 24-hour interim restricted entry interval (prohibits routine entry to perform hand labor tasks even if wearing PPE). Uses within the scope of the WPS include all commercial and research use of fenitrothion to produce agricultural plants. Fenitrothion pest bait products (ant and roach) fall outside the scope of WPS.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

All pertinent product chemistry data requirements are satisfied for the fenitrothion 95% T registered to Sumitomo Chemical America, Inc. (EPA Reg. No. 39398-4).

1. Identification of the Active Ingredient

Fenitrothion [O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate] is a cholinesterase inhibiting insecticide/acaricide. The molecular structure of fenitrothion is shown on page 2. Other pertinent information for fenitrothion follows:

Empirical Formula:	$C_9H_{12}NO_5PS$
Molecular Weight:	277.2
CAS Registry No.:	122-14-5
PC Code:	105901

Technical fenitrothion is a yellowish-brown oil which decomposes at 140-145°C (at 0.1 mmHg) and has a specific gravity of 1.32-1.34. Its solubility in water at 20°C and 30°C is 5 mg/kg and 14 mg/kg, respectively. Fenitrothion solubility at 22-25°C in methanol and acetone is $> 50\%$ w/w and in hexane is $< 10\%$ w/w.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for fenitrothion is adequate and will support reregistration. The requirement to conduct a six month ocular toxicity study in dogs is reserved until the Agency develops protocols for the testing. A replacement acute inhalation study was submitted to the Agency on December 13, 1994. This study is in review.

a. Acute Toxicity

Acute toxicity data on fenitrothion are summarized in the Table below:

Acute toxicity summary for fenitrothion.

TEST	RESULT (mg/kg)	CATEGORY
81-1: Oral LD50 Sumithion Technical (97.2%)	LD50 = 330 mg/kg (M), LD50 = 800 mg/kg (F)	II
81-2: Dermal LD50 Sumithion Technical (97.2%)	LD50 = 890 mg/kg (M), LD50 = 1200 mg/kg (F)	II
81-3: Inhalation LC50* Sumithion 8-E (77% a.i.)	LC50 = 5.0 mg/l	II*
81-4: Eye effects Sumithion 8-E (77% a.i.)	PIS = 0.1/110 at 72 hrs., PIS = 0/110 at 7 days.	III
81-5: Dermal Irritation Sumithion 8-E (77% a.i.)	PIS = 2.75 (mild irritant)	III
81-6: Dermal Sensitization Sumithion Technical (97.2%)	Animals treated with 0.1 ml of 5% and 1% sumithion - results negative	N/A
81-8: Neurotoxicity-acute delayed: hen Sumithion Technical (97.2%)	Mortality - 3/16 after first administration; 3/13 after second administration; Negative at 500 mg/kg	N/A
81-8-SS Neurotoxicity Screen: rat Fenitrothion Technical (94.3%)	NOEL and LEL = 12.5 and 50 mg/kg for males in the study. NOEL could not be determined for the females.	N/A

* Unacceptable study, a new study was received on December 13, 1994.

The data summarized in the acute toxicity Table (Section B.1.a.) indicate that fenitrothion presents a potential acute health hazard.

Because of the numerous deficiencies in the 81-3 acute inhalation LC50 study, a replacement study was submitted and is now in review. The original study was not conducted with the technical grade material. Although the LC50 was reported as greater than 5 mg/L, only the nominal concentration was reported, making it difficult to assign the proper toxicity category (the nominal concentration can be significantly larger than the analytically determined concentration). In addition, the individual animal data were not reported. Due to the inadequacies in the acute inhalation LC50 study (81-3) the toxicity category was moved from category IV to toxicity category II.

b. Subchronic Toxicity

Guideline 82-1, 90-day feeding-rodent, is satisfied by the two year chronic feeding/oncogenicity study (see c. & d. Chronic Toxicity, Carcinogenicity). Guideline 82-1, a 90-day feeding-

nonrodent, is satisfied by the one-year dog feeding study. (MRIDs 00071965, 254868)

In a 21-day dermal study (Guideline 82-2), fenitrothion (93.7%) was applied to the skin of New Zealand white rabbits. The dose levels were 0, 3, 10, 50 or 250 mg/kg/day. The Systemic NOEL equals 3 mg/kg/day and the Systemic LOEL equals 10 mg/kg/day based on inhibition of plasma cholinesterase (40%) and brain (20%) cholinesterase in females. The dermal NOEL was not determined. The dermal LOEL is 3 mg/kg/day based on dermal irritation and desquamation of the epidermis. (MRID 42058301)

In a 90-day inhalation study (Guideline 82-4), Crl (WI) BR strain rats were exposed to 0, 0.2, 1.0, or 10 µg/l of Sumithion Technical (94.5%). At the 10 µg/l exposure level, plasma cholinesterase activity in males and red blood cell (RBC) cholinesterase activity in males and females was inhibited. Brain cholinesterase was inhibited in females at 1 µg/l and 10 µg/l. A NOEL of 0.2 µg/l was determined on the basis of brain cholinesterase inhibition in females. (MRID 40891001)

c. Chronic Toxicity

A two-year chronic feeding/oncogenicity study was conducted in the Charles River/CD strain rat. The compound was administered in the diet at doses of 0, 0.5, 1.5 or 5 mg/kg/day (0, 10, 30 or 100 ppm). The cholinesterase LEL equals 10 ppm (LDT) (brain and plasma). (MRID 00071965)

A 22-month chronic feeding/oncogenicity study was conducted in the Wistar strain rat. The compound was administered in the diet at doses of 0, 0.125, 0.25, or 0.5 mg/kg/day (0, 2.5, 5.0 or 10 ppm). The systemic NOEL is 10 ppm; the systemic LOEL is > 10 ppm. The cholinesterase NOEL is 2.5 ppm; the cholinesterase LEL is 5.0 ppm (plasma). At 10 ppm, RBC cholinesterase was reduced. (MRID 40420501)

A two-year chronic feeding/oncogenicity study was conducted in B6C3F1 mice. The compound was administered in the diet at 0, 3, 10, 100, or 1000 ppm (0, 0.45, 1.51, 13.07, or 144.32 mg/kg/day for the females, and at 0.37, 1.45, 12.62, or 134.28 mg/kg/day for the male). The study was conducted at adequate dosage based on a 26-29% suppression in body weight gain at 1000 ppm (both sexes) and a depression of cholinesterase observed at 100 and 1,000 ppm

(both sexes). The systemic NOEL is 3 ppm (0.45 mg/kg/day); systemic LEL is 10 ppm (1.45 mg/kg/day) based on decreased body weight gains, decreased RBC, brain, and plasma cholinesterase activity. (MRIDs 41925201, 42507701 and 41507704)

A one-year feeding study was conducted in beagle dogs. The compound was administered in the diet at 0, 5, 10, or 50 ppm (0, 0.125, 0.25, or 1.25 mg/kg/day). The cholinesterase NOEL is 5 ppm; cholinesterase LEL is 10 ppm (plasma cholinesterase inhibited); systemic NOEL is 5 ppm; and systemic LEL is 10 ppm (increased incidence of abdominal lymph node hemorrhage). (MRID 254868)

d. Carcinogenicity

Fenitrothion has been classified by the RfD committee on the basis of its carcinogenic potential in **Group E** - evidence of non-carcinogenicity for humans.

e. Developmental Toxicity

A developmental toxicity study was conducted with pregnant Sprague-Dawley rats which were administered 0, 3, 8 or 25 mg/kg/day fenitrothion from day 6 through day 15 of gestation. The maternal NOEL equals 8 mg/kg/day, and the maternal LEL equals 25 mg/kg/day based on a decrease in the percentage body weight gain and the absolute body weight (days 11 through 19 of gestation), decreased mean corrected terminal body weight and tremors in 9 of the 24 females. The Developmental NOEL equals 8 mg/kg/day, and the Developmental LEL equals 25 mg/kg/day based on an increased incidence of fetuses and litters with one full and one rudimentary 13th rib. (MRID 40604002)

A developmental toxicity study was conducted with HRA: (NZW) SPF strain rabbits. The compound was administered by gavage at doses of 0, 3, 10 or 30 mg/kg. The maternal NOEL is 10 mg/kg/day, and the maternal LEL is 30 mg/kg/day (increased mortality, abortion, tremors, ataxia and dyspnea and reduced body weight gain). The developmental NOEL is 30 mg/kg/day (HDT). (MRIDs 264497, 00162548, and 40430601)

f. Reproductive Toxicity

A 2-generation reproduction study was conducted with Sprague-Dawley (Crl:COBS CD SD BR) rats. Fenitrothion was administered by gavage in a corn oil vehicle at doses of 0, 10, 40, or 120 ppm (Male: 0.68, 2.74, or 8.40 mg/kg/day; Female: 0.77, 3.19 or 10.37 mg/kg/day). The parental toxicity NOEL is 40 ppm based on the following observations: 1) decreased food consumption, body weight and weight gain in both generations and sexes at 120 ppm. The parental toxicity LEL is 120 ppm. The reproductive toxicity NOEL is 40 ppm based on the following observations: 1) decreased fertility in the F_0; and decreased numbers of implantation sites, decreased viability and lactation. The reproductive LEL is 120 ppm. The HED RfD/Peer Review Committee (July 13, 1993) concluded: "… the data do not indicate treatment-related change in the fertility indices." (MRIDs 41689001, and 42668801)

g. Mutagenicity

A Gene Mutation Assay (Ames Assay) was conducted using fenitrothion technical (98.6%). Doses ranged from 100 to 2000 µg/plate. Fenitrothion is mutagenic in Salmonella typhimurium strain TA100 with S-9 activation, but not mutagenic in the nitroreductase deficient strain TA100 with S-9 activation. The selected dose range was adequate for demonstrating a mutagenic effect in TA100, but the results indicate a false-positive response associated with bacterial nitroreductase activity. Since mammals lack the type of nitroreductase found in bacteria, fenitrothion is not considered to be a potential mammalian mutagen. (MRID 00163432)

A Chromosome Aberration in vitro study with CHO cells was conducted using fenitrothion. Fenitrothion was found to be negative in Chinese hamster cells treated up to cytotoxic and insoluble levels, 300 µg/ml with and without S9 activation. (MRID 40789201)

An Unscheduled DNA Synthesis Assay with rat hepatocyte study was conducted using fenitrothion (96.7%). Fenitrothion was found to be positive for inducing unscheduled DNA synthesis (UDS) in primary rat hepatocyte cultures, but only at the HDT, 30 µg/ml, a cytotoxic dose (60-70% relative cell viability). (MRID 40789202)

h. Metabolism

C^{14}-fenitrothion administered to male and female Wistar rats, male and female rabbits, or male beagle dogs as a single dose of 15 mg/kg was absorbed rapidly and excreted nearly to completion in 48 hours with approximately 90% and 5% of the excreted dose eliminated in the urine and feces, respectively. Expired air from rats contained no radioactivity; C^{14} levels in the tissues were not measured. There were no sex- or species-related differences in the total excretion. A single oral dose (105 mg/kg) in rats with labeled fenitrothion for 5 days did not alter the excretion profile. Seventeen metabolites were isolated in the urine of rats, rabbits, and dogs, but only eight were identified. The parent compound was not detected in the urine of any animal. In the feces, no metabolites other than those found in the urine were present. (MRIDs 00069960, 40408906)

The urinary metabolites of fenitrothion have been identified in the male and female rat. The fecal metabolites have been identified in the male but not the female rat. The major metabolic routes appear to be (1) the demethylation of the phosphate moiety, (2) desulfuration of the phosphate moiety and (3) the hydrolysis of the phosphate moiety from the phenyl moiety as reflected by the types of metabolites found in the urine and feces. The pattern of distribution and elimination of fenitrothion in male and female rats was similar regardless of receiving a single nontoxic dose (15 mg/kg) exposure, a single toxic dose (105 mg/kg) exposure or repeated nontoxic dose exposure (15 mg/kg every other day for 5 times, and then treated with 15 mg/kg of radiolabeled fenitrothion). Fenitrothion is excreted in the urine (95% of total dose) and in the feces (about 5% of the remaining dose) within 7 days of exposure. Fenitrothion and/or its metabolites were not detected in the expired air of either male or female rats. No major sex differences were observed in the distribution, metabolism or the excretion of fenitrothion.

i. Other Toxic Endpoints

An acute ocular toxicity study was conducted with Sprague-Dawley (SD) (Crj:CD) rats using fenitrothion (94.5%). Doses were administered by oral gavage at the following levels: 0, 20, or 200 mg/kg for males, and 0, 40, or 400 mg/kg for females. The cholinesterase NOEL could not be determined. The cholinesterase LOEL was less than 20 and 40 mg/kg (LDT) based on erythrocyte

cholinesterase inhibition in male and female rats, respectively. The ocular NOEL is greater than 200 mg/kg for males, and 400 mg/kg for females, based on lack of changes clearly related to treatment in electroretinography (ERG) and ophthalmic examination of the anterior portions of the eye. The ocular LOEL was not determined. No residual effect was observed on the electroretinograph following doses which produced signs of toxicity and were accompanied by depression of plasma and erythrocyte cholinesterase activity. No indications of ocular toxicity were observed. (MRID 41249601)

A 13-week subchronic study was conducted with Sprague-Dawley (SD) (Crj:CD) rats using fenitrothion (94.5%). Doses were administered in the feed at the following doses: 0, 2.5, 5, 10 or 30 ppm (Males: 0, 0.14, 0.282, 0.570 or 1.70 mg/kg/day; Females: 0, 0.169, 0.331, 0.648, or 1.96 mg/kg/day). The cholinesterase NOEL is 5 ppm based on a statistically significant inhibition of plasma cholinesterase in female rats to approximately 54% of the control activity levels. In addition, at 30 ppm, statistically significant inhibition of plasma, erythrocyte and brain cholinesterase was observed in female rats, and of plasma and erythrocyte cholinesterase in male rats. (MRID 41249602)

No effect was observed on the ERG at the end of dosing either in comparison to pretreatment values or in comparison to concurrent control values. The high dose showed depression of plasma, erythrocyte and brain cholinesterase at the end of the study. The study showed no evidence of ocular toxicity.

A six month ocular toxicity study in dogs, required in the 1991 Data Call In, is in a reserved status until a test protocol is developed.

j. Reference Dose

The Agency concluded that an RfD should be established based upon a NOEL of 0.125 mg/kg/day for systemic effects (histo-pathological changes in lymph nodes) and plasma cholinesterase inhibition observed at 0.25 mg/kg/day in a long-term feeding study in dogs. An Uncertainty Factor (UF) of 100 was used to account for the inter-species extrapolation and intra-species variability. **On this basis the RfD was calculated to be 0.0013 mg/kg/day.**

The Joint FAO/WHO Meeting On Pesticide Residues (JMPR) reports an ADI of 0.005 mg/kg bw (1988). (Pesticide Residues In Food - 1988. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and in the Environment and a WHO Expert Group on Pesticide residues. FAO Plant Protection and Production Paper 92, 1988.)

2. Exposure Assessment

a. Dietary Exposure

Plant Metabolism

The qualitative nature of the residue in wheat grain is understood adequately based upon available rice metabolism/degradation data. Data indicate that fenitrothion per se, desmethyl fenitrothion, and p-nitrocresol are the major components of the residue. Additional metabolites retaining the aryl phosphate or phosphorothioate moiety which were present in very small amounts (i.e., collectively $< 3\%$ of the TRR in rice grain) were fenitrooxon, fenitrothion S-isomer, desmethylfenitrooxon, and desmethylfenitrothion S-isomer. The HED Metabolism Committee has determined that the food additive regulation for residues in wheat gluten should be in terms of the parent compound only. No additional data are required.

Residue Analytical Methods - Plants

A GLC method, which was published and described in the Journal of Agriculture and Food Chemistry 17:271-276, has been deemed adequate for data collection and enforcement purposes. A successful EPA method tryout (MTO) was conducted on wheat gluten using the preferred GLC method. Although certain inconsistences in the EPA method tryout (MTO) reports were identified, they are irrelevant to the method's adequacy for data collection and enforcement purposes. The method will be published in PAM Vol. II.

Residues of fenitrothion have been subjected to multiresidue protocols required in the 40 CFR 158.125(b)(15) and published in the Addendum to Pesticide Assessment Guidelines Subdivision O - Residue Chemistry Data Requirements Multiresidue Protocols. Fenitrothion is adequately recovered using FDA multiresidue analytical methods.

Storage Stability

The available storage stability data indicate that residues of fenitrothion are stable under frozen (-18°C) storage conditions in/on wheat and wheat gluten for up to 147 and 174 days, respectively. These data are adequate to support the available residue data.

Magnitude of the Residue in Plants

All data requirements for the magnitude of the residue in plants have been evaluated and deemed adequate with the assumption that the magnitude data which have been submitted to the Agency adequately reflect the maximum registered use rate of fenitrothion on stored wheat in Australia. All data requirements for the magnitude of the residue in wheat gluten as a result of the postharvest application of fenitrothion to stored wheat in Australia have been evaluated and deemed adequate. No additional data are required.

Animal Data Requirements

Fenitrothion is not registered for use on any domestic crop; therefore, residues of fenitrothion are not expected to enter the diet of food animals. In the event that future registrations for use of fenitrothion on plant commodities used for animal feeds are approved, or regulations are established covering importation of animal products from countries in which fenitrothion is registered for use, additional data may be required.

b. Occupational and Residential Exposure

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

(1) Use Summary

Fenitrothion applications to ornamentals in greenhouses/outdoors can be made using ground-based and hand-held equipment. Such equipment includes, but is not limited to, the following:

groundboom; low-pressure handwands; high-pressure handwands; knapsack/backpack sprayers; overhead boom sprayers; liquid broadcast spreaders; and powered personal sprayers.

Application methods for outdoor terrestrial and greenhouse scenarios include: basal bark treatments, broadcast applications, and spot treatments. Basal bark treatments can be repeated every 90 days while spot treatments and broadcast applications can be repeated every 7 days. Applications are made to run-off on various ornamental plants (non-food) using up to 100 gallons of spray solution per acre at spray solution concentrations ranging from approximately 0.12% up to 2% active ingredient (w/v).

Indoor residential use sites include ant/roach baits and mosquito control uses. The registrant has requested (Feb 28, 1995) voluntary cancellation of mosquito control uses.

(2) Summary of Toxicity Concerns Impacting Occupational Exposures

Acute Toxicity

The Agency has determined that the appropriate short-term endpoints to use for occupational risk assessments are the NOELs from the 21-day dermal toxicity study and the 90-day inhalation study for inhalation exposure. Due to the inadequacies with the acute inhalation study the toxicity category was moved from categories IV to toxicity category II. The inhalation study has been resubmitted and is currently in review. Fenitrothion is not a sensitizer. The vapor pressure for fenitrothion is low (2.14×10^{-4} mmHg @ 25 C).

Other Adverse Effects

The Agency has determined that the primary occupational route of exposure to fenitrothion is dermal. On this basis, the Agency determined that the most appropriate NOEL to establish a dermal margin of exposure is from the 21-day dermal study in rabbits. The systemic NOEL in this investigation was 3 mg/kg/day based on 40% inhibition of plasma cholinesterase in both sexes and 20% inhibition of brain cholinesterase in females, observed at 10 mg/kg/day. Clinical signs indicative of cholinesterase inhibition were observed at 250 mg/kg/day (HDT) in this study. (MRID 42058301)

A 90-day inhalation study was conducted with rats exposed to 0, 0.2, 1.0, or 10 µg/l of technical grade material (94.5%). The 0.2 µg/l NOEL from this investigation was selected to estimate the MOE for the occupational inhalation exposure component. The 1.0 µg/l LEL was based on inhibition of plasma cholinesterase in males and RBC cholinesterase in males and females. (MRID 40891001)

Additional evidence of cholinergic inhibition was found in the 81-8-SS Acute Oral Neurotoxicity Study in rats in the form of clinical signs. The NOEL of 12.5 mg/kg/day was based on tremors, ataxia, gait capacity, and decreases in body temperature and motor activity observed at 50 mg/kg/day. This investigation did not assess cholinesterase enzyme activity as recommended in the neurotoxicity test guidelines. If the cholinesterase had been monitored in this investigation, the NOEL for neurotoxicity may have been lower than 12.5 mg/kg/day. Clinical signs of cholinergic inhibition were also observed in an oral developmental toxicity study in rabbits. The maternal NOEL of 10 mg/kg/day was based on mortality, abortion, tremors, ataxia, dyspnea, and reduced body weight gain at 30 mg/kg/day. Since it can be presumed that ChE inhibition occurred at lower levels than those which resulted in cholinergic signs in the acute neurotoxicity study, it is reasonable to assume a single dermal exposure could produce the effects noted at 10 mg/kg in the 21-day dermal study and that the NOEL of 3 mg/kg is appropriate to use for estimating risk following a single dermal exposure. When considered together, the acute oral and 21-day dermal studies indicate maximum ChE inhibition occurs within one to several days and that 100% absorption can be assumed for the dermal route. (MRIDs 42666901, 40430601)

(3) Summary of Potential Occupational Exposures

The dermal and inhalation exposures may be acute, intermittent, or chronic.

Handlers (Mixers, Loaders, Applicators, etc.) Exposures: The Agency has determined that there is an exposure potential for handlers (mixers, loaders, applicators, etc.) during the usual use-patterns associated with fenitrothion. Exposures to mixer, loaders and applicators are likely when fenitrothion is applied to ornamentals both outdoors or in greenhouses.

Post-Application Exposures: The Agency has determined that there is a potential for an exposure risk for persons entering treated

sites after application is complete. Post-application exposures are likely following applications to ornamentals outdoors and in greenhouses.

(4) Handler (Mixers, Loaders, Applicators, Etc.) Exposures & Assumptions

Based on the toxicological endpoints and the significant potential for exposure, fenitrothion continues to meet the Agency's criteria for the requirement of mixer/ loader/applicator exposure data. Mixer/loader/applicator and indoor air residue exposure data were required by the Fenitrothion Registration Standard (1987).

The following documents were submitted to the Agency in support of Subdivision U requirements for the reregistration of fenitrothion:

- Safe Use of Pesticides; Third Report of the World Health Organization (WHO) Expert Committee on Vector Biology and Control--Fenitrothion Aspects Excerpted From WHO Technical Report Series 634 (MRID 40408928),

- Determination of Urinary Metabolites as a Measurement of Exposure of Spraymen and Householders to Fenitrothion and Malathion in Haiti--Presented at the 23rd Meeting of the Collaborative International Pesticide Analytical Council/Sponsored by the Vector Biology and Control Division, Bureau of Tropical Diseases, Centers for Disease Control (MRID 40408929), and

- Exposure of Mixer/Loader/Applicators to Pestroy (fenitrothion) Insecticide Applied to Ornamentals by Hand-Held Spraygun Equipment (MRID 41096301). [Note: An addendum was submitted for this study (i.e., MRID 42970301, Representative Chromatograms and Analytical Data To Supplement Study of Exposure of Mixer/Loader/Applicators to Pestroy (Fenitrothion) Insecticide Applied by Hand-Held Spraygun Equipment, 1988.]

These documents were each reviewed by the Agency and determined to be unacceptable. The WHO and CDC studies were considered unacceptable because of the study design, the level of detail provided therein, and the associated lack of quality control/quality assurance regimens during the biological monitoring of workers. Additionally, the Mixer/Loader/Applicator exposure study is unacceptable because of several major inadequacies:

quality control/quality assurance regimen was inadequate and the label specified PPE requirements were not adhered to in the study design; storage stability data were not provided and field fortification data were inadequate to support the submission; and insufficient data were provided regarding the cultural practices associated with fenitrothion use on ornamentals; and the addenda submitted by the registrant did not upgrade the acceptability of the original data. (MRIDs 41096301, 42970301)

The WHO and CDC studies are not upgradable in order to satisfy the requirements specified in Subdivision U. The chemical specific mixer/loader/applicator exposure study (MRID 41096301) and the associated addenda (MRID 42970301) also do not currently meet the criteria specified in Subdivision U. However, because the mixer/loader/applicator exposure study is upgradable by correcting the deficiencies cited above, the data were utilized for an exposure assessment and corresponding MOE values were calculated based on these data.

Based on the use patterns described above, several handler exposure scenarios are possible given the various types of application equipment and procedures that might be employed by fenitrothion users. Typical equipment used to treat ornamentals (in greenhouses and in outdoor nurseries) were considered in this assessment. The Pesticide Handlers Exposure Database was used for all exposure estimates except for mixing/application using a high pressure handwand. The data for this scenario were chemical-specific data submitted to support the reregistration of fenitrothion (MRIDs 41096301, 42970301).

All exposure values presented in this RED are based on the assumption that fenitrothion handlers are wearing the following personal protective equipment: coveralls worn over short-sleeved shirt and short pants; socks plus shoes; chemical resistant gloves; and a respirator with a protection factor of 5 (i.e., disposable dust/mist mask). For several scenarios, exposure data for the exact clothing/PPE ensemble requirements were not available. As a result, the Agency applied standard protection factors to each data set to normalize the data in order to represent the standard clothing/PPE ensemble as closely as possible.

Various uncertainties and caveats must be considered when completing any risk assessment of this nature. In fact, a majority of the exposure data used in this assessment were questionable due

to inadequate quality control data and/or an inadequate number of replicates to sufficiently assess each scenario. These considerations must be acknowledged during the interpretation of the exposure assessment. All potential mixer/loader/applicator exposure scenarios and any available data are presented below.

Daily exposure is calculated using the following formula:

Daily exposure (mg ai/kg bw/day)

$$= \frac{\text{unit exposure(mg ai/lb ai) x use(lb ai/A) x Daily Acres Treated (A/day)}}{\text{body wt (kg)}}$$

Summary Exposure Values Which Conform to the WPS Clothing Requirements For Fenitrothion[a]. This table discusses labeled uses prior to risk mitigation.

Exposure Scenario	Daily Dermal Exposure (mg/kg/day)	Daily Inhalation Exposure (mg/kg/day)
Mixer/Loader Exposures[a]		
Open Mixing Wettable Powders	0.022	0.000038
Open Mixing Liquids	0.26	0.00014
Applicator Exposures		
Low Pressure Handwand Application	0.31	0.00023
High Pressure Handwand Application	0.10	0.000015
Mixer/Loader/Applicator Exposures		
Mixing and Application with Low Pressure Handwands	2.65	0.00040
Knapsack/ Backpack Application	0.20	0.00062
Mixing and Application with High Pressure Handwand	0.22	0.00338

a Reported mixer/loader exposure levels represent the maximum amount of chemical which can be handled on a daily basis.

These daily exposures to fenitrothion by handlers are used to assess the risk to those handlers.

(5) Additional Occupational Exposure Studies

Foliar residue dissipation along with post-application dermal and inhalation exposure data were required in the 1987 Fenitrothion Registration Standard. Data submitted by the registrant were inadequate to calculate post-application exposures for any of the appropriate use sites described above for fenitrothion. Based on the toxicological endpoints and the significant potential for exposure, fenitrothion continues to meet the Agencies' criteria for the requirement of post-application exposure/residue dissipation data.

The following post-application exposure scenarios are of concern to the Agency: (1) greenhouse worker exposure after treatment of ornamental plant beds and potted plants; and (2) outdoor worker exposure after contact with treated ornamental plants and foliage.

Exposures After Applications to Ornamentals: No actual exposure data were generated to support reregistration of fenitrothion for use on ornamentals in outdoor or greenhouse sites. The registrant submitted theoretical determinations of exposure potential based solely on a subjective assessment of agricultural and pesticide application practices. Adequate QA/QC data were not included. In addition, the determination of the leaf area of elm saplings was inconclusive, the estimation of fenitrothion half-life in the report was not justified, and inhalation exposure potential was ignored.

Exposures After Applications to Residences: The registrant has requested (Feb 28, 1995) voluntary cancellation of all malaria control uses. The bait uses of fenitrothion would result in minimal inhalation exposure and no dermal exposure because they are formulated in metal containers.

(6) Post Application Worker Exposures and Assumptions

Additional handler exposure studies are required at this time. There are no exposure data to support powered personal sprayer and liquid spreader application. Mixer/loader/applicator low and high-pressure handwand and knapsack/backpack data (Guideline 231, 232, 233 and 234) are required to support these uses. The following Table summarizes handler data that are required to support fenitrothion reregistration.

Mixer/loader/applicator data requirements for fenitrothion

Guideline Series	Study Category (Title)	Required Scenarios
231	Estimation of Dermal Exposure at Outdoor Sites	(1) Low-pressure handwand applications to ornamentals (2) Knapsack/Backpack application to ornamentals (3) High-pressure handwand application to ornamentals
232	Estimation of Inhalation Exposure at Outdoor Sites	(1) Low-pressure Handwand applications to ornamentals (2) Knapsack/Backpack application to ornamentals 3) High-pressure handwand application to ornamentals
233	Estimation of Dermal Exposure at Indoor Sites	(1) Indoor application to ornamentals
234	Estimation of Inhalation Exposure at Indoor Sites	(1) Indoor application to ornamentals

Additional post-application exposure studies are required at this time. The following Table summarizes post-application data that are required to support fenitrothion reregistration.

Summary Post-Application Monitoring Requirements

Guideline Series	Study Category (Title)	Required Scenarios
132-1a	Dissipation of Dislodgeable Foliar Residues	(1) Ornamentals, nursery stock/greenhouses
133-3	Measurement of Dermal Exposure	(1) Post-application exposure during ornamental propagation activities
133-4	Measurement of Inhalation Exposure	(1) Post-application exposure during ornamental propagation activities

3. Risk Assessment

a. Dietary

Toxicological Endpoints

Chronic exposure calculated in this analysis was compared to a Reference Dose (RfD) of 0.0013 mg/kg body weight/day, based on a No-Observed-Effect-Level (NOEL) of 0.125 mg/kg bwt/day and an Uncertainty Factor of 100. The NOEL was taken from a one-year feeding study in dogs which demonstrated plasma cholinesterase inhibition and lymph node hemorrhaging.

Residue parameters

There are no food uses of fenitrothion currently registered which are subject to reregistration. A food additive regulation exists in 40 CFR 185.2200(a) for residues of fenitrothion and two of its metabolites in wheat gluten resulting from postharvest application of the insecticide to stored wheat in Australia.

The HED Metabolism Committee has concluded that only fenitrothion **per se** needs to be regulated in wheat gluten; the Residue Chemistry Chapter recommends that the food additive regulation expression for residues of fenitrothion be amended to specify fenitrothion only at 15 ppm. In the DRES analysis, the existing food additive regulation of 30 ppm was entered as the food additive regulation and the recommended tolerance of 15 ppm was entered as an anticipated residue.

Dietary Risk

The Dietary Risk Evaluation System (DRES) does not specifically have a consumption estimate for "wheat gluten." The closest food category in DRES is "wheat flour." In an effort to get a more realistic consumption estimate for wheat gluten, the Agency estimated the amount of wheat gluten imported from Australia. According to USDA, all wheat gluten consumed in the United States is imported; around 40,000 metric tons of wheat gluten are imported into this

country annually, with about 40 percent of this coming from Australia. Using these estimates, assuming that the U.S. population is approximately 255,462,000 (1992 Census), and assuming the average body weight of the U.S. population to be 58.9 kg (the mean body weight of respondents in the 1977-78 Nationwide Food Consumption Survey, from which DRES consumption estimates are derived), a consumption estimate for Australian wheat gluten of 0.002913 g/kg bwt/day was calculated. By comparing this consumption estimate to that for flour (1.2572489 g/kg bwt/day), a conversion factor of 0.23, reflecting gluten consumption as a percentage of wheat flour consumption, was derived and used in the DRES analysis.

Using the derived wheat gluten consumption estimate and the recommended residue of 15 ppm, exposure to the overall U.S. population was estimated at 0.000043 mg/kg bwt/day, which represents 3% of the RfD. If one assumes that wheat gluten is consumed by children at the same ratio to the overall U.S. population's consumption that wheat flour is, the estimated exposure for children 1 through 6 is 0.000097 mg/kg bwt/day or 8% of the RfD. If the existing food additive regulation of 30 ppm is used, these exposure and risk estimates are doubled (7% of the RfD for the overall U.S. population, 15% of the RfD for children aged 1 through 6).

The acute neurotoxicity endpoint is appropriate for dietary risk assessment. An acute dietary risk from consumption of Australian gluten is unlikely because gluten is mixed with flour.

b. Occupational and Residential

The toxicological endpoints of concern for occupational and residential exposure to fenitrothion are dermal toxicity (cholinesterase inhibition) resulting from intermediate (one week to several months) exposures and inhalation toxicity (cholinesterase inhibition) resulting from chronic exposure. To estimate MOEs for intermediate exposures, a NOEL of 3 mg/kg/day was used based on systemic toxicity from a 21-day dermal toxicity study. Because the effects are from a dermal study, a dermal absorption of 100% is assumed. To estimate MOEs for chronic exposures, a NOEL of 0.049 mg/kg/day was used based on the inhalation toxicity from a

90-day inhalation study. An inhalation absorption of 100% is assumed.

The calculations indicate that MOEs are less than 100 for: (1) applicators when low-pressure handwands are used; and (2) for mixer/loader/applicators when low-pressure or knapsack/backpack equipment is used.

MOE estimates are listed in the following table for use scenarios considered eligible for reregistration. These calculations include proposed risk mitigation labeling.

Exposure Scenario	Short term and Intermediate MOE	
	Dermal	Inhalation
Mixer/Loader Exposures		
Open Mixing Wettable Powders	140	1303
Open Mixing Liquids	448	13,720
Applicator Exposures		
Low Pressure Handwand Application	42	26
High Pressure Handwand Application	129	60,978
Mixer/Loader/Applicator Exposures		
Mixing and Application with Low Pressure Handwands	5	521
Knapsack/ Backpack Application	65	340
Mixing/Application High Pressure Handwand	305	279

It should be assumed that these MOEs represent a conservative estimate. Because the unit exposure data were of poor quality and the number of replicates were insufficient, the MOE estimates provided may either understate or overstate risk to handlers from

the ornamental uses. Chemical specific data are needed to adequately estimate potential risk.

Risk from Post-Application Exposure/Residential Use

Due to the lack of exposure data, the Agency is unable to estimate the post-application risk to workers following applications to ornamentals outdoor or in greenhouses. Minimal inhalation and no dermal exposure would result from the ant and roach bait uses, therefore the risk from these uses are believed to be negligible.

The registrant requested voluntary cancellation of both malaria control product registrations. The Agency had calculated low MOEs for this use and it is not eligible for reregistration.

C. Environmental Assessment

1. Environmental Fate

All environmental fate guidelines needed to support terrestrial nonfood, greenhouse nonfood, and domestic outdoor use sites are fulfilled at this time, with the exception of the terrestrial field dissipation (164-1) study. It is unlikely that the additional information provided by this guideline will change the overall qualitative assessment for fenitrothion. The data would have a bearing on any quantitative assessment of fenitrothion exposure.

The registrant has proposed major risk mitigating label modifications, i.e., deleting Christmas tree use, allowing only spot ornamental treatments rather than broadcast applications, reducing the application rate on a per acre basis (0.3 lbs ai/acre), limiting the number of fenitrothion applications to three per year, and increasing the minimum interval between applications to one month. If these proposed label changes are made to all fenitrothion end-use products, the terrestrial field dissipation study will not be required.

a. Environmental Chemistry, Fate and Transport

(1) Hydrolysis

Phenyl-labeled [^{14}C]-fenitrothion degraded with half-lives of 191 to 200 days in sterile buffered (pH 5 - 9) solutions. The major degradate in Ph 5 and pH 7 buffered solutions was demethylated fenitrothion. The major degradate in pH

9 buffered solution was 3-methyl-4-nitrophenol. (MRIDs 40717901, 00090500)

(2) Photodegradation in water

Phenyl-labelled [^{14}C]-fenitrothion degraded with a half-life of 4-7 days. The major non-volatile degradate was 0,0-dimethyl 0-(3-carboxyl-4-nitro-phenyl) phosphorothioate which reached a maximum of 12.4% of the applied radioactivity by 14 to 30 days after application. (MRIDs 40717902, 00159953, 00159952, 00088273, 00061839)

(3) Photodegradation in soil

Fenitrothion degraded with a half-life of 85 days when applied to a sandy loam soil and exposed to a light source (simulating sunlight). Seven degradates were identified, each reaching a maximum of less than or equal to 4.7% of applied radioactivity. (MRIDs 41346901, 00088273, 40865501)

(4) Photodegradation in air

This data requirement is waived because fenitrothion has a very low vapor pressure, approximately 5 x 10^{-6} mm Hg at 20EC. (MRID 41148901)

(5) Aerobic soil metabolism

Fenitrothion degrades with a half-life of approximately 2 days in sandy loam soil. The major nonvolatile degradate was 3-methyl-4-nitrophenol which reached a maximum concentration of 20% of the applied radioactivity at 1 to 3 days. Other degradates identified were fenitrooxon, desmethylfenitrooxon, and 3-methyl-4-nitroanisole each reaching a maximum of less than or equal to 0.9% of applied by 21 days posttreatment. $^{14}CO_2$ was the major volatile degradate which reached a reported maximum concen-tration of 71.1% of the applied radioactivity 365 days after application. (MRIDs 41295101, 00061842, 00159950, 00126945)

(6) Anaerobic aquatic metabolism

The anaerobic aquatic half-life for fenitrothion is 0.82 days. Less than 1.0% (approximately 0.01 ppm) of applied radioactivity was identified as parent material 1 month after application. During the testing period, cumulative volatiles reached 1.1% of applied, 50% of which was $^{14}CO_2$. In addition, non-extractable ^{14}C-residues increased to 73.9% of recovered radioactivity by day 365 posttreatment of which approximately 85% was fractionated into fulvic and humic acid. Three extractable degradates were identified, 3-methyl-4-nitrophenol (15% of applied at day 2 after application), aminofenitrothion (13% of applied at day 3 post-treatment), and acetylaminofenitrothion (13% of applied at day 3 post treatment) during the testing period. One minor extractable degradate was identified, formylaminofenitrothion (maximum 4.9% of applied at day 7 posttreatment). By day 273, all degradates were less than 1.3% of applied radioactivity (MRIDs 41615701, 00159950, 00159949, 00061842)

(7) Leaching/adsorption/desorption

Aged: Aged fenitrothion residues were reported to be found mainly in the top 5 inches of soil columns. An average 3.8% of the recovered fenitrothion was volatilized from the soil columns during the testing period. The major nonvolatile degradate, 3-methyl-4-nitrophenol, and parent fenitrothion were not detected in the leachate from the columns during leaching.

Unaged: In sand, sandy loam, silty clay loam, and silty clay soil, fenitrothion was slightly mobile to immobile (K_{ads} = 4.9 to 32). In addition, in pond sediment fenitrothion appears immobile (K_{ads} = 830), as well. Desorption values were similar (K_{des} values = 6.8 to 42; for pond sediment approximately 550). Adsorption/desorption values were strongly correlated with the organic matter of the soils. (MRIDs 40420502, 00159956, 00159951, 00126947, 00061842)

(8) Soil Dissipation Studies (164-1)

Fenitrothion and 3-methyl-4-nitrophenol (3M4NP) indirectly applied to soil 0 to 3 inches depth had reported half-lives of 18 and 25 days, respectively, in Evesboro loamy sand soil. In another study fenitrothion and 3-methyl-4-nitrophenol (3M4NP) indirectly applied to soil 0 to 3 inches depth had reported half-lives of 3 and 12 days, respectively. Because fenitrooxon was not present at discernible levels except in sufficient soil samples, no half-live was calculated for fenitrooxon. Fenitrooxon was believed to be a transient compound that converts to 3M4NP. Fenitrothion and the major degradate 3M4NP are expected to be slightly persistent and relatively immobile in soil, i.e., leaching of fenitrothion and/or it's major degradates is not expected. (MRID 41646601)

Another terrestrial field dissipation study is of uncertain value for several reasons the most important being a poor mass balance, i.e., recovery of the applied dose was < 50%. However, it is unlikely that additional information will significantly affect the overall qualitative assessment.

(9) Bioaccumulation in fish

Fenitrothion appears to accumulate rapidly but at low concentrations. Maximum BCFs (bioconcentration factor) of 33X, 341X, and 129X for edible, nonedible, and whole fish tissues, respectively, were reached by Day 3 postexposure. Depuration was fairly rapid with 93.2 to 95% depuration of accumulated radioactive residues by Day 3 of depuration. Other degradates in edible and non-edible tissues at concentrations equal to or greater than 0.05 ppm identified were a sulfate conjugate of 3-methyl-4-acetylaminophenol, a sulfate conjugate of 3-methyl-4-nitrophenol, a hydroxymethyl derivative of oxidized desmethylfenitrothion, and glucuronide conjugates of 3-methyl-4-acetylaminophenol and 3-hydroxymethyl-4-nitrophenol. (MRIDs 41654001, 40847001)

(10) Volatility (lab)

The volatility of fenitrothion from a sandy loam soil at 50% and 75% moisture capacity was evaluated for 21 days

at 25 plus or minus 1°C. Approximately 88% of applied radioactivity was recovered as extractable fenitrothion residues. From 0.13 to 2.2% of applied radioactivity was recovered as volatile material during the testing period, and approximately 6% of applied radioactivity was recovered as soil bound residues. Two volatiles, parent fenitrothion and 3M4NP (3-methyl-4-nitrophenol), were identified which reached maximum concentrations of 89.5% and 4.2% of volatile material (approximately 2% of applied radioactivity), respectively. A minor peak (less than 2% of volatile material) was discernible in Day 21 and Day 14 and Day 21 of the 50% and 75% moisture content soil samples which co-chromatographed with fenitrooxon. There was an unknown volatile which reached a maximum concentration of 0.8% of applied radioactivity (10.3% of volatile material). The authors reported that the rate of volatilization appeared to be dependent on soil moisture. Furthermore, the vapor pressure of fenitrothion was observed to decline for the soil at both moisture contents treated. The average vapor pressure was 5.75×10^{-6} mm Hg at Day 1 and dropped to 3.36×10^{-6} mm Hg at Day 21 for the 75% moisture content soil samples. The average vapor pressure was 5.25×10^{-6} mm Hg and dropped to 2.21×10^{-6} mm Hg after 21 days for the 50% moisture content soil samples. (MRID 41148902)

b. Environmental Fate Assessment

This environmental fate assessment is based on acceptable laboratory data and supplemental field data. These laboratory data indicate that the major routes of dissipation are biotic microbial mediated processes to CO_2 and abiotic aquatic photolysis. The half life for aerobic soil metabolism is 2.1 days, 0.82 days for anaerobic aquatic metabolism, and 4-7 days for abiotic aquatic photolysis in sterile pH 5-9 solutions. Furthermore, fenitrothion appears to be non-mobile when applied to silty clay loam, silty clay, and sandy loam soils (K_{ads} = 13.0-32.0). Even though the field data are supplemental, fenitrothion in different formulations appears to dissipate fairly rapidly, with a half life of 3 to 25 days and does not appear to be mobile. It is found in mainly the top 6" of soil. Therefore, based on the present data base, fenitrothion is expected to be slightly persistent and relatively non-mobile in the soil environment.

CO_2 was the major degradate for aerobic soil metabolism and photolysis. For aerobic soil metabolism, CO_2 was 27.5% of applied at Day 5 posttreatment, and for photolysis, was 41.2 to 42.0% of applied for photodegradation in water and 4.3% of applied for photodegradation on soil by Day 30 posttreatment. During the anaerobic aquatic testing period cumulative volatiles reached 1.1% of applied of which 50% was determined to be $^{14}CO_2$. Major nonvolatile degradates for aerobic soil metabolism, anaerobic aquatic metabolism, and photolysis appear to be 3-methyl-4-nitro-phenol (approximately 1 to 22% of applied), aminofenitrothion (approximately 13% of applied), acetyl-aminofenitrothion (approximately 13% of applied), formylaminofenitrothion (4.9% of applied), o,o-dimethyl o-(3-carboxy-4-nitrophenyl)phosphorothionte (12.4% of applied), fenitrooxon (less than or equal to 4.3% of applied), demethylate fenitrothion (approximately 1% of applied), and desmethylfenitrooxon (less than or equal to 4.3% of applied). Other degradates identified [o,o-dimethyl o-(3-methyl-4-nitrophenyl)phosphorothioate-3-methyl-4-nitrophenol, o-methyl (5-methyl o-(3-methyl-4-nitrophenyl)phen-phorothioate, o-methyl o-hydrogen o-(3-methyl-4-nitro-phenyl)phosphate, o,o-dimethyl o-(3-carboxy-4-nitrophenyl)phosphate, 5-methylfenitrothion, and carboxyfenitrooxon] were each present at concentrations of less than or equal to 2%. Even though fenitrothion does dissipate fairly rapidly when exposed to aerobic conditions and a light source, it hydrolyses slowly in sterile aqueous solutions with a hydrolysis half life of 100 to 200 days in pH 5-9 solutions. The major degradates reported discernible in pH 5 and pH 9 solutions were demethylated fenitrothion at 10.3% of applied and 3-methyl-4-nitrophenol at 1.7% of applied. The major degradate in the pH 9 solution was 3-methyl-4-nitrophenol at 15.1% of the applied. Demethylated fenitrothion comprised up to 5.6% of applied.

Persistence of the individual metabolites has not been verified. However, it does appear in laboratory and field data that they degrade fairly rapidly to CO_2, as well. In addition, laboratory and field data indicate that fenitrothion degradates are relatively non-mobile. Although all soil segments treated with aged fenitrothion contained

radioactive residues, the majority, 68.2-69.2% of the applied, of the [^{14}C]residues in the soil columns were concentrated in the surface 1-inch layer. The 1 to 2 inch soil segment contained less than or equal to 2.6 to 5.4% of the applied radioactivity. Other soil segments contained less than or equal to 3.3% of the applied radioactivity. Fenitrothion was not detected in leachate from the columns. Extensive extraction and thin layer chromatography (TLC) analysis of the leachate resulted in the isolation of thirteen distinct areas of radioactivity plus the origin. None of these areas contained less than 0.002 ppm of radioactivity. The field data indicate that fenitrothion residues do not leach below the 0 to 12 inches soil depth.

Bioaccumulation data indicate that fenitrothion accumulated in fish with low maximum BCFs, 33X, 341X, 129X for edible, nonedible, and whole fish tissue, respectively, and were reached in bluegill by Day 3 of exposure. In addition, depuration was reported to be 93.2 to 95% of the accumulated radioactive residues by Day 3 of depuration.

2. Ecological Effects

a. Ecological Effects Data

The ecotoxicological data base is adequate to characterize the toxicity of fenitrothion to nontarget terrestrial and aquatic organisms when used on terrestrial food, feed and nonfood sites. Wildlife toxicology data (71-1) for 3-methyl-4-nitrophenol, the major fenitrothion degradate, are now required. It is unlikely that the additional information provided by this study will change the overall qualitative assessment for fenitrothion. The data would have a bearing on any quantitative assessment of fenitrothion exposure.

(1) Terrestrial Data

In order to establish the toxicity of fenitrothion to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland

game bird (preferably bobwhite quail or ring-necked pheasant).

(a) Avian Acute Toxicity

Avian Acute Oral Toxicity Findings

Species	% Test Material	LC_{50}/LD_{50}	Conclusions
Bobwhite quail *	TGAI	LC_{50} = 157 ppm	highly toxic
Ring-necked pheasant	TGAI	LD_{50} = 34.5 mg/kg	

* - Most sensitive species is the bobwhite quail; mallard duck LC_{50} = 2482 ppm

These results indicate that fenitrothion is highly toxic to birds. (MRIDs 00022923, 00126885)

(b) Avian Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Present product labeling of fenitrothion allows several applications of the end-use product per growing season.

Avian Reproduction Findings

Species	Reproductive Impairment
Bobwhite Quail	Reduced egg production = 17.0 ppm (LOEL) NOEL = 13.0 ppm

Chronic effects (reduced egg production) were observed during the avian reproduction study with bobwhite quail at the 17.0 ppm concentration level. The No-Observed Effect Level (NOEL) was determined to be 13.0 ppm. (MRID 41958401).

(c) Toxicity to Nontarget Mammals

The minimum data required to establish the toxicity of fenitrothion to mammals is an acute oral toxicity study.

Mammalian Acute Oral Toxicity Findings

Species	% Test Material	LD_{50}	Conclusions
Rats	97.2%	330 mg/kg	moderately toxic
Rats	77%	355 mg/kg	

The available mammalian data indicate that fenitrothion is moderately toxic to small mammals on an acute basis. (MRIDs 232483, 246664, 002739)

(2) Aquatic Data

(a) Freshwater Fish Toxicity

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warm water species (preferably the bluegill sunfish).

Freshwater Fish Acute Oral Toxicity Findings

Species	% Test Material	LC_{50} (ppb)	Conclusions
Rainbow trout	95	2400	moderately toxic
Bluegill sunfish	95	3900	
Brook trout	95	1720	
Cutthroat trout	technical	2880	

The results of the four 96-hour acute toxicity studies indicate that fenitrothion is moderately toxic to both cold and warm water fish. (MRIDs 40094602, 00125909, 00120401)

(b) Freshwater Fish Chronic Effects

Data from a fish early-life stage test is required if an active ingredient is persistent in water, or chronic exposure is otherwise expected.

Freshwater Fish Early-life Stage Findings

Species	% Test Material (TGAI)	NOEL/MATC/LOEL (ppb)
Rainbow trout	94.5	46/64/88

The LOEL is based upon effects on the weight and length of rainbow trout. The guideline requirement for fish chronic toxicity testing on the technical material has been satisfied. (MRID 40891201)

(c) Freshwater Invertebrate Toxicity

The minimum testing required to assess the hazard of a pesticide is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

Freshwater Invertebrate Toxicity Findings

Species	% Test Material (TGAI)	EC_{50}/LC_{50} (ppb)	Conclusions
Daphnia magna	95	11	very highly toxic
Gammarus	95	4.3	
Pateronarcella	95	5.1	
Daphnia magna	76.8	2.3	

There is sufficient information to characterize fenitrothion as very highly toxic to aquatic invertebrates. The guideline requirement is satisfied. (MRIDs 40094602, 00120401, 40620901)

(d) Freshwater Aquatic Invertebrate Chronic Effects

Data from a freshwater aquatic invertebrate life-cycle study is required if an active ingredient is persistent in water.

Freshwater Aquatic Invertebrate Life-cycle Findings

Species	% Test Material (TGAI)	NOEL/MATC/LOEL (ppb)
Daphnia magna	94.5	0.087/0.19/0.23

The 21 day LOEL is based upon adult daphnid survival. (MRID 40891101)

(e) Estuarine/Marine Toxicity

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The terrestrial nonfood use of fenitrothion may result in exposure to the estuarine environment.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

Estuarine/Marine Acute Toxicity Findings

Species	% Test Material (TGAI)	EC_{50}/LC_{50} (ppb)	Conclusions
Eastern oyster embryo larvae	75	450	moderately to very highly toxic
Pink Shrimp	75	1.5	
Sheepshead minnow	75	> 1000	

There is sufficient information to characterize fenitrothion as moderately to very highly toxic to estuarine organisms. (MRID 40228401)

(3) Non-Target Insects Data

The minimum data required to establish the acute toxicity to honey bees is an acute contact LD_{50} study with the technical material.

Nontarget Insect Acute Contact Toxicity Findings

Species	Test Material	LD_{50}	Conclusions
Honey bee	TGAI	0.02 ug/bee	highly toxic
Honey bee	TGAI	0.38 ug/bee	

There is sufficient information to characterize fenitrothion as highly toxic to bees. (MRIDs 05001991, 00036935)

(4) Non-Target Plants Data

Plant testing was not required for this insecticide.

b. Ecological Effects Risk Assessment

This section consists of numerous risk assessments each covering a different combination of endpoint and exposure scenarios. Each risk assessment includes a risk quotient which combines the toxicity and exposure information. For each risk quotient there is an established value above which the risk is considered to be at a high level of concern (LOC). In addition to these high risk values, restricted use is considered when the risk quotient exceeds the 0.1 for acute aquatic risk or 0.2 for acute avian risk. The generic risk quotients and their respective LOC's for each risk assessment are provided in the following table. Note that the same risk quotients are used for nonendangered and endangered species, but the acute LOC is lower for endangered species.

Endpoint/ Scenario	Risk Quotient	Non-endangered LOC	Endangered LOC
Mammalian acute	EEC/LC_{50}	0.5	0.1
Mammalian chronic	EEC/LEL	1.0	1.0
Avian acute	EEC/LC_{50}	0.5	0.1

Endpoint/ Scenario	Risk Quotient	Non-endangered LOC	Endangered LOC
Avian chronic	EEC/LEL	1.0	1.0
Aquatic acute	EEC/LC_{50}	0.5	0.05
Aquatic Chronic	EEC/LEL	1.0	1.0
Non-target insects/ plants	Not quantified	N/A	N/A

1. Non-Endangered Terrestrial Organisms

Avian Species (Acute)

Fenitrothion labels do not specify the amount of active ingredient (ai) that may be applied per acre during each application. The chemical may be applied once per week. For this risk assessment, the Agency assumes that 100 gallons of spray solution may be applied per acre. The 76.8% ai formulation containing 8 lbs of fenitrothion per gallon may be applied in concentrations of 3 pts. of product per 100 gallons. Therefore, fenitrothion may be applied at 3 lbs ai/acre (8 lbs/gal x 1 gal/8 pt x 3 pt/100 gal x 100 gal/acre). The Tables below provide the risk quotients for terrestrial organisms.

The weight of a ring-necked pheasant is estimated to be 1.135 kg. The number of LD_{50}s/square foot is calculated as follows:

$$\frac{\text{3.0 lbs ai/acre x 454,000 mg/43,560 sq ft}}{\text{3.5 mg/kg x 1.135 kg}} = \text{0.8 LD50s/sq ft}$$

A ring-necked pheasant can consume up to 9.2% of its body weight per day. The number of LD_{50}s/day resulting from exposure to residues on short grass, insects, and seeds are calculated as follows:

$$\frac{\text{3.0 lbs ai/acre x 240 x 0.092}}{\text{34.5 mg/kg}} = \text{1.9 LD50s/day (grass eaters)}$$

$$\frac{3.0 \text{ lbs ai/acre} \times 58 \times 0.092}{34.5 \text{ mg/kg}} = 0.5 \text{ LD50s/day (insect eaters)}$$

$$\frac{3.0 \text{ lbs ai/acre} \times 12 \times 0.092}{34.5 \text{ mg/kg}} = 0.1 \text{ LD50s/day (seed eaters)}$$

The maximum residue levels on short grass following a 3 lbs ai/acre application is 3.0 x 240 ppm = 720 ppm (Kenaga 1972). The avian dietary EEC/LC50 risk quotients on short grass, insects, and seeds are calculated as follows:

$$\frac{3.0 \times 240 \text{ ppm}}{157 \text{ ppm}} = 4.6 \text{ (grass eaters)}$$

$$\frac{3.0 \times 58 \text{ ppm}}{157 \text{ ppm}} = 1.1 \text{ (insect eaters)}$$

$$\frac{3.0 \times 12 \text{ ppm}}{157 \text{ ppm}} = 0.2 \text{ (seed eaters)}$$

Based upon maximum exposures, high acute risk is expected for birds consuming grass and insects following a single 3.0 lb ai/acre application. Although the acute risk to seed eating birds is less, the risk still exceeds the restricted use Level of Concern (LOC) of 0.2. All of the risk quotients exceed the endangered species LOC of 0.1 See the Table below.

Acute Risk Quotients for Birds (Single Application)

Maximum Application Rate	Risk Quotient - LD50/ft^2 *	Risk Quotient - LD50/day *	Risk Quotient (EEC/LC50) **
3.0 lbs/ai/acre	0.8	1.9 (grass) 0.5 (insects) 0.1 (seeds)	4.6 (grass) 1.1 (insects) 0.2 (seeds)

* The bird LD50 value is 34.5 mg/kg
** The bird LC50 value is 157 ppm

To get below the high risk LOC, the application rate would need to be reduced to 0.3 lbs ai/acre for non-endangered species and 0.06 lbs ai/acre for endangered species. The registrant has proposed lowering the application rate to 0.3 lbs ai/acre, see Section IV.

Avian Species (Chronic)

Based upon maximum exposure values, high chronic risk to seed, insect, and grass eating birds will occur when exposed to a single as well as multiple applications of fenitrothion at 3.0 lbs ai/acre. The registrant has proposed numerous label modifications including a lower use rate, a restriction on the maximum number of applications per year and a retreatment interval increased from one week to one month. See Section IV for a detailed discussion.

Chronic Risk Quotient (EEC/NOEL) for Birds

Number of 3.0 lb/ai/A Applications per year	Risk Quotient EEC/NOEL[1] (seeds)	Risk Quotient EEC/NOEL[1] (grass)	LOC
1	2.8 (36 ppm)	55.4 (720 ppm)	HR[2] $\geq$ 1
5[3]	13.8 (180 ppm)	277 (3,600 ppm)	HR $\geq$ 1

1 The reproductive NOEL is 13 ppm.
2 HR = High Risk
3 Current labels do not limit the total number of applications/year. Therefore, it is assumed that five applications may be applied per season with no degradation.

Mammals

The following table provides risk quotients (EEC/one day LC50) for a single 3 lb ai/acre application of fenitrothion (broadcast):

Acute Risk Quotients for Mammals (Single application)

Species (One day LC50)	Expected Food (EEC ppm)	Risk quotient EEC/one day LC50	LOC
Meadow vole (540 ppm)	Grass (720)	1.3	HR[1] > 0.5 RU[2] > 0.2 ES[3] > 0.1
Least shrew (300 ppm)	Insects (174)	0.6	HR[1] > 0.5 RU[2] > 0.2 ES[3] > 0.1
Old field mouse (2,043 ppm)	Seeds (36)	0.02	HR[1] > 0.5 RU[2] > 0.2 ES[3] > 0.1

1 - HR = High Risk
2 - RU = Restricted Use
3 - ES = Endangered Species

These risk quotients exceed the endangered species (ES) LOC of 0.1, the restricted use (RU) LOC of 0.2 and the high risk (HR) LOC of 0.5. Risk quotients are calculated based on the LD50 value for laboratory rats (330 mg/kg). The percentage of body weight mammals consume per day is estimated to be 16, 61, and 110% for the old field mouse, meadow vole, and least shrew, respectfully (Davis and Golly 1963). Current fenitrothion labels do not restrict the number of applications that may be applied per year. Risk quotients based upon multiple applications may be substantially greater than those shown in the table above.

2. Non-Endangered Aquatic Organisms

Freshwater (Acute)

Since the labels do not specify the amount of fenitrothion that may be applied per unit area, it is assumed that 100 gallons of spray solution may be applied per acre. The aquatic EEC's for an unincorporated ground application are calculated as follows:

3 lbs ai/acre x 0.02 (% runoff) x 10 acres x 61 ppb = 36.6 ppb

The following table provides acute risk quotients for freshwater aquatic organisms. High acute risk from a single application is expected for freshwater invertebrates. Acute risk to fish is below all levels of concern for a single application. Multiple applications would result in higher risks.

Acute Risk Quotients for Freshwater Aquatic Organisms Following a Single 3.0 lb ai/acre Application

Species	EEC for 6 ft deep aquatic habitat (ppb)	Risk Quotient EEC/LC50[1] or EEC/EC50[1]	LOC
Freshwater fish	36.6	0.02	HR[2] ≥ 0.5 RU[3] ≥ 0.2 ES[4] ≥ 0.1
Freshwater invertebrates	36.6	8.5	HR[2] ≥ 0.5 RU[3] ≥ 0.2 ES[4] ≥ 0.1

1 - LC_{50} is 1,720 ppb for freshwater fish and the EC_{50} is 4.3 ppb for freshwater invertebrates.)
2 - HR = High Risk
3 - RU = Restricted Use
4 - ES = Endangered Species

Freshwater (Chronic)

The labels do not specify the maximum number of applications of fenitrothion that may be applied per year, however, the EEC is based upon a single application. The risk quotient from a single application exceeds the endangered species and high risk levels of concern for freshwater invertebrates. Chronic risk to freshwater fish from a single application is below all levels of concern. For multiple applications, it is expected that the risk would be higher. The following table provides chronic risk quotients for freshwater aquatic organisms.

Chronic Risk Quotients for Freshwater Aquatic Organisms Following a Single 3.0 lb ai/acre Application.

Species	Chronic Geometric Mean MATC (ppb)	EEC for 6 ft deep aquatic habitat (ppb)	Risk Quotient (EEC/MATC)
Freshwater fish	64	36.6	0.57
Freshwater Invertebrates	0.19	36.6	229

Estuarine/Marine

The following table provides acute risk quotients for marine/estuarine organisms. The acute risk quotient, from a single application, exceeds the endangered species and high risk levels of concern for marine/estuarine invertebrates (arthropods). Acute risks to fish and mollusc from a single application are below all levels of concern. For multiple applications the risk may be greater.

Acute Risk Quotients for Marine/Estuarine Organisms

Species	LC50/ EC50 (ppb)	EEC for 6 ft deep aquatic habitat	Risk Quotient EEC/LC50
Marine/estuarine fish	1,000	36.6	0.04
Marine/estuarine invertebrate	1.5	36.6	24.4
Marine/ estuarine mollusc	450	36.6	0.08

3. Effects on Beneficial Insects:

The data indicates that fenitrothion is highly toxic to honey bees. The acute contact LD50 value is 0.02 ug/bee. Honey bees that are exposed to this chemical may be adversely effected.

4. Endangered Species

As described in the above risk assessment sections, endangered species LOCs are exceeded for acute effects to aquatic invertebrates and in some instances for acute effects to birds and wild mammals. Endangered species LOCs are also exceeded for chronic effects to birds and aquatic invertebrates.

Limitations on the use of fenitrothion may be required to protect endangered and threatened species. However, these limitations have not yet been defined (and may be formulation specific). The Agency anticipates that consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the program. Following the completion of the consultation registrants will be informed of any required label modifications that are necessary. Such modifications would most likely consist of generic label statements referring pesticide users to the limitations contained within county bulletins.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing fenitrothion active ingredients. The Agency made its reregistration eligibility determination based upon chemical specific data required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. In addition, the Agency made extensive use of the Pesticide Handlers Exposure Database (PHED) for occupational exposure estimates.

Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of fenitrothion, and lists the submitted studies that the Agency found acceptable. It also identifies unacceptable studies and the specific studies required for fenitrothion reregistration.

1. Eligibility Decision

The Agency has determined that fenitrothion uses as currently registered pose adverse effects to humans, aquatic organisms and wildlife. The technical registrant, Sumitomo Chemical Company, has submitted a draft label for Sumithion 8E significantly reducing fenitrothion use on ornamentals. These proposed label changes have mitigated human health and ecological impact concerns making the high-pressure handwand treatment of ornamentals use eligible for reregistration. This eligibility determination for reregistration is contingent upon all ornamental end-use product labels (there are three products registered for use on ornamentals) being revised as proposed.

On February 28, 1995 the registrant requested voluntary cancellation of the mosquito (malaria) control uses of fenitrothion.

The Agency defers making a regulatory decision on both the low-pressure handwand and knapsack/backpack methods of application until chemical-specific worker exposure studies are submitted. Uncertainties in the existing worker exposure database do not allow the Agency to determine, with confidence, the appropriate MOEs for these exposure scenarios. However, the Agency believes it is in the public's best interest to implement the human health and ecological effect exposure/risk mitigation measures negotiated with the registrant at this time. Therefore, the Agency has decided not to delay issuing the fenitrothion RED until these studies are submitted and reviewed. The Agency is requiring the registrant to submit the worker exposure studies on an accelerated schedule, i.e., one year from issuance of this document. Details concerning the required label changes can be found in Section V, Actions Required by Registrants. When the chemical specific exposure data

required by this RED are received, the Agency will make a regulatory decision regarding the reregistration eligibility of the low-pressure handwand and knapsack/backpack methods of application.

Fenitrothion has significant potential for causing adverse effects in aquatic organisms, wildlife and the environment. Sumitomo Chemical Co. has proposed eliminating the highest risk uses, and reducing the maximum application rate for all other uses. The proposed label changes and the fact that this insecticide is not widely used (< 1% of U.S. nursery acreage are treated annually) were given consideration in making the reregistration decision for this insecticide. The high-pressure handwand treatment of ornamentals and the two bait formulations are eligible for reregistration. Details are discussed in the following section.

2. Eligible and Ineligible Uses

The registrant requested on February 28, 1995 that the malaria control uses of fenitrothion be cancelled. These uses are not eligible for reregistration due to the low MOEs for post-application exposure.

Treatment of ornamental plants involves a significant potential for causing adverse effects to handlers, reentry workers, and nontarget terrestrial and aquatic organisms including endangered species. The registrant has proposed revised labeling which deletes high exposure/risk uses: Christmas tree use, basal bark treatment (drench treatment) and limiting the treatment of shade trees to only those in nurseries. Consequently, Christmas tree use, basal bark treatment and use on shade trees other than those in nurseries are not eligible for reregistration. Additionally, the registrant has reduced the ornamental treatment rate to 0.3125 lbs ai/acre (30 gallons of Sumithion 8E, diluted at 0.5 ounces per 3 gallons, per acre (previously no limit was established); proposed limiting use to spot treatment only rather than broadcast use (i.e., deleting overhead boomsprayers, groundboom and liquid broadcast sprayer application from the label); proposed increasing the retreatment interval from one week to one month; proposed restricting the maximum number of applications per year to 3 (previously unspecified); and proposed labeling for restricted use. The following uses are eligible for reregistration:

- Treatment of ornamental plants in nurseries and greenhouses only, with high-pressure handwands provided the following restrictions are added to the label: restricted use classification, maximum application rate of 0.3125 lbs ai/acre, a maximum number of applications of three per year is imposed, the minimum retreatment interval is increased to once per month, use on Christmas trees is deleted, deletion of the drench treatment for control of the southern pine bark beetle, and treatment of shade trees is limited to those in nurseries and greenhouses.

- Ant and roach baits

RESULTING RISK

ECOLOGICAL - The proposed mitigation measures reduce the risk quotients for nontarget aquatic organisms by a factor of 10. Risk quotients are still exceeded for acute (0.85) and chronic risk (22.9) to aquatic invertebrates. However, the chronic risk estimate assumes no degradation between applications. Additionally, voluntary deletion of broadcast methods of application will reduce the probability of fenitrothion runoff reaching aquatic systems. The Agency has not recalculated terrestrial organism LOC's. Since fenitrothion is applied to ornamentals to the point of dripping, the application rate within specific areas that are treated is potentially much higher than 0.3 lbs ai/acre. For instance, if it is assumed that 10% of a nursery is treated at a rate of 0.3 lbs ai/acre, then the application rate within the treated area is 3.0 lb ai/acre. The risk quotients for terrestrial animals have not been reduced, however, the amount of acreage in which fenitrothion poses a high risk has been significantly reduced. The Agency estimates that less than 3000 acres will be treated per year.

HUMAN HEALTH - The MOE's for high pressure handwand application are greater than 100; however this is based on uncertain data and additional confirmatory data are required.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for fenitrothion. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

There are no registered food uses for fenitrothion in the U.S. A food additive regulation of 30 ppm is established for fenitrothion residues in or on imported wheat gluten from Australia [40 CFR §185.2200(a)]. The food additive regulation is adequately supported and poses no health risk. The food additive regulation expression for residue of fenitrothion should be amended to specify fenitrothion only at 15 ppm.

2. Restricted Use Classification

All end-use products of fenitrothion labeled for outdoor use must have a restricted use classification due to the acute and chronic toxicity of fenitrothion to non-target species.

3. Reference Dose Exceedance

There are no RfD exceedance issues associated with the registered uses of fenitrothion. The Agency concluded that an RfD should be established based upon a NOEL of 0.125 mg/kg/day for systemic effects (histopathological changes in lymph nodes) and plasma

cholinesterase inhibition observed at 0.25 mg/kg/day in a long-term feeding study in dogs. An Uncertainty Factor (UF) of 100 was used to account for the inter-species extrapolation and intra-species variability. On this basis the RfD was calculated to be 0.0013 mg/kg/day. The Joint FAO/WHO Meeting On Pesticide Residues (JMPR) reports an ADI of 0.005 mg/kg bw (1988). Even if one assumes that residues are present at tolerance levels (an unlikely assumption) exposure and risk estimates would be 7% for overall population and 15% of the RfD for children aged 1 through 6.

4. Risk Mitigation

The Agency has determined that registered uses of fenitrothion exceed levels of concern for many uses. In response to these concerns mitigation measures are required (see section V).

MALARIA CONTROL USES

The registrant has requested that malaria control uses of fenitrothion be cancelled. This use is not eligible for reregistration.

5. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered mammals, birds and aquatic invertebrates to fenitrothion. Based on the conclusions discussed in the preceding sections of this risk assessment, endangered species LOCs are exceeded in some instances for acute effects to birds, wild animals and aquatic organisms. Endangered species LOCs are also exceeded for chronic effects to birds and aquatic invertebrates.

Currently the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will address the adverse impacts. The program would require use restrictions to protect endangered and threatened species in the country. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish in the Federal Register a description of the program and have available enforceable county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modification will occur in the future under the Endangered Species Protection Program.

6. Labeling Rationale

a. Occupational/Residential Labeling Rationale/Risk Mitigation

Compliance with Worker Protection

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in. Registered uses of fenitrothion outside the scope of the WPS include the recently registered bait products, one for roaches and another for ants.

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 9311, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

Personal Protective Equipment (PPE) and Engineering Controls for Handlers (Mixer/ Loader/Applicators)

Occupational-Use Products (WPS and NonWPS Uses)

To EPA's knowledge, at this time some of the registered uses of fenitrothion are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some are outside the scope of the WPS. The PPE requirements will pertain to both the WPS and nonWPS uses by occupational handlers, since the potential exposure to occupational handlers is similar for WPS and nonWPS uses.

For each occupational end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.
- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.
- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

EPA has special concerns about the high acute toxicity (based on the mixer/loader/applicator exposure assessment) of fenitrothion and is, therefore, establishing baseline handler PPE requirements for any end-use product that contains fenitrothion.

Handler PPE for Homeowner-Use Products

Only the two bait formulations of fenitrothion are intended primarily for homeowner use.

Post-application/Entry Restrictions

Restricted Entry Interval: Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: product-specific REI's established on the basis of adequate data and interim REI's that are longer than those that would be established under the WPS.

As an interim measure until adequate reentry data became available, the 1987 Fenitrothion Registration Standard established a reentry interval of 24 hours for fenitrothion for all uses on agricultural plants, including ornamentals, Christmas trees, and forestry trees. The 24-hour interim reentry interval (permits routine entry to perform hand labor tasks if PPE is worn) was converted into a 24-hour interim restricted entry interval (prohibits routine entry to perform hand labor tasks even if wearing PPE) through modifications to the labeling specified in PR Notice 93-7, which implemented the labeling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides (WPS).

Data needed to assess the risks to agricultural workers from post-application exposures to fenitrothion are unavailable at this time, so the Agency is unable to establish a permanent restricted entry interval. However, the Agency is concerned about the post-application exposures of agricultural workers to fenitrothion, since the MOE's for mixers, loaders, and applicators are low. Therefore, as an interim measure until data are available to establish a permanent REI, the Agency will increase the interim restricted entry interval to 48 hours for all uses of fenitrothion within the scope of the WPS. In addition, the REI increases to 72 hours when fenitrothion is applied in outdoor areas where the average rainfall is less than 25 inches per year.

Early Entry PPE The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry by workers if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since EPA has special concerns about the high acute toxicity of fenitrothion, the Agency is establishing PPE for dermal protection that is more stringent than the PPE that would otherwise be established based on the acute toxicity of the active ingredient. Since fenitrothion is classified as category II for eye irritation potential, protective eyewear is required.

EPA believes that existing WPS protections are sufficient to mitigate inhalation exposures to workers who enter treated areas outdoors or in a greenhouse after fenitrothion has been applied. The Agency will not, therefore, establish a respirator requirement for early-entry workers. The WPS prohibits anyone (except those who are entering to perform a specific handler task and are wearing handler PPE, including the respirator) from entering a treated area for the first four hours following application, unless there will be no contact with pesticides, including pesticides on plants or in soil, water, or air. The WPS places additional restrictions on entry during (and immediately following) applications in enclosed areas when the applicator is required to wear a respirator. These restrictions include:

- prohibiting anyone (except those who are participating in the application and who are wearing the PPE required for applicators) from being in the entire enclosed area (greenhouse) during the application.

- prohibiting anyone (except those who are entering to turn on ventilation equipment and who are wearing the PPE required for applicators) from entering the greenhouse after application is complete until specific ventilation criteria have been met (e.g. 2 hours of mechanical ventilation, 4 hours of passive ventilation, etc.).

Occupational Use Products (Non-WPS Uses)

To EPA's knowledge, at this time some registered uses of fenitrothion are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency is establishing entry restrictions for all nonWPS occupational uses of fenitrothion end-use products. For specific language refer to Section V of this document.

Homeowner Use Products (nonWPS Uses)

Only the ant and roach bait formulations are intended primarily for homeowner use.

Additional Labeling Requirements

The Agency is requiring additional labeling statements to be located on all end-use products containing fenitrothion that are primarily for occupational use. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products. In addition, the technical registrant must submit a food additive petition changing the food additive regulation for fenitrothion as indicated in Section IV.B.1, Tolerance Reassessment.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of fenitrothion for the above eligible uses (ornamentals in nurseries and greenhouses only) has been reviewed and determined to be substantially complete. However, additional confirmatory data are needed to fulfill guideline requirements for the studies listed below:

71-1	Acute Oral LD50 for Bobwhite Quail with the major degradate: 3-methyl-nitrophenol.
71-4	Chronic Toxicity to Birds with the major degradate: 3-methyl-nitrophenol. (reserved pending results of 71-1 studies).
85-4-SS	Six Month Ocular Toxicity Study in Dogs (Reserved)
164-1	Terrestrial Field Dissipation

The following data are required before the Agency can make a regulatory decision regarding reregistration eligibility for the low-pressure handwand and knapsack/backpack methods of application:

132-1(a)	Foliar Dissipation
133-3	Occupational Postapplication Dermal Exposure
133-4	Occupational Postapplication Inhalation Exposure
231	Estimation of Dermal Exposure at Outdoor Sites
232	Estimation of Inhalation Exposure at Outdoor Sites
233	Estimation of Dermal Exposure at Indoor Sites
234	Estimation of Inhalation Exposure at Indoor Sites

These data are considered confirmatory for the high-pressure handwand method of application.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into a insecticide for the following uses(s): ornamental use in greenhouses, nurseries and for use in ant and roach baits."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "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 the support of such uses(s)."

(b) "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 the support of such uses(s).

Other current label precautions are still applicable and are required for product reregistration if the product is to remain in compliance with FIFRA.

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. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

a. Restricted Use Classification

The Agency has determined that all fenitrothion products labeled for use outdoors must be restricted-use based on acute, subchronic, and chronic effects to humans and/or non-target species. The following statement must appear on all end-use products:

Restricted Use Pesticide

"This is a restricted use product due to toxicity to fish and aquatic organisms."

"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."

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10.

b. Changes Relating to Label Rates, Uses and Number of Applications

The following changes must be made to all fenitrothion end-use ornamental products.

1) Restricted use classification for all fenitrothion end-use products labeled for outdoor use.

2) Deletion of Christmas tree farm and Southern Pine Bark Beetle uses.

3) Deletion of broadcast application from the label; all ornamental uses will be restricted to spot treatments.

4) The use rate must be limited to 0.3125 lbs ai/acre and the maximum number of applications per year must be limited to three.

5) The minimum interval between applications must be increased to one month.

6) The use on shade trees must be limited to those in nurseries and/or greenhouses.

7) Application is limited to high-pressure handwands, low-pressure handwands, and knapsack/backpack sprayers.

c. Occupational/Residential Labeling

(1) Personal Protective Equipment Requirements for Pesticide Handlers (mixers, loaders, applicators, etc);

Sole-active-ingredient end-use products that contain fenitrothion must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

- **Handler PPE for Occupational-Use Products** (products NOT intended primarily for home use -- (see tests in PR Notice 93-7 and 93-11):

Minimum (Baseline) Personal Protective Equipment Requirements:

Some of the registered uses of fenitrothion are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some are outside the scope of the WPS. The minimum (baseline) PPE requirements pertain to both the WPS and nonWPS uses by occupational handlers, since the potential exposure to occupational handlers is similar for WPS and nonWPS uses.

"Applicators and other handlers must wear:

--Coveralls over long-sleeved shirt and long pants
--Chemical-resistant gloves (see instructions * below)
--Chemical-resistant footwear plus socks
--Chemical-resistant headgear for overhead exposure
--Chemical-resistant apron when cleaning equipment, mixing, or loading" (see instructions ** below)
--Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)

* The glove statement for fenitrothion is the statement established through the instructions in Supplement Three of PR Notice 93-7.
** The words "mixing, or loading" may be removed if the product is formulated as "ready-to-use."

Actual End-Use Product Personal Protective Equipment Requirements: The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum (baseline) personal protective equipment, if any, specified above. The more protective PPE requirements must

be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling: The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

(2) Entry Restrictions; Labeling

Sole-active-ingredient end-use products that contain fenitrothion must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

- **Occupational-Use Products (Products NOT Intended Primarily For Home Use):**

--Uses Within the Scope of the WPS

Restricted-Entry Interval: A restricted entry interval (REI) is required for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products (see tests in PR Notices 93-7 and 93-11). This REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The Agency is requiring the following entryrestrictions for all uses of fenitrothion within the scope of the Worker Protection Standard:

"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. Each 48-hour REI is increased to 72 hours in outdoor areas where the average rainfall is less than 25 inches per year."

Early-Entry Personal Protective Equipment (PPE):

There are special risk concerns about fenitrothion since it a toxicological endpoint of concern for systemic toxicity and the MOE's for handlers were marginal. The PPE required for early entry following applications of the fenitrothion is:

--coveralls over long-sleeve shirt and long pants,
--chemical-resistant gloves,
--chemical-resistant footwear plus socks,
--chemical-resistant headgear for overhead exposures, and
--protective eyewear.

User Safety Statements:

The Agency is requiring the following user safety statements to be located on end-use products containing fenitrothion:

User Safety Requirements:

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations:

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

d. Environmental Hazard

The following statement is required for end-use products:

ENVIRONMENTAL HAZARD

"This pesticide is toxic to birds and aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this 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 registrants may distribute and sell fenitrothion products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
NON-FOOD/NON-FEED												
BATHROOM PREMISES/HARD SURFACES				Use Group: INDOOR RESIDENTIAL								
Bait application., When needed., By hand.	B/S	NA		UC	*	NS	NS	NS	NS	AN	NS	CAS
COMMERCIAL STORAGES/WAREHOUSES PREMISES (INDOOR)				Use Group: INDOOR NON-FOOD								
Bait application., When needed., By hand.	B/S	NA		UC	*	NS	NS	NS	NS	AN	NS	CAS
COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIP. (INDOOR)				Use Group: INDOOR NON-FOOD								
Bait application., When needed., By hand.	B/S	NA		UC	*	NS	NS	NS	NS	AN	NS	CAS
COMMERCIAL/INSTITUTIONAL/INDUSTRIAL PREMISES/EQUIPMENT (OUTDOOR)				Use Group: TERRESTRIAL NON-FOOD CROP								
Bait application., When needed., By hand.	B/S	NA		UC	*	NS	NS	NS	NS	AN	NS	CAS
HOUSEHOLD/DOMESTIC DWELLINGS				Use Group: INDOOR RESIDENTIAL								
Bait application., When needed., By hand.	B/S	NA		UC	*	NS	NS	NS	NS	AN	NS	CAS
HOUSEHOLD/DOMESTIC DWELLINGS INDOOR PREMISES				Use Group: INDOOR RESIDENTIAL								
Bait application., When needed., By hand.	B/S	NA		UC	*	NS	NS	NS	NS	AN	NS	CAS
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES				Use Group: OUTDOOR RESIDENTIAL								
Bait application., When needed., By hand.	B/S	NA		UC	*	NS	NS	NS	NS	AN	NS	CAS
ORNAMENTAL AND/OR SHADE TREES				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL								
Bark treatment., Foliar., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	90	1	C93, C94, CAL
				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP								
Basal bark treatment., When needed., Hand held sprayer.	EC	NA		UC	*	NS	NS	NS	NS	90	1	C46
Basal bark treatment., When needed., Power sprayer.	EC	NA		UC	*	NS	NS	NS	NS	90	1	C46
Broadcast., Foliar., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1	C46

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
ORNAMENTAL AND/OR SHADE TREES (con't)				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP (con't)									
	EC	NA		UC	*	NS	NS	NS	NS	7	1		C93, C94, CAL
Broadcast., Nurserystock., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
	EC	NA		UC	*	NS	NS	NS	NS	7	1		C93, C94, CAL
Spot treatment., Foliar., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
	EC	NA		UC	*	NS	NS	NS	NS	7	1		C93, C94, CAL
Spot treatment., Nurserystock., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
	EC	NA		UC	*	NS	NS	NS	NS	7	1		C93, C94, CAL
ORNAMENTAL HERBACEOUS PLANTS				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
Broadcast., Foliar., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
	EC	NA		UC	*	NS	NS	NS	NS	7	1		C93, C94, CAL
Broadcast., Nurserystock., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
	EC	NA		UC	*	NS	NS	NS	NS	7	1		C93, C94, CAL
Spot treatment., Foliar., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
	EC	NA		UC	*	NS	NS	NS	NS	7	1		C93, C94, CAL
Spot treatment., Nurserystock., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
	EC	NA		UC	*	NS	NS	NS	NS	7	1		C93, C94, CAL
ORNAMENTAL NONFLOWERING PLANTS				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
Broadcast., Foliar., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
Broadcast., Nurserystock., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
Spot treatment., Foliar., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
Spot treatment., Nurserystock., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
Broadcast., Foliar., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	1		C46

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	@ Max. Rate Max. # Apps /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
ORNAMENTAL WOODY SHRUBS AND VINES (con't)				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP (con't)							
	EC	NA		UC	* NS NS	NS NS	7	1			C93, C94, CAL
Broadcast., Nurserystock., Sprayer.	EC	NA		UC	* NS NS	NS NS	7	1			C46
	EC	NA		UC	* NS NS	NS NS	7	1			C93, C94, CAL
Spot treatment., Foliar., Sprayer.	EC	NA		UC	* NS NS	NS NS	7	1			C46
	EC	NA		UC	* NS NS	NS NS	7	1			C93, C94, CAL
Spot treatment., Nurserystock., Sprayer.	EC	NA		UC	* NS NS	NS NS	7	1			C46
	EC	NA		UC	* NS NS	NS NS	7	1			C93, C94, CAL
NOT SPECIFIED											
EATING ESTABLISHMENTS				Use Group: INDOOR FOOD+INDOOR NON-FOOD							
Bait application., When needed., By hand.	B/S	NA		UC	* NS NS	NS NS	AN	NS			CAS

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LEGEND
444444

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Microbial claims only.

Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.

Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).

Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"

Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.

Min. Interv (days) : Minimum Interval between Applications (days)

Restr. Entry Interv (days) : Restricted Entry Interval (days)

PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

- * : Non-specific
- C : Coarse
- M : Medium
- F : Fine
- O : Others

FORMULATION CODES

- B/S : BAIT/SOLID
- EC : EMULSIFIABLE CONCENTRATE
- WP : WETTABLE POWDER

ABBREVIATIONS

- AN : As Needed
- NA : Not Applicable
- NS : Not Specified (on label)
- UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

- DCNC : Dosage Can Not be Calculated
- No Calc : No Calculation can be made
- W : PPM calculated by weight
- V : PPM Calculated by volume
- U : Unknown whether PPM is given by weight or by volume
- cwt : Hundred Weight
- nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

- C46 : Do not apply through any type of irrigation system.
- C93 : Do not apply directly to water.
- C94 : Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.
- CAG : Do not apply where runoff is likely to occur.
- CAL : Do not contaminate water, food or feed.
- CAS : Do not contaminate food or feed.

* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

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

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Fenitrothion covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Fenitrothion in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

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

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Fenitrothion

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	40124301, letter dated 11/17/92, 42815801, ltr with CSF dated 10/19/93
61-2A	**Start. Mat. & Mnfg. Process**	All	00150221, 00128047, 41423201, 41679401
61-2B	**Formation of Impurities**	All	00150221, 40124301
62-1	**Preliminary Analysis**	All	00150221, 40124302, letter dated 11/17/92
62-2	**Certification of limits**	All	40124302, 42815801, ltr dated 10/19/93
62-3	**Analytical Method**	All	00150221, 00126960, 00128033, 00079252, 41621701, letter dated 11/17/92
63-2	**Color**	All	00150221, 00163504
63-3	**Physical State**	All	00150221, 00163504
63-4	**Odor**	All	00150221, 00163504
63-5	**Melting Point**	All	00163504
63-6	**Boiling Point**	All	00150221, 00126960, 00163504
63-7	**Density**	All	00150221, 00163504
63-8	**Solubility**	All	00126960, 00150221, 00163504
63-9	**Vapor Pressure**	All	00163504
63-10	**Dissociation Constant**	All	00163504
63-11	**Octanol/Water Partition**	All	00163504
63-12	**pH**	All	00163504

REQUIREMENT		USE PATTERN	CITATION(S)
63-13	**Stability**	All	00088340, 00126960, 00150221, 00163504
63-14	**Oxidizing/Reducing Action**	All	40124303
63-15	**Flammability**	All	00163504
63-16	**Explodability**	All	40124303
63-17	**Storage stability**	All	00163504
63-18	**Viscosity**	All	42632301
63-19	**Miscibility**	All	40124303
63-20	**Corrosion characteristics**	All	00163504, 42632401
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	C	00126885
71-1B	**Acute Avian Oral - Quail/ (Degradate)**	C	DATA GAP
71-2A	**Avian Dietary - Quail**	C	00022923
71-2B	**Avian Dietary - Duck**	C	00022923
71-4A	**Avian Reproduction - Quail**	C	41958401
71-4A	**Avian Reproduction - Quail (Degradate)**	C	Reserved - Pending results of 74-1 studies
71-4B	**Avian Reproduction - Duck**	C	41243502 (Partially fulfilled)
72-1A	**Fish Toxicity Bluegill**	C	40094602

Data Supporting Guideline Requirements for the Reregistration of Fenitrothion

REQUIREMENT		USE PATTERN	CITATION(S)
72-1B	**Fish Toxicity Bluegill - (Degradates)**	N/A	N/A
72-1C	**Fish Toxicity Rainbow Trout**	C	40094602
72-1D	**Fish Toxicity Rainbow Trout - (Degradate)**	N/A	N/A
72-2A	**Invertebrate Toxicity**	C	00120401
72-2B	**Invertebrate Toxicity - Daphnia Magna (Degradate)**	C	Data Gap
72-3A	**Estuarine/Marine Toxicity - Fish**	C	40228401
72-3B	**Estuarine/Marine Toxicity - Mollusk**	C	40228401
72-3C	**Estuarine/Marine Toxicity - Shrimp**	C	40228401
72-3D	**Estuarine/Marine Toxicity Fish - (Degradate)**	N/A	N/A [1]
72-3E	**Estuarine/Marine Toxicity Mollusk - (Degradate)**	N/A	N/A [2]
72-3F	**Estuarine/Marine Toxicity Shrimp - (Degradate)**	N/A	N/A [3]
72-4A	**Early Life Stage Fish**	C	40891201
72-4B	**Life Cycle Invertebrate**	C	40891101
72-5	**Life Cycle Fish**	N/A	N/A
72-6	**Aquatic Organism Accumulation**	N/A	N/A

REQUIREMENT		USE PATTERN	CITATION(S)
72-7A	**Simulated Field - Aquatic Organisms**	N/A	N/A
72-7B	**Actual Field - Aquatic Organisms**	N/A	N/A
141-1	**Honey Bee Acute Contact**	C	05001991
141-2	**Honey Bee Residue on Foliage**	C	00126931
141-5	**Field Test for Pollinators**	N/A	N/A
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	All	**00061091**
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	All	**00071960**
81-3	**Acute Inhalation Toxicity - Rat**	All	**DATA GAP**
81-4	**Primary Eye Irritation - Rabbit**	All	**00127970**
81-5	**Primary Dermal Irritation - Rabbit**	All	**00062976, 00105950**
81-6	**Dermal Sensitization - Guinea Pig**	All	**00069955**
81-7	**Acute Delayed Neurotoxicity - Hen**	All	**00069955**
82-1A	**90-Day Feeding - Rodent**	L	**00071965**
82-1B	**90-Day Feeding - Non-rodent**	L	**00143017**
82-2	**21-Day Dermal - Rabbit/Rat**	I	**42058301**
82-3	**90-Day Dermal - Rodent**	N/A	**N/A**
82-4	**90-Day Inhalation - Rat**	I	**40891001**
82-5A	**90-Day Neurotoxicity - Hen**	N/A	**N/A**
82-5B	**90-Day Neurotoxicity - Mammal**	All	**00069955**

Data Supporting Guideline Requirements for the Reregistration of Fenitrothion

REQUIREMENT		USE PATTERN	CITATION(S)
83-1A	**Chronic Feeding Toxicity - Rodent**	All	**00143017, 40420501**
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	L	**40420501**
83-2A	**Oncogenicity - Rat**	L	**00071965**
83-2B	**Oncogenicity - Mouse**	L	**41925201, 42507701, 42507702, 42507703, 42507704**
83-3A	**Developmental Toxicity - Rat**	L	**40604002**
83-3B	**Developmental Toxicity - Rabbit**	L	**00162548, 40430601**
83-4	**2-Generation Reproduction - Rat**	L	**41689001, 42668801**
84-2A	**Gene Mutation (Ames Test)**	L	**00163432**
84-2B	**Structural Chromosomal Aberration**	L	**40789201**
84-4	**Other Genotoxic Effects**	L	**40789202**
85-1	**General Metabolism**	L	**00069960, 40408906**
85-2	**Dermal Penetration**	N/A	**N/A**
86-1	**Domestic Animal Safety**	N/A	**N/A**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	C	**DATA GAP**
132-1B	**Soil Residue Dissipation**	N/A	**N/A**
133-3	**Dermal Passive Dosimetry Exposure**	C,I	**DATA GAP**
133-4	**Inhalation Passive Dosimetry Exposure**	C,I	**DATA GAP**

REQUIREMENT		USE PATTERN	CITATION(S)
231	**Estimation of Dermal Exposure at Outdoor Sites**	C,I	**DATA GAP**
232	**Estimation of Inhalation Exposure at Outdoor Sites**	C,I	**DATA GAP**
233	**Estimation of Dermal Exposure at Indoor Sites**	C,I	**DATA GAP**
234	**Estimation of Inhalation Exposure at Indoor Sites**	C,I	**DATA GAP**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	C	00090500, 40717901
161-2	**Photodegradation - Water**	C	00061839, 00088273, 00159952, 00159953
161-3	**Photodegradation - Soil**	C	00088273, 40865501
161-4	**Photodegradation - Air**	N/A	WAIVED
162-1	**Aerobic Soil Metabolism**	C	00126945, 00159950 00061842, 41295101
162-2	**Anaerobic Soil Metabolism**	N/A	N/A
162-3	**Anaerobic Aquatic Metabolism**	C	00061842, 00159949 00159950, 41615701
162-4	**Aerobic Aquatic Metabolism**	N/A	N/A
163-1	**Leaching/Adsorption/Desorption**	C	00061842, 00126947, 00159951, 00159956, 40420502
163-2	**Volatility - Lab**	C	41148902

Data Supporting Guideline Requirements for the Reregistration of Fenitrothion

REQUIREMENT		USE PATTERN	CITATION(S)
163-3	**Volatility - Field**	N/A	N/A
164-1	**Terrestrial Field Dissipation**	C	DATA GAP
164-2	**Aquatic Field Dissipation**	N/A	N/A
164-3	**Forest Field Dissipation**	N/A	N/A
164-5	**Long Term Soil Dissipation**	N/A	N/A
165-1	**Confined Rotational Crop**	N/A	N/A
165-2	**Field Rotational Crop**	N/A	N/A
165-3	**Accumulation - Irrigated Crop**	N/A	N/A
165-4	**Bioaccumulation in Fish**	C	40847001, 41654001
165-5	**Bioaccumulation - Aquatic NonTarget**	N/A	N/A
166-1	**Ground Water - Small Prospective**	N/A	N/A
166-2	**Ground Water - Small Retrospective**	N/A	N/A
166-3	**Ground Water - Irrigated Retrospective**	N/A	N/A
201-1	**Droplet Size Spectrum**	N/A	N/A
202-1	**Drift Field Evaluation**	N/A	N/A
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	L [4]	00069962, 00069963, 00113146
171-4B	**Nature of Residue - Livestock**	N/A	N/A

Data Supporting Guideline Requirements for the Reregistration of Fenitrothion

REQUIREMENT		USE PATTERN	CITATION(S)
171-4C	**Residue Analytical Method - Plants**	L	00062928, 00113146, 00135034, 41468701, 41000801, 41679402
171-4D	**Residue Analytical Method - Animal**	N/A	N/A
171-4E	**Storage Stability**	L	00150219, 00150223, 41468701, 41000802
171-4F	**Magnitude of Residues - Potable H2O**	N/A	N/A
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	N/A	N/A
171-4K	**Crop Field Trials**	N/A	N/A
171-4L	**Processed Food Wheat gluten**	L	00113146, 00150224, FAO/WHO(1974), FAO/WHO(1979), 41468701, ltr dated 11/17/92
171-5	**Reduction of Residues**	N/A	N/A

1 - This study is not required provided the registrants revised all ornamental labels to restrict uses on shade trees to only those in nurseries.

2 - This study is not required provided the registrants revised all ornamental labels restrict uses on shade trees to only those in nurseries.

3 - This study is not required provided the registrants revised all ornamental labels restrict uses on shade trees to only those in nurseries.

4 - Fenitrothion is not registered for use on food or feed commodities in the United States. Data were required to support the tolerance for wheat gluten imported into this country.

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Fenitrothion

GUIDE TO APPENDIX C

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.

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION

00022923 Lethal Dietary Toxicities of Environmental Pollutants to Birds (1975). U.S. Fish and Wildlife Service, Special Scientific Report--Wildlife No. 191. Patuxent Wildlife research Center; Laurel, MD.

00061091 Miyamoto, J.; Kadota, T. (1972) Toxicological Studies with Sumithion. (Unpublished study received on unknown date under unknown admin. no.; submitted by Sumitomo Chemical Co., Ltd., Baltimore, Md.; CDL:127719-B)

00061839 Ohkawa, H.; Mikami, N.; Miyamoto, J. (1974) Photodecomposition of Sumithion. Agricultural and Biological Chemistry 38(11): 2247-2255. (Also in unpublished submission received Mar 19, 1976 under 10308-2; submitted by Sumitomo Chemical Co., Ltd., Baltimore, Md.; CDL:227775-F)

00061842 Takimoto, Y.; Hirota, M.; Inui, H.; et al. (1975) Decomposition and Leaching of Radioactive Sumithion in 4 Different Types of Soil under Laboratory Conditions. (Unpublished study received Mar 19, 1976 under 10308-2; prepared by Sumitomo Chemical Co., Ltd., Japan, submitted by Sumitomo Chemical Co., Ltd., Baltimore, Md.; CDL:227775-I)

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42815800	Sumitomo Chemical America, Inc. (1993) Submission of product chemistry data in response to EPA's review of Sumithion Technical CSF. Transmittal of 1 study.
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APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Fenitrothion. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for Fenitrothion and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Fenitrothion RED Fact Sheet (included in Appendix G)

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 86-5

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the

entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an

application for an EUP should be subdivided into sections A, B, C,... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).
- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product

produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI

claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit

disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

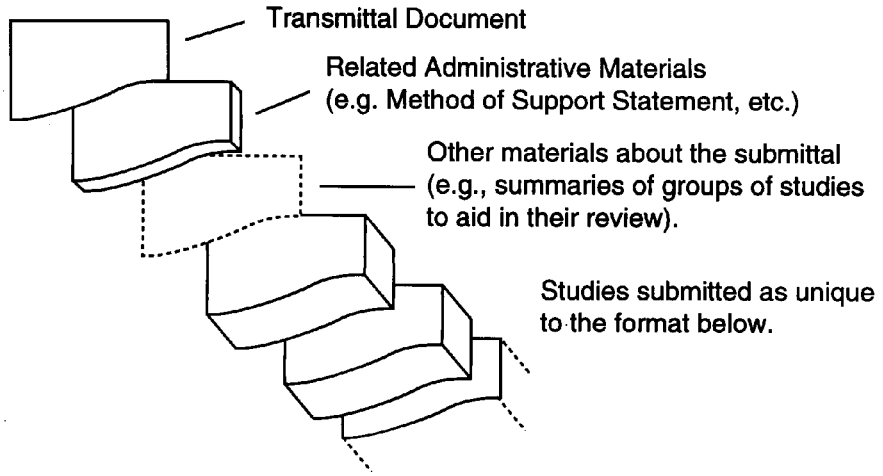
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

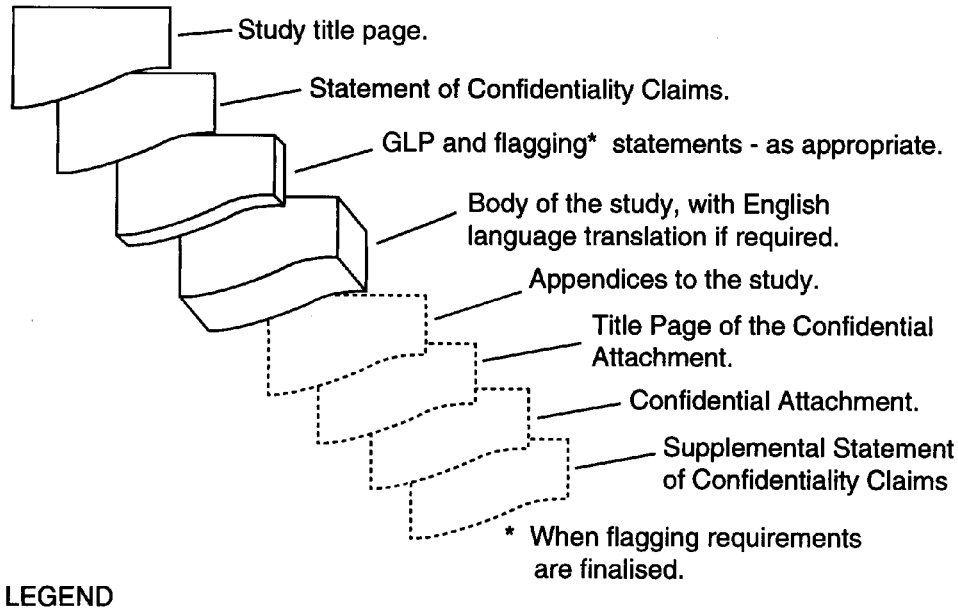
Submitter_____

ATTACHMENT 7.

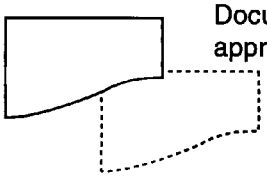
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual

product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Combined Generic and Product Specific Data Call-In

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC
DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You are Receiving this Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and

Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's

Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data

requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each

registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly Met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 'Raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submitting the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according

to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements

described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five

years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you

will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   i. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

   unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received <u>after</u> the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, <u>unless</u> you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. <u>REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS</u>

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. <u>INQUIRIES AND RESPONSES TO THIS NOTICE</u>

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the <u>Data Call-In Chemical Status Sheet</u>.

All responses to this Notice must include completed <u>Data Call-In Response Forms</u> (Attachment 2)and completed <u>Requirements Status and Registrant's Response Forms</u> (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary

cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

/s/

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

Attachment 1. Chemical Status Sheets

Fenitrothion DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Fenitrothion.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Fenitrothion. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Fenitrothion Generic Data CallIn (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Fenitrothion are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Fenitrothion are needed. These data are needed to fully complete the reregistration of all eligible Fenitrothion products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Dennis McNeilly at (703) 308-8066.

All responses to this Notice for the generic data requirements should be submitted to:

Dennis McNeilly, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Fenitrothion

FENITROTHION DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Fenitrothion.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Fenitrothion. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Fenitrothion Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Fenitrothion are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Fenitrothion are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Fenitrothion products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Fenitrothion, please contact Dennis McNeilly at (703) 308-8066.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Moana Appleyard at (703) 308-8175.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Moana Appleyard
Chemical Review Manager
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Fenitrothion**

Attachment 2. Combined Generic and Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form**. **BOTH** "Data Call-In Response" forms must be completed.

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1.**ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2.**ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3.**ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4.**ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5.**ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b.**ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data

Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a.**ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agrèe to satisfy the data requirements by responding "yes."

Item 7b.For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 8.**ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9.**ON BOTH FORMS:** Enter the date of signature.

Item 10.**ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11.**ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 3. Generic and Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

Instructions For Completing
The
"Requirements Status and Registrant's Response Forms"
For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"
Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific

requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

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

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for

acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use

data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low-volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF FENITROTHION PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2),

Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Six products were found which contain fenitrothion as the active ingredient. The products have been placed into two batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in each batch. Table 2 lists the products which have been placed in the "no batch" category.

Table 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	506-174	Fenitrothion 0.015	Solid
	506-175	Fenitrothion 1.0	Solid
2	2217-715	Fenitrothion 76.8	Liq
	39398-13	Fenitrothion 73.06	Liq

The following table lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. Registrants of these products are responsible for meeting the acute toxicity data requirements separately for each product.

Table 2 (No Batch)

EPA Reg. No.	% Active Ingredient	Formulation Type
39398-4	Fenitrothion 95.0	Liq
2217-714	Fenitrothion 45.0	Liq

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at > 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at < 0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 0.1%.
2.____ Degree of accountability or closure > ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at > 0.1% and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*_____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*_____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C (+2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of < 2 or > 11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share Data Compensation Forms, Confidential Statement of Formula Form and Instructions

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
2070-0057
Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved OMB No. 2070-0107, 2070-0057 Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-017 July 1995

R.E.D. FACTS

Fenitrothion

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0445, fenitrothion.

Use Profile

Fenitrothion is an organophosphate insecticide and acaricide used for commercial greenhouse and outdoor use on ornamentals, including trees, to control a variety of insects and mites. Fenitrothion also is marketed in two new bait products used to control ants and roaches in and around homes, stores, restaurants, warehouses, and other sites. Two mosquito control products used in other countries (not in the U.S.) to prevent malaria are being voluntarily cancelled by the manufacturer. No food or feed uses are registered, however a food additive regulation is established for residues of fenitrothion in or on wheat gluten imported from Australia.

Fenitrothion is applied to ornamentals using ground-based and hand-held equipment. Annual usage on ornamentals is small and appears to be decreasing. Fenitrothion formulations include a wettable powder, emulsifiable concentrate, and bait.

Regulatory History

Fenitrothion was first registered as a pesticide in the U.S. in 1975, for control of the spruce budworm in forests. EPA issued a Data Call-In (DCI) in 1984 requiring additional chronic toxicity data, and a Registration Standard in July 1987 (PB88-191697) which evaluated the studies submitted in response to the DCI. Certain label restrictions were necessary including

a 24-hour interim reentry interval for greenhouse and nursery ornamental uses, and restricted-use classification for the forestry uses. EPA issued a second DCI in June 1991, and required labeling to reflect the high toxicity to birds, honeybees, and aquatic invertebrates. Precautions were imposed to protect endangered species. The registrant requested cancellation of the forestry uses in 1992.

Through implementation of the labeling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides (WPS), the 24-hour interim reentry interval was converted to a 24-hour interim restricted entry interval. Uses within the scope of the WPS include all commercial and research uses of fenitrothion to produce agricultural plants, including use on ornamentals. Fenitrothion ant and roach bait products, registered in January 1995, fall outside the scope of the WPS.

The Agency currently is requiring additional exposure data for fenitrothion before it can make a regulatory decision on the eligibility of low pressure handwand and knapsack/backpack methods of application. Six fenitrothion products are eligible for reregistration.

Human Health Assessment

Toxicity

In studies using laboratory animals, fenitrothion generally has been shown to be of moderate to high acute toxicity. It is moderately toxic by the acute oral and dermal routes and has been placed in Toxicity Category II (the second highest of four categories) for this effect. It is slightly toxic for acute eye effects and is a mild dermal irritant (Toxicity Category III). Fenitrothion is not a skin sensitizer.

Fenitrothion is classified as a Group E carcinogen, indicating that it is non-carcinogenic to humans. It is a cholinesterase inhibitor as indicated in several chronic and subchronic toxicity tests performed on laboratory animals.

Studies indicate that fenitrothion does not cause reproductive effects. Fenitrothion is not considered to be a mammalian mutagen. Metabolism studies indicate that fenitrothion is excreted in the urine and feces within seven days of exposure.

A rat study did not indicate ocular toxicity. A six-month ocular study on dogs, required by the 1991 DCI, is in reserve status until a test protocol is developed.

Dietary Exposure

Although no food uses currently are registered, people may be exposed to residues of fenitrothion through the diet. A food additive regulation for fenitrothion and two of its metabolites has been established (40 CFR 185.2200(a)) for residues in wheat gluten resulting from postharvest application of the insecticide to stored wheat in Australia. An acute risk to the U.S. population from consumption of Australian wheat gluten is unlikely because gluten is mixed with flour before it is eaten.

Since fenitrothion is not registered for use on any domestic crops, its residues are not expected to enter the diet of food animals in the U.S..

EPA developed a U.S. consumption estimate for Australian wheat gluten, and assessed dietary exposure and risk posed by fenitrothion residues in that commodity. For the overall U.S. population, such exposure represents 3% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The exposure level of the most highly exposed subgroup, children aged 1 through 6, represents 8% of the RfD. If the food additive regulation of 30 ppm is used instead of EPA's consumption estimate, these exposure and risk estimates are doubled to 7% of the RfD for the overall U.S. population and 15% of the RfD for children aged 1 through 6. Dietary exposure and risk are minimal.

Occupational and Residential Exposure

Based on current use patterns, fenitrothion handlers (mixers, loaders, and applicators) may be exposed to this pesticide during and after normal use. Exposure to fenitrothion is most likely to occur during and after its application to ornamentals, either outdoors or in greenhouses. The primary route of occupational exposure is dermal. Inhalation exposure may be acute, intermittent, or chronic.

Although most of the exposure data available were questionable, EPA assessed worker exposure and risk to fenitrothion using the toxicological endpoints dermal toxicity resulting from intermediate exposure, and inhalation toxicity resulting from chronic exposure, both of which may result in cholinesterase inhibition. Exposure estimates are based on the assumption that fenitrothion handlers wear certain personal protective equipment. Margins of Exposure (MOEs) are less than 100 (the margin believed sufficiently protective) for applicators using low pressure handwands and for mixer/loader/applicators using low-pressure or knapsack/backpack equipment. Due to a lack of post-application exposure data, EPA was unable to estimate exposure or risk to workers following use of fenitrothion on ornamentals.

Because they are formulated as enclosed baits, the two fenitrothion ant and roach control products approved in early 1995 for residential use result in considerably less human exposure than the ornamental uses, during and after application.

Human Risk Assessment

Based on the available toxicity studies, EPA has determined that fenitrothion presents a potential acute health hazard. It is of moderate to high acute toxicity and is a cholinesterase inhibitor. However, it has been classified as non-carcinogenic to humans ("Group E"). Dietary exposure to fenitrothion residues in wheat gluten is extremely low, and dietary risk appears to be minimal.

Of greater concern is the risk posed to fenitrothion handlers, particularly mixers/loaders/applicators using low pressure handwands or knapsack/backpack equipment to treat ornamentals. The MOEs for these handlers are inadequate. EPA is deferring a regulatory decision for fenitrothion products applied using these methods until chemical-specific worker exposure studies, due within one year, are submitted. Thus, for ornamentals, high pressure handwand treatment is the only application method eligible for reregistration at this time.

EPA is employing a number of risk mitigation measures to protect fenitrothion handlers. For example, the Agency is requiring "baseline" personal protective equipment (PPE); a 48-hour restricted-entry interval (REI) which is more stringent than the (24-hour) interim REI set by the Worker Protection Standard for Agricultural Pesticides (WPS); and upgraded PPE for early entry. The 48-hour REI is increased to 72 hours when any fenitrothion product is used in an outdoor area where the average rainfall is less than 25 inches per year. (See RED Risk Mitigation and Labeling sections for more details.)

Environmental Assessment

Environmental Fate Assessment

Fenitrothion's major routes of dissipation are biotic microbial mediated processes to carbon dioxide and abiotic aquatic photolysis. Fenitrothion appears to be non-mobile when applied to silty clay loam, silty clay, and sandy loam soils. It appears to dissipate fairly rapidly with a half life of 3 to 25 days, and does not appear to be mobile. Fenitrothion is expected to be slightly persistent and relatively non-mobile in the soil environment. Its metabolites also appear to degrade fairly rapidly to carbon dioxide, and are relatively non-mobile. Residues do not leach below 0-12 inches soil depth.

Ecological Effects

Fenitrothion is highly toxic to birds on an acute basis, and causes chronic effects (reduced egg production) in reproduction studies using bobwhite quail. It is moderately toxic to small mammals and both cold and warm water fish on an acute basis. However, it is highly toxic to aquatic invertebrates, and moderately to very highly toxic to estuarine organisms. It also is highly toxic to bees.

Ecological Effects Risk Assessment

High acute risk is expected for birds consuming grass and insects, and high chronic risk to seed-, insect-, and grass-eating birds will occur, following single as well as multiple applications of fenitrothion at 3 lbs. active ingredient (ai)/acre. Risk quotients for mammals and estuarine/ marine organisms are exceeded. High acute risk to freshwater invertebrates is expected from a single application of fenitrothion. Honey bees exposed to this pesticide may be adversely effected.

To reduce these risks, the registrant has proposed numerous label modifications for products used on ornamentals including a lower use rate, a restriction on the maximum number of applications per year, and an increase in the retreatment interval from one week to one month. (See Risk Mitigation, below.)

Endangered species levels of concern (LOCs) are exceeded for acute effects to aquatic invertebrates and in some instances to birds and wild mammals, as well as for chronic effects to birds and aquatic invertebrates. Limitations on the use of fenitrothion may be required in the future to protect threatened and endangered species when the Endangered Species Protection Program goes into effect.

Risk Mitigation

To lessen the acute toxicity risks of fenitrothion, EPA, in conjunction with the registrant, has developed and is requiring the following risk mitigation measures.

- All fenitrothion products labeled for outdoor use must be classified as restricted use pesticides.
- Use of fenitrothion on Christmas tree plantations, on shade trees other than those in nurseries, and basal bark (drench) treatment are being voluntarily deleted from product labels by the registrant. These uses pose the greatest potential for exposure to non-target species.
- For the remaining ornamental uses, the registrant has proposed significant label revisions to reduce ecological risk, including:
  - Reduce application rate to 0.3125 lbs./acre;
  - Reduce maximum number of applications to three per year;
  - Increase minimum interval between applications to one month;
  - Remove broadcast application from the label, limiting use to spot treatment only.
- Due to concerns about the high acute toxicity of fenitrothion, EPA is establishing baseline personal protective equipment (PPE) requirements for handlers of all end-use products, and is establishing early-entry PPE requirements including dermal protection PPE and protective eyewear.
- Due to concerns about the post-application exposure of agricultural workers, EPA is increasing the interim Restricted Entry Interval (REI) from 24 to 48 hours for all uses within the scope of the WPS. This REI is further increased to 72 hours when fenitrothion products are used outdoors in areas where the average rainfall is less than 25 inches per year. The REI will be reassessed upon receipt and review of the chemical specific exposure data required in the RED.

Additional Data Required

EPA is requiring the following additional generic studies for fenitrothion to confirm its regulatory assessments and conclusions:

- Acute oral LD50 for Bobwhite Quail (3-methyl-nitrophenol);
- Terrestrial Field Dissipation;
- Chronic Toxicity to Birds (**reserved**);
- Six Month Ocular Toxicity Study in Dogs (**reserved**).

Before EPA can make a reregistration eligibility decision regarding the low pressure handwand and knapsack/backpack methods of application, the following studies must be submitted:

- Foliar Dissipation;
- Occupational Post-application Dermal Exposure;
- Occupational Post-application Inhalation Exposure;
- Estimation of Dermal Exposure at Outdoor Sites;
- Estimation of Inhalation Exposure at Outdoor Sites;
- Estimation of Dermal Exposure at Indoor Sites;
- Estimation of Inhalation Exposure at Indoor Sites.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All fenitrothion end-use products must comply with EPA's current pesticide product labeling requirements, and with the following. For a comprehensive list of labeling requirements, please see the fenitrothion RED document.

Restricted Use Classification

All fenitrothion products labeled for outdoor use must be classified for restricted use, and the following statement must appear on product labels:

"Restricted Use Pesticide

Due to toxicity to fish and aquatic organisms.

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."

Changes in Rates, Uses, and Number of Applications

The following changes must be made to all ornamental end-use products:

- Restricted use classification;
- Delete Christmas tree farm and Southern Pine Bark Beetle uses;
- Delete broadcast application--all ornamental uses are limited to spot treatments;
- Limit use rate to 0.3125 lbs ai/acre and limit the maximum number of applications per year to three;
- Increase the minimum interval between applications to one month;

- Limit use on shade trees to those in nurseries and/or greenhouses;

- Limit application to high pressure handwands, low pressure handwands, and knapsack/backpack sprayers. .

Personal Protective Equipment (PPE) Requirements

The following minimum, baseline PPE requirements pertain to both WPS and nonWPS uses by occupational handlers:

"Applicators must wear:

- Coveralls over long-sleeved shirt and long pants;

- Chemical-resistant gloves;

- Chemical-resistant footwear plus socks;

- Chemical-resistant headgear for overhead exposure;

- Chemical-resistant apron when cleaning equipment, mixing, or loading;

- Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

Entry Restrictions

EPA is requiring the following entry restrictions for all uses within the scope of the WPS:

"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. Each 48-hour REI is increased to 72 hours in outdoor areas where the average rainfall is less than 25 inches per year."

The PPE required for early entry following applications of fenitrothion is:

- Coveralls over long-sleeved shirt and long pants;

- Chemical-resistant gloves;

- Chemical-resistant footwear plus socks;

- Chemical-resistant headgear for overhead exposures; and

- Protective eyewear.

User Safety Statements

EPA is requiring the following user safety statement on all end-use products containing fenitrothion:

User Safety Requirements:

"Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Environmental Hazard

The following statement is required for end-use products:

"ENVIRONMENTAL HAZARD

This pesticide is toxic to birds and aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."

Regulatory Conclusion

EPA has determined that products containing fenitrothion are eligible for reregistration **except** products labeled for application to ornamentals using low pressure handwand and knapsack/backpack spray equipment (products applied using high pressure handwand equipment are eligible for reregistration). The use of eligible fenitrothion products in accordance with labeling and risk mitigation measures specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA.

EPA does not have enough information at this time to make an eligibility decision for fenitrothion products labeled for use on ornamentals and applied using low pressure handwand and knapsack/backpack spray equipment. The Agency is requiring additional worker exposure studies in order to develop a more complete data base and make a reregistration eligibility decision regarding these uses of fenitrothion.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for fenitrothion during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher

server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the fenitrothion RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the fenitrothion RED, or reregistration of individual products containing fenitrothion, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.