United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-94-024
September 1994

Reregistration Eligibility Decision (RED)

Fenbutatin-oxide

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 which includes the active ingredient fenbutatin-oxide. 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 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 Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Susan Jennings at (703) 308-8021.

Sincerely yours,

Louis P. True, Jr., Acting 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. Complete the two response forms provided with each DCI letter by following the instructions contained in each DCI. **You must submit the response forms for each product and for each DCI within 90 days of the date you receive the RED; 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 RED issuance date (the cover letter 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 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; 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 Citation of Data**. Complete and sign this form (EPA form 8570-29) for each product. **Cite-all is not a valid option for reregistration.**

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 ALL DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-XXXX)*** ***** XXXX = the case code for the RED (see front cover of RED)
Office of Pesticide Programs (H7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-XXXX)***
Office of Pesticide Programs (H7504C)
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

Fenbutatin-Oxide

LIST A

CASE 0245

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

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FENBUTATIN-OXIDE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

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Lawrence Schnaubelt	Reregistration Branch
Susan Jennings	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
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
LOEL	Lowest Observed Effect Level
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.
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
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
PPE	Personal Protective Equipment

GLOSSARY OF TERMS AND ABBREVIATIONS

ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration 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
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision Document (RED) addresses the reregistration eligibility of the pesticide fenbutatin-oxide, Bis [tris (2-methyl-2-phenylpropyl)tin] oxide or hexakis (2-methyl-2-phenylpropyl)-distannoxane. Fenbutatin-oxide is a foliarly applied pesticide produced by E.I. DuPont de Nemours and Company for use on citrus, apples and stone fruits for the control of mites. Fenbutatin-oxide formulations include wettable powder, emulsifiable concentrate and soluble concentrate. Fenbutatin-oxide is applied aerially or through airblast or groundboom equipment.

Fenbutatin-oxide was initially registered in the United States in October 1974 for use as a miticide (acaricide) by Shell Chemical Company. The first end-use product was registered in August 1975 for use on apples, pears and some citrus crops. Since that time, several other food crops and outdoor and greenhouse ornamentals have been added to the label. The registration was transferred to E.I. DuPont de Nemours and Company in October 1986. A Registration Standard for fenbutatin-oxide was issued in March 1987 (NTIS #PB87-190690) and evaluated the studies submitted to support the registration of the miticide. The Registration Standard also required additional product chemistry, ecotoxicity, human toxicity, occupational exposure, environmental fate and residue chemistry information. The Agency has now completed its review of the fenbutatin-oxide data base including the data submitted in response to the 1987 Registration Standard.

The Agency has determined that the uses of fenbutatin-oxide will not cause unreasonable risk to humans or the environment and that these uses are eligible for reregistration, provided certain risk mitigation measures are implemented and that the use of fenbutatin-oxide is restricted to pesticide certified applicators. These actions and the corresponding monitoring program are necessary due to fenbutatin-oxide's very high toxicity to aquatic organisms. The Agency is requiring additional studies for product chemistry, bioaccumulation in fish and spray drift. These data are confirmatory and are not expected to change the regulatory decision on fenbutatin-oxide.

Based on the results of its reregistration review, the Agency classified fenbutatin-oxide as a Group E carcinogen (signifies evidence of non-carcinogenicity in humans) and established a reference dose of 0.05 mg/kg/day. The reference dose is based on a NOEL of 5.2 mg/kg/day for reduced body weight and food consumption in both sexes of pups of the first and second generations at 17.4 and 20.3 mg/kg/day in a two-generation study in rats. The dietary risk assessment is based on a worst-case scenario, assuming treatment of 100% of acreage and highest legal residue values which result in an overestimation of exposure and risk. However, when using anticipated residues, none of the population subgroups has an exposure which exceeds 10% of the RfD. A reassessment of tolerances is included in this document with recommended changes to some previously established tolerances.

Available data indicate that fenbutatin-oxide is practically non-toxic to birds on an acute basis and extremely toxic to both freshwater and estuarine aquatic organisms. However,

because the chemical binds strongly to soil, it may be less available to fish in the water column. The miticide presents some risk to birds and mammals and considerable risk to aquatic organisms on a chronic basis. Fenbutatin-oxide is relatively immobile and persistent in the environment, with no apparent major route of dissipation. To reduce the risks to aquatic organisms, the Agency is reclassifying fenbutatin-oxide products to be used only by pesticide certified applicators. The registrant has also agreed to a series of risk mitigation measures, including an educational program for the applicators, application rate reductions and use restrictions/limitations. The registrant will also institute a monitoring program, including more accurate aquatic models and sediment sampling, to assess the adequacy of the mitigation measures. These measures are discussed in more detail in the Risk Management and Reregistration Decision section.

Before reregistering the products containing fenbutatin-oxide, 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 registration" 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 fenbutatin-oxide. The document consists of six sections. Section I is the introduction. Section II describes fenbutatin-oxide, 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 fenbutatin-oxide. Section V discusses the reregistration requirements for fenbutatin-oxide. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available upon request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Fenbutatin-oxide
- **Chemical Name:** Bis [tris (2-methyl-2-phenylpropyl)tin] oxide or hexakis (2-methyl-2-phenylpropyl)-distannoxane
- **Chemical Family:** Organotin
- **CAS Registry Number:** 13356-08-6
- **OPP Chemical Code:** 104601
- **Empirical Formula:** $C_{60}H_{78}OSn_2$
- **Trade Name:** Vendex
- **Basic Manufacturer:** E.I. DuPont de Nemours and Company

B. Use Profile

The following is information on the current registered uses with an overview of use sites and application methods. A detailed table of these uses for fenbutatin-oxide is in Appendix A.

For fenbutatin-oxide:

Type of Pesticide: non-systemic organotin acaricide

Use Sites: greenhouse food/non-food crop, terrestrial food/non-food crop

Target Pests: mites, aphids, thrips, mealybugs, whiteflies and scales

Formulation Types Registered: technical grade (98%), wettable powder (50%), emulsifiable concentrate (42%), soluble concentrate (less than 1%, 42%)

Method and Rates of Application:

Equipment - aerial, airblast and groundboom

Method and Rate - Foliar application is mostly by ground equipment, with some aerial application. Maximum application rate varies from 1.25 lbs. a.i./A on tree nuts to 2 lbs. a.i./A on citrus and eggplant.

Timing - Application frequencies per year range from twice (citrus, stone fruits and tree nuts) to four (pome fruits and strawberries) to nine (papayas).

Use Practice Limitations: None

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of fenbutatin-oxide. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

The table below summarizes fenbutatin-oxide's percent of U.S. crops treated annually from 1989 - 1991:

Site[1]	Acres Grown[2] (000)	Multiple Acres Treated (000)	Percent Crop Treated	Pounds AI Applied (000)
Almonds	401	15 - 30	4 - 7	10 - 30
Apples	482	5 - 15	1 - 3	1 - 10
Cherries	98	1 - 2	1 - 2	1 - 2
Eggplant	5	1 - 2	< 1	1 - 2
Grapefruit	144	75 - 95	52 - 66	70 - 120
Grapes	741	25 - 55	3 - 7	20 - 45
Lemons	63	2 - 5	3 - < 10	2 - 5
Oranges	622	230 - 255	37 - 41	245 - 280
Peaches	186	5 - 10	3 - 5	2 - 6
Pears	71	1 - 5	1 - < 10	1 - 5
Plums/Prunes	131	1 - 2	< 1	1
Raspberries	11	1 - 2	< 1	1
Tangerines	17	1 - 10	6 - 59	5 - 10
Walnuts	180	3 - 5	2 - 3	1 - 5
Total	3,152	366 - 493	N/A	361 - 522

There are no known usage data available for Christmas trees, ornamentals, papaya, and aquatic sites. There is no known usage on pecans and strawberries. Data based on proprietary sources, DuPont, USDA, and state statistics.

[1] Site identification based on EPA's Reference Files System.

[2] 1989 acreage was the most consistent source (USDA/NASS), although not the only one used.

D. Data Requirements

Data requested in the March 31, 1987, Registration Standard for fenbutatin-oxide included studies on product chemistry, residue chemistry, ecological effects, environmental fate, toxicology, and occupational and residential exposure. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency that are needed to support reregistration of currently registered uses.

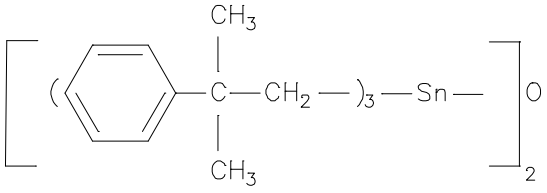
E. Regulatory History

Fenbutatin-oxide was registered in the United States in October 1974 for use as a miticide (acaricide) by Shell Chemical Company. The first end-use product was registered in August 1975 for use on apples, pears and some citrus crops. Since that time, several other food crops and outdoor and greenhouse ornamentals have been added to the labeling. The registration was transferred to E.I. DuPont de Nemours and Company in October 1986. A Registration Standard for fenbutatin-oxide was issued in March 1987 (NTIS #PB87-190690) which evaluated the studies submitted to support the registration of the miticide. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Fenbutatin-oxide [hexakis(2-methyl-2-phenylpropyl)distannoxane] is a non-systemic organotin acaricide with the following molecular structure:



Fenbutatin-Oxide

The physical and chemical characteristics of the TGAI of fenbutatin-oxide [hexakis(2-methyl-2-phenylpropyl)distannoxane] are described below (MRID's 00053791, 00113071, 40365801, 40506901, 40590501, 40696401, 40696402 and 40843601):

Color:	White
Physical State:	Crystalline solid
Odor:	Odorless
Melting Point:	145° C
Density:	0.42g/cm^3
Solubility:	Soluble in water at only 12.7 ppb at 20° C. Organic solvent solubilities range from 377 to 6 g/L, with solubility in dichloromethane > benzene > xylene > octanol > acetone (23° C)
pH:	Data Gap

The Agency has evaluated the product chemistry data base and has concluded that available preliminary analysis data are not fully acceptable and additional data must be submitted. Although data gaps exist for the formation of impurities and pH (guidelines 61-2b and 63-12), the Agency considers the requirement of these studies as confirmatory and not critical to the reregistration eligibility decision. The data requirements and the data gaps are given in Appendix B.

B. Human Health Assessment

1. Toxicology Assessment

The March 31, 1987, Registration Standard required the following toxicology studies:

Acute Oral Toxicity
Acute Inhalation Toxicity - Rat
90-Day Feeding - Non-Rodent
21-Day Dermal - Rabbit
Chronic Toxicity - Non-Rodent
Oncogenicity - Mouse
2-Generation Reproduction - Rat
Gene Mutation (Ames Test)
Structural Chromosomal Aberration
Other Genotoxic Effects
General Metabolism

The toxicological data base on fenbutatin-oxide is adequate and will support reregistration eligibility. The data requirements are listed in Appendix B and summaries of available studies are provided below.

a. Acute Toxicity

Technical fenbutatin-oxide (hexakis, Vendex) 98% a.i. demonstrated an acute oral LD_{50} of 4400 mg/kg in rats. An acute dermal toxicity study in rabbits demonstrated an LD_{50} of more than 2000 mg/kg, while the acute inhalation LC_{50} in rats was 0.074 mg/L. Fenbutatin-oxide was a severe eye irritant when tested in rabbits' eyes and produced only mild erythema and edema when a dose of 0.5 gram was tested in rabbits' skin. Guinea pigs did not demonstrate dermal sensitization when challenged with up to 10% fenbutatin-oxide solution.

The table below summarizes the values and categories for the various acute toxicity studies.

Test	Result	Category	MRID No.
Oral LD_{50}	4400 mg/kg	3	40473504
Dermal LD_{50} - Rabbit	> 2000 mg/kg	3	00112990
Inhalation LC_{50}	0.074 mg/kg	2	40473502 40473503
Eye Irritation - Rabbit*	Severe	1	00112990
Dermal Irritation*	Mild	4	00112990
Dermal Sensitization*	None	N/A	00112990

* Data pertaining to acute eye irritation, dermal irritation and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

b. Subchronic Toxicity

When technical fenbutatin-oxide was administered by dermal application to rabbits for three weeks at doses of up to 5 mg/kg/day no systemic toxicity was demonstrated. Locally, erythema and edema were observed at 0.5 mg/kg/day. (MRID 40641201)

c. Chronic Toxicity

When fenbutatin-oxide was administered to rats at dietary levels of 0, 50, 100, 300 and 600 ppm (equivalent to 0, 2.5, 5.0, 15 and 30 mg/kg/day) for two years, the NOEL for systemic toxicity was 100 ppm and the LEL was 300 ppm. The LEL was based on decreased leucocytes in female rats and reduced body weight in both sexes at all reporting points (3, 6, 12 and 24 months). At the mid- and high-dose levels, serum alkaline phosphatase was reduced and testes weight was increased in males. There was no correlative testicular histopathology. (MRID's 00037582, 00067049, 00113001)

A chronic dog study, in which fenbutatin-oxide was administered in gelatin capsules for two years at doses of 0, 2.5, 5.0, 15, 30 and 60 mg/kg/day, did not demonstrate any toxicity other than clinical observations of vomiting and diarrhea at doses of 15 mg/kg/day or more. The NOEL was 5 mg/kg/day and the LEL was 15 mg/kg/day

(MRID 00113002). Additional data submitted in response to the Registration Standard substantiated these results (MRID's 40977001, 41192401).

d. Carcinogenicity

When fenbutatin-oxide was administered to rats at dietary levels of 0, 50, 100, 300 and 600 ppm for two years, no increase in tumor incidence was observed at any dosage. The chemical was tested at adequate dose levels, since there was a significant decrease in body weight for both sexes receiving 300 and 600 ppm of the chemical. (MRID's 00037582, 00067049, 00113001)

Fenbutatin-oxide was tested in mice at dietary levels of 0, 50, 100, 300 and 600 ppm (equivalent to 0, 7.5, 15, 45 and 90 mg/kg/day). No increase in tumor incidence was observed at the highest dose tested. The study was conducted at adequate dosage, since there was a significant decrease in body weight for animals administered 300 and 600 ppm. The NOEL and LEL were 100 and 300 ppm, respectively, and were based on the body weight changes. (MRID's 00037581, 00067048, 00113000)

The Agency has classified fenbutatin-oxide as "Group E" for carcinogenic potential, indicating evidence of non-carcinogenicity for fenbutatin-oxide.

e. Developmental Toxicity

Mated female rats were administered fenbutatin-oxide (98.7% a.i.) by gavage at doses of 0, 15, 30 and 60 mg/kg/day from the sixth day through the fifteenth day of gestation. Aspirin (300 mg/kg) served as the positive control compound. Significant dose-related body weight reductions occurred at the mid- and high-dose levels in the treated rats. The treated dams exhibited no compound related effects (e.g. numbers of corpora lutea, implantation sites, resorptions, live and dead fetuses, mean fetal weight, or the sex ratio of pups). The NOEL and LOEL for maternal toxicity were 15 and 30 mg/kg/day, respectively, due to reduced body weight. (MRID 00072693)

Groups of mated female New Zealand white rabbits were administered fenbutatin-oxide in gelatin capsules at doses of 0, 1, 5 and 10 mg/kg/day from the sixth day through the eighteenth day of

gestation. Thalidomide (150 mg/kg) served as the positive control on gestation days 8 and 9. The NOEL for maternal toxicity was 1 mg/kg/day. The LEL was 5 mg/kg/day based on anorexia, gastric lesions and abortions at that dose. The LEL was established due to an increased incidence of abortions at 5 mg/kg and 10 mg/kg. (MRID's 00049230, 00069880, 00079319)

f. Reproductive Toxicity

Technical fenbutatin-oxide (94-99% a.i.) was tested in a 2-generation rat reproductive study at dietary doses of 0, 40, 75, 250 and 500 ppm (equivalent to 0, 2.79, 5.20, 17.4 and 37.9 mg/kg/day in males and 0, 3.22, 5.98, 20.3 and 43.9 mg/kg/day in females). The only parental toxicity observed in both P1 and F1 generations was decreased body weight and food consumption at 250 ppm and 500 ppm. The NOEL and LOEL were 75 ppm and 250 ppm, respectively.

Ingestion of fenbutatin-oxide did not affect fertility, length of gestation or pup viability. Pup body weight was reduced during lactation. The NOEL and LOEL for reproductive toxicity were 75 and 250 ppm, based on the reduced pup body weight. (MRID 41540601)

g. Mutagenicity

Technical fenbutatin-oxide (98% a.i.) was evaluated in a Salmonella typhimurium/Ames plate incorporation assay in tester strains TA 1535, TA 97, TA 98 and TA 100, with and without metabolic activation at concentrations of 5, 10, 50, 100 and 300 Fg/plate. None of the doses tested increased the number of revertant colonies. Preliminary studies indicated that cytoxicity was induced at 1.2 Fg/plate. Thus, fenbutatin-oxide did not induce mutations in Salmonella typhimurium strains when tested up to cytoxic levels. (MRID's 40473501, 40770601)

Technical fenbutatin-oxide did not increase the frequency of mutation in Chinese Hamster ovary cells, when tested at up to cytoxic levels both with and without metabolic activation. The 0, 0.025, 0.05, 1.0 and 1.5 Fg/ml levels were tested without metabolic activation. The 0, 0.05, 0.5, 1.0, 2.5, 5.0 and 7.5 Fg/ml levels were tested with metabolic activation. Cytoxicity was observed at 1 Fg/ml without metabolic activation and at 7.5 Fg/ml with metabolic activation. (MRID 40590504)

Technical fenbutatin-oxide did not induce chromosomal aberrations in human lymphocytes obtained from the venous blood of healthy male and female donors when tested at concentrations of 0.7, 1.0, 4.0 and 5.0 Fg/ml with and without metabolic activation. The chemical was tested up to cytoxic levels. (MRID 40590502)

Fenbutatin-oxide did not increase the micronucleated polychromatic erythrocytes in the bone marrow of mice when administered at dosage levels of 500, 2500 and 5000 mg/kg. (MRID 40590503)

Technical fenbutatin-oxide did not produce unscheduled DNA synthesis in rat primary hepatocytes at concentrations of up to 1.0 Fg/ml. (MRID 40590505)

h. Metabolism

The absorption, distribution, metabolism, and excretion of fenbutatin-oxide was studied in male and female Sprague-Dawley rats. The rats were treated with a single oral dose of 10 mg/kg of [^{119}mSn]-labelled fenbutatin-oxide, a single dose of 500 mg/kg of [^{119}mSn]-labelled fenbutatin-oxide or 14 repeated daily doses of unlabelled fenbutatin-oxide at 10 mg/kg followed by a single labelled dose at 10 mg/kg. Fenbutatin-oxide was excreted virtually unchanged in the feces. Over a 5-day period, 83-100% of the radioactivity was found in the feces and urine. The amount of radioactivity was very low over a 5-7 day period, indicating that the potential for bioaccumulation of fenbutatin-oxide is minimal. The highest radioactivity levels were found in the liver, kidney, and heart. Thin layer chromatography analysis of fecal extracts showed that unchanged fenbutatin-oxide accounted for 86-96 percent of the radioactivity extracted from the feces, with two minor metabolites comprising another 1-3%. One of these metabolites was tentatively identified as IN-CG200, however, the other remained unidentified. IN-CG200 [1,3-dihydroxy-1,1,3,3-tetrakis(2-methyl-2-phenylpropyl)distannoxane] is an impurity in the test compound. (MRID 41069101)

The metabolism study demonstrates that approximately 1% of fenbutatin-oxide is absorbed from the gastrointestinal tract when the chemical is administered orally. This is based on the fact that at both single and repeated low dose level, 98.8% and 100% of the administered compound were recovered unchanged from the feces of treated rats, with an additional 0.9% and 0.3% from the cage wash. In addition, the total

radioactivity recovered in the carcasses, tissues and gastrointestinal tract contents ranged from a mean of 0.1% to 1.1% of the administered dose over all dosing groups, with only negligible quantities reported from the males and females in the 500 mg/kg group. The Agency believes that the skin will not absorb a larger percentage of the chemical than the gastrointestinal tract, so that no more than 1% of a daily dose over a 14-day period would be absorbed through the skin.

i. Reference Dose

The Agency's Reference Dose Committee determined the reference dose (RfD) for systemic toxicity of fenbutatin-oxide to be 0.05 mg/kg/day. The reference dose was based on the NOEL of 5.2 mg/kg/day for reduced body weight and food consumption in both sexes of pups of the first and second generations at 17.4 and 20.3 mg/kg/day in a two-generation study in rats.

2. Exposure Assessment

a. Dietary Exposure

The March 31, 1987, Registration Standard required the following dietary exposure studies:

Nature of the Residue in Livestock
Residue Analytical Methods for Plants
Residue Analytical Methods for Livestock
Storage Stability
Confined Rotational Crops
Magnitude of the Residue in Crop Field Trials

The data requirements are listed in Appendix B and summaries of available studies are provided below.

The conclusions regarding the reregistration eligibility of fenbutatin-oxide on the crops listed in Table A are based on the use patterns registered by the basic producer, E. I. du Pont de Nemours & Co., Inc., as reflected on the product labels for the 50% WP and the 4 lb/gal EC formulations (EPA Reg. Nos. 352-480 and 352-493), which are currently the only fenbutatin-oxide products registered for food or feed uses.

Plant Metabolism

The qualitative nature of the residue in plants is adequately understood. Studies with apples and oranges indicate that residues are primarily found on the fruits' surface. Since the parent compound comprises the majority of the terminal residue in plants, only the parent will be included in the tolerance expression for plant commodities. (MRID 00113018)

Animal Metabolism

The qualitative nature of the residue in animals is adequately understood. Studies with goats and poultry revealed similar metabolic profiles. The terminal residue to be regulated in livestock consists of fenbutatin oxide and its metabolites dihydroxybis(2-methyl-2-phenylpropyl) stannane (SD-31723) and 2-methyl-2-phenylpropylstannoic acid (SD-33608). (MRID 41183801)

Residue Analytical Methods for Plants and Animals

An adequate enforcement method is available for fenbutatin-oxide residues in plants and animals. The GLC/FPD method MMS-R-494-2 has successfully undergone Agency method validation for plants and animals and has satisfied the requirements of PR Notice 88-5 concerning independent laboratory validation. Method MMS-R-494-2 individually quantifies each analyte to a detection limit of 0.05 ppm.

A spectrophotometric method for determining total organotin and a GLC/EC method (MMS-R-391-1) for determining the parent compound are published in PAM, Vol. II as Methods I and II, respectively. These methods are inadequate for both data collection and enforcement purposes. In addition, the TLC methods MMS-R-391-1, published in PAM, Vol. II as Method A, and MMS-R-345-1 (the section for SD-31723 analysis only), are adequate only for confirming GLC results. (MRID's 41110901 and 41520701)

Storage Stability

Data have been submitted concerning the storage stability of fenbutatin-oxide and its related metabolites in or on samples of almonds, apples, cucumbers, eggplants, grapes, oranges, plums, and strawberries. These data indicate that residues of fenbutatin oxide are stable in or on almonds (28 months), apples (14 months), cucumbers (21 months),

eggplants (8.5 months), grapes (13 months), oranges (12 months), plums (12 months), and strawberries (28 months). The available storage stability data adequately support the residue field trial data. (MRID 41110901 and 41520701)

Accumulation in Confined Rotational Crops

Uncharacterized fenbutatin-oxide residues (less than 0.09 ppm, fresh weight) accumulated in turnip roots planted 30, 120, and 365 days after [^{119m}Sn]fenbutatin-oxide was applied at a rate of 7.9 lb a.i./A to sandy loam soil. Uncharacterized fenbutatin-oxide residues (0.056 ppm, fresh weight) also accumulated in mature wheat straw planted 30 days after application. Residues did not accumulate in immature wheat straw, mature lettuce, mature turnip foliage, or mature wheat grain at any rotational interval. Total radioactive residues in soil samples taken at treatment, planting, and harvest, varied from 4.4 ppm at treatment to 1.8 ppm at 453 days post-treatment. Fenbutatin-oxide was the only component identified in all soil extracts analyzed and represented more than 94% of the extractable radioactivity after 453 days. (MRID 41520702)

b. Occupational and Residential Exposure

The March 31, 1987, Registration Standard required an occupational and residential exposure study on foliar dislodgeable residues. This data requirement is listed in Appendix B and a summary of the available study is provided below.

Occupational and residential exposure can be expected based on the currently registered uses of products containing fenbutatin-oxide. However, due to the lack of toxicological concerns additional occupation and residential exposure data are not required. There are no special toxicological concerns about fenbutatin-oxide that warrant the establishment of active-ingredient-based personal protective equipment (PPE) requirements for handlers. The Agency will base the PPE requirements for pesticide handlers on the acute toxicity of the end-use products.

Foliar Based Restricted Entry Interval (REI)

The foliar dislodgeable residue data consist of leaf disc samples collected after four fenbutatin-oxide applications were applied to oranges grown in California and Florida. In Florida, the 50% wettable powder

formulation was applied, while in California both the 50% wettable powder and the 4 lb/gal EC formulation were applied. Due to the similarity of the residues across formulation types and locations, the registrant averaged all the data for statistical analysis. On the first day after the final application of fenbutatin-oxide these averaged residues peaked at 2.53 µg/cm^2 and dissipated 56 days after the final application to a level of 0.92 µg/cm^2.

Post Application Exposure

To conduct a post-application risk assessment, the Agency used a dermal absorption factor of one percent. This factor was derived from the metabolism study as discussed earlier in the metabolism summary.

Because foliar dislodgeable residue studies were conducted without concurrent dermal exposure data, dermal exposure was estimated using generic transfer coefficients (cm^2/hr). These coefficients assume worker exposure to treated foliage occurs at a constant rate during reentry activities; and are based on the work of Zwieg, Leffingwell, and Popendorf. To determine REI's for fenbutatin-oxide, a transfer coefficient of 10,000 was used for orchard crops and 4,000 was used for low growing/greenhouse crops. Reentry levels that provide an acceptable margin of exposure of 100 (based on an 8 hour work day) are 11 µg/cm^2 for orchard crops and 28 µg/cm^2 for low growing and greenhouse crops. Both levels are well above residue levels detected in the field study.

Entry Restrictions for WPS Uses

The Worker Protection Standard for Agricultural Pesticides (WPS) -- 40 CFR Part 170 established the interim 48-hour REI based on fenbutatin-oxide's Toxicity Category I eye irritation potential. The Agency has determined that the 48-hour REI for all WPS sites should be retained as a prudent measure to mitigate risk to workers entering treated areas after application.

For occupational end-use products containing fenbutatin-oxide as an active ingredient, the Agency has determined that a 48-hour restricted-entry interval is required for each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The basis for this requirement is that fenbutatin-oxide is categorized as toxicity category I (severe) for eye irritation potential. The WPS REI in effect until now was 48 hours. The 48-hour interim WPS REI was established through labeling modifications specified in PR

Notice 93-7, which implemented the labeling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides.

The PPE required for early entry is: coveralls, chemical-resistant gloves, shoes, socks and protective eyewear. The clothing requirements are based on fenbutatin-oxide's classification of category III for acute dermal toxicity and category IV for skin irritation potential, as well as EPA's lack of special concerns about other adverse effects. The protective eyewear is required due to fenbutatin-oxide's category I classification for eye irritation potential. The Agency will not require a respirator for early-entry workers, since the WPS places very specific restrictions on these workers. The Agency believes that existing WPS protections are sufficient to mitigate post-application inhalation exposures of workers.

Some registered uses of fenbutatin-oxide are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency has determined that, at this time, the entry restrictions discussed in this section need not apply to uses of fenbutatin-oxide outside the scope of the Worker Protection Standard for Agricultural Chemicals, including out-of-scope commercial uses. The predicted frequency, duration and degree of post-application exposure from these uses do not warrant the risk mitigation measures being required for persons engaged in the production of agricultural plants for commercial or research purposes.

3. Risk Assessment

a. Dietary

Toxicological Endpoint

The chronic dietary risk estimate analysis used a Reference Dose of 0.05 mg/kg body weight/day, based on a No Observed Effect Level of 5.2 mg/kg bwt/day and an uncertainty factor of 100. The NOEL was derived from a reproduction study in rats that demonstrated reduced body weight and food intake in both sexes of pups of the first and second generation.

Residue Information

Food uses in this analysis are the published and recommended tolerances being supported in the reregistration of fenbutatin-oxide.

Published tolerances for this chemical are listed in Tolerance Index System (TIS) and 40 CFR §180.362, 185.3550 and 186.3550.

The analysis used anticipated residues for several commodities. An anticipated residue value was derived for dried apples (26.9 ppm) which is higher than the established tolerance for raw apples (15 ppm). This occurs because the tolerance level is based on the raw agricultural commodity (RAC) "apples" and no tolerance is set for "dried apples." Separate anticipated residues are available for these two items.

Results

The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population, without any refinements was calculated to be 136% of the RfD. This value may overestimate the risk because the TMRC assumes all crops have tolerance level residues and that 100% of all crops are treated with fenbutatin-oxide.

The Anticipated Residue Contribution (ARC) for the overall U.S. population from crops that may be treated with fenbutatin-oxide is 0.002132 mg/kg bwt/day, or 4% of the RfD. The subgroup most highly exposed, children one to six years old, has an ARC from all uses of 0.004 mg/kg bwt/day, or 8% of the RfD. None of the subgroups in the Dietary Risk Exposure System has an exposure which exceeds 10 percent of the RfD.

b. Occupational and Residential

Exposure by humans to fenbutatin-oxide may occur during handling (mixing, loading, application, etc.) tasks and during post-application exposures. Since fenbutatin-oxide is classified as toxicity category I for eye irritation potential, eye irritation is a particular concern.

C. Environmental Assessment

1. Environmental Chemistry, Fate and Transport

The March 31, 1987, Registration Standard required the following environmental fate studies:

Hydrolysis
Photodegradation in water
Photodegradation in soil
Aerobic soil metabolism
Anaerobic soil metabolism
Leaching/adsorption and desorption
Confined rotational crop
Lab volatility
Bioaccumulation in fish
Terrestrial field dissipation
Droplet size spectrum
Drift field evaluation

All of these data requirements have been fully satisfied, except for the bioaccumulation in fish (165-4) and spray drift (201-1 and 202-1) requirements. Although it has been shown that fenbutatin-oxide does accumulate in fish tissues, a new fish accumulation study is required in order to determine the actual extent of this accumulation. The additional information will be used as confirmatory data and is not expected to change the overall environmental fate assessment.

Due to concerns about the toxicity of fenbutatin-oxide to aquatic organisms, the spray drift data requirements were imposed to assess the extent of exposure of these organisms in nearby water bodies and canals to fenbutatin-oxide as a result of its application to orchards. These studies are being reserved pending the work currently being conducted by industry's Spray Drift Task Force. Detailed information regarding the fate of fenbutatin-oxide in the environment is presented below.

a. Hydrolysis

Fenbutatin-oxide was stable to hydrolysis at pH's 5, 7, and 9 in sterilized buffered aqueous solutions kept in darkness at approximately 25°C. After 30 days of incubation in each test solution, fenbutatin-oxide comprised more than 90% of the originally applied radioactivity. (MRID 40790901)

b. Photodegradation in Water

Fenbutatin-oxide photodegraded in sterile water at pH 7 with a half-life of 55 days under continuous irradiation. This half-life would translate to a half-life of over 100 days if the chemical were exposed to 12 hours of irradiation alternated with 12 hours of darkness. The only major photolytic degradation product was IN-CG200 {1,3-dihydroxy-1,1,3,3-tetrakis (2-methyl-2-phenylpropyl) distannoxane}. This degradation product comprised 22.8% of total radioactivity by day 15 of continuous exposure by a xenon lamp equipped with a filter to eliminate wavelengths less than 290 nm. (MRID 40790902)

c. Photodegradation on Soil

Fenbutatin-oxide is relatively stable towards photodegradation on soil. The half-life of fenbutatin-oxide was 128 days on sandy loam soil irradiated on a 12-hour photoperiod with a xenon arc lamp for 31 days. The major degradate was 1,3-dihydroxy-1,1,3,3-tetrakis(2-methyl-2-phenylpropyl)distannoxane (IN-CG200), comprising a maximum of 3.4% of the applied radioactivity at 31 days posttreatment. Fenbutatin-oxide did not degrade in the dark controls. (MRID 40696403)

d. Aerobic Soil Metabolism

Fenbutatin-oxide was relatively stable in the three soils tested. After 12 months under aerobic conditions in loamy sand, silty clay loam and sandy clay loam soils, 80.0%, 76.5% and 79.7% of the applied radioactivity was removed as undegraded fenbutatin-oxide, respectively. (MRID 40257001)

e. Anaerobic Soil Metabolism

Fenbutatin-oxide was relatively stable in the three soils tested, with 77.5%, 79.8% and 80.8% of the applied radioactivity being recovered as undegraded fenbutatin-oxide after 60 days under anaerobic conditions in loamy sand, silty clay loam, and sandy clay loam, respectively. (MRID 40257002)

f. Leaching and Adsorption/Desorption

Unaged fenbutatin-oxide was immobile to slightly mobile in columns of two loamy sand soils, a silty clay soil, and a sandy clay soil. More than 90% of the ^{119}Sn residues did not move out of the treated layer. Fenbutatin-oxide residues aged 30 days were slightly mobile in a

column of loamy sand soil. ^{119}Sn residues were distributed throughout the column (92% in the upper 6 cm) and 1% were recovered in the leachate. ^{119}Sn in fenbutatin-oxide comprised 98% of the recovered extractable radioactivity in the soil. (MRID 40257003)

Fenbutatin-oxide with a 0.2% surfactant at 0.1, 1.0, and 10 ug/ml, was slightly mobile to immobile (K_{ads}: 6.9-3587) in two loamy sand soils, a silty clay soil and a sandy clay loam soil. Less than 5% of the adsorbed pesticide desorbed from the soil. (MRID 40257004)

Fenbutatin-oxide with a 1% acetone co-solvent at 5, 1, 0.2 and 0.04 mg/ml was immobile (K_d: 1282 - 2333) in a loamy sand, sandy loam and silty loam soil. Less than 0.5% of the adsorbed pesticide desorbed from the soil. (MRID 43336401)

g. Soil Field Dissipation

Fenbutatin-oxide (Vendex 4L and Vendex 50WP) applied to three separate soils at a rate of 8 lbs a.i./acre was found to have a half-life of greater than 1 year in the field. In addition to its persistence, fenbutatin-oxide was also characterized as having low mobility. At the Delaware and Washington sites, 99% of the residues were found in the 0-10 cm depth after 18 months. Throughout the study, the 0-10 cm segment contained more than 94% of the total residues found. In California, there were no significant residues deeper than 10 cm before 18 months. At no time were residues detected in the 30-90 cm soil depths. The degradates 1,3-dihydroxy-1,1,3,3-tetrakis(2-methyl-2-phenylpropyl) distannoxane {SD31723} and 2-methyl-2-phenylpropyl stannonic acid {SD33608} were found at low concentrations (less than 0.22 ppm). (MRID's 42074501 and 41608501)

h. Long-Term Soil Field Dissipation

Fenbutatin-oxide was persistent under field conditions. It dissipated with half-lives between 271 and 1367 days from the upper 30 cm of bareground plots of silt loam soil located in Delaware, loam soil located in Washington, and loam/sandy loam soil located in California. These plots had been treated at 8 lb a.i./A/year for 3 years with fenbutatin-oxide (Vendex 4L Miticide, 4.0 lb a.i./gallon FlC; or Vendex 50 WP Miticide, 50% WP). Fenbutatin-oxide and its metabolites demonstrated low mobility at all of the test sites throughout the course of the study. After the third application, approximately 90% of the residues remained in the top 10 cm of soil at each of the sites. Of the three sites, only California (2% of total residues) showed residues in soil

at the 60-90 cm level. The degradates identified in the treated soil were 1,3-dihydroxy-1,1,3,3-tetrakis(2-methyl-2-phenylpropyl) distannoxane (SD 31723) and 2-methyl-2-phenylpropyl stannonic acid (SD 33608).

At the Delaware site, fenbutatin-oxide dissipated with a half-life of 1367 days from the upper 30 cm of bareground plots of silt loam soil that were treated in August 1988, 1989, and 1990. At the Washington site, fenbutatin-oxide dissipated with a half-life of 714 days from the upper 30 cm of bareground plots of loam soil that were treated in August 1988, June 1989, and June 1990. At the California site, fenbutatin-oxide dissipated with a half-life of 271 days (95% confidence interval: 201-418 days) from the upper 30 cm of bareground plots of loam/sandy loam soil that were treated in June 1988, 1989, and 1990.

These long half-lives caused residue levels to increase with successive applications. Based on the half-life data, the maximum expected concentrations found in the soils (0-30 cm depth) are 0.43 ppm at Madera, CA; 4.15 ppm at Newark, DE; and 4.27 ppm at Wapato, WA. (MRID 42896801)

i. Accumulation in Fish

To accurately define the bioaccumulation potential of fenbutatin-oxide, a new study is needed. In the submitted study, the calculated bioconcentration factors (BCF's) were not accurate. In this study the accumulation of fenbutatin-oxide in the various tissue fractions did not plateau during the 28-day exposure period so that the actual BCF's may be significantly higher than those presented. The additional data are confirmatory and are not expected to change the overall environmental fate assessment. (MRID 40696404)

2. Environmental Fate Assessment

Fenbutatin-oxide is persistent in the environment, with no apparent major route of dissipation. Chemical degradation studies have demonstrated that fenbutatin-oxide is relatively unsusceptible to hydrolysis or photodegradation in water or on soil. After 30 days of incubation in the hydrolysis study, at least 90% of the applied radioactivity in each test solution was undegraded parent. Estimated photolytic half-lives in water and on soil were longer than 100 and 128 days, respectively. The degradate 1,3-dihydroxy-1,1,3,3-tetrakis(2-methyl-2-phenylpropyl)distannoxane {SD31723} was detected in both photodegradation studies, comprising a maximum of

11.4% of the applied radioactivity in the photodegradation in water study and 3.4% in the photodegradation on soil study.

Microbial degradation of fenbutatin-oxide in soil is also very slow. After 12 months in loamy sand, silty clay loam and sandy clay loam soils, 80.0%, 76.5% and 79.7%, respectively, of the applied radioactivity was recovered as undegraded fenbutatin-oxide. Under anaerobic conditions, 77.5%, 79.8%, and 80.8% of the applied radioactivity was recovered as undegraded fenbutatin-oxide after 60 days in the same three soils. Neither of the soil metabolism studies was able to identify any extractable degradates.

Fenbutatin-oxide is relatively immobile in the environment. It is slightly soluble in water (12.7 ppb at 20°C), has a low vapor pressure and binds strongly to soil. Column leaching and batch equilibrium adsorption/desorption studies have demonstrated that fenbutatin-oxide is not likely to move through soil. In the column leaching studies, little downward movement of fenbutatin-oxide was observed beyond the application site (top 3 cm) for all four soils examined (two loamy sands, a silty clay loam, and a sandy clay loam). Freundlich K_{ads} values derived from a batch equilibrium study with fenbutatin-oxide and a 0.2% Ortho X-77 surfactant ranged from 6.9 to 30.4 in two loamy sand soils and a silty clay soil, and 3587.5 in sandy clay loam soil. In a second batch equilibrium study using fenbutatin-oxide with a 1% acetone co-solvent, K_d values ranged from 1282 to 2333 in loamy sand, sandy loam and silty loam soils. These data suggest that fenbutatin-oxide binds strongly to soil and therefore is not expected to leach.

Although fenbutatin-oxide is persistent, residues did not tend to accumulate in crops planted in sandy loam soil that had been previously treated with 7.9 lbs a.i./A 30, 120, or 365 days prior to planting. This may be partially due to fenbutatin-oxide's propensity to bind to soil. Residues did not accumulate in immature wheat straw, mature lettuce, mature turnip foliage or mature wheat grain at any rotational interval. However, residues were found in turnip roots (less than 0.09 ppm) planted 30, 120, and 365 days after application and in wheat straw (0.056 ppm) planted 30 days after application.

Fenbutatin-oxide does accumulate in fish tissues, as expected from its high octanol-water partition coefficient ($K_{ow} = 1.4 \times 10^5$). Bioconcentration factors of 340-500x for muscle tissue, 1100-1600x for visceral tissue, 450-640x for the remaining carcass and 490-730x for whole fish were determined for bluegill sunfish exposed to fenbutatin-oxide at 0.00013 mg/L or 0.00068 mg/L. However, the lack of a plateau in the concentration of fenbutatin-oxide in the various tissues could indicate that the actual BCF's are higher. The degradate 1,3-dihydroxy-1,1,3,3-tetrakis(2-methyl-2-phenylpropyl) distannoxane {SD31723} was identified in the muscle and visceral tissue (18-21% of the

extractable residues). Depuration of accumulated residues was somewhat limited, with only 51-75% of the accumulated residues being eliminated by day 14 of the depuration period.

In the field, fenbutatin-oxide exhibited the same characteristics of persistence and immobility as in the laboratory. The calculated half-lives for the dissipation of fenbutatin-oxide ranged from 271 days in California loam/sandy loam soil to 714 days in Washington loam soil to 1367 days in Delaware silt loam soil. These dissipation rates were measured from the upper 30 cm of bareground plots treated with 8 lb a.i./A/year of fenbutatin-oxide for 3 years (Vendex 4L Miticide, 4.0 lb a.i./gallon FlC; or Vendex 50 WP Miticide, 50% WP). The long half-life caused residue levels to increase with each successive application. Throughout the course of the study, fenbutatin-oxide and its metabolites displayed low mobility at all of the test sites. After the third application approximately 90% of the residues remained in the top 10 cm of soil at each of the sites. Madera was the only one of the three sites to show residues (2% of the total) in soil at the 60-90 cm level. The degradates identified in the treated soil were 1,3-dihydroxy-1,1,3,3-tetrakis(2-methyl-2-phenylpropyl) distannoxane (SD 31723), and 2-methyl-2-phenylpropyl stannonic acid (SD 33608).

3. Ecological Effects

The March 31, 1987, Registration Standard required the following ecological effects data:

Avian toxicity
Fish toxicity (TEP)
Invertebrate Toxicity
Estuarine/Marine acute fish toxicity
Estuarine/Marine acute mollusk toxicity
Estuarine/Marine acute shrimp toxicity
Early life stage fish
Life cycle invertebrate
Aquatic organism accumulation

The data submitted for the estuarine fish early life stage (guideline 72-4a) and estuarine shrimp life cycle (guideline 72-4b) data requirements were invalid largely due to difficulties with the saltwater medium required in the estuarine tests. In the absence of the chronic estuarine testing, the chronic freshwater results will be used for the chronic estuarine risk assessments. The use of these estimates introduces uncertainty into the chronic assessment for estuarine fish and invertebrates. Although data from the estuarine chronic

studies would reduce this uncertainty, these studies are not being required at this time.

The submitted avian reproduction studies provided No Observed Effect Level's (NOEL's), but did not provide Lowest Effect Level's (LEL's). To calculate the chronic risk, the Agency estimated the LEL to be equal to the NOEL. This is a conservative estimate and introduces uncertainty into the avian chronic assessment. Additional avian reproduction studies conducted at higher dose levels could reduce this uncertainty, however, the Agency is not requiring additional data at this time.

a. Acute Toxicity to Birds

Based on acute toxicity data, fenbutatin-oxide is practically nontoxic to birds. An avian acute oral study performed on the bobwhite quail resulted in an LD_{50} value of more than 2510 mg/kg. (MRID 00113073)

Fenbutatin-oxide is also practically nontoxic to birds on a subacute dietary basis. Two studies, one on the mallard duck and one on the bobwhite quail, produced LC_{50} values greater than 5620 ppm. (MRID 00113074, 40473505)

b. Chronic Toxicity to Birds

Avian reproduction studies were required for fenbutatin-oxide, since the product's persistence may cause birds to be repeatedly or continually exposure to the pesticide.

Two avian reproduction studies, one on the mallard duck and one on the bobwhite quail, showed no effect on reproduction at dietary levels up to 150 ppm. (MRID's 41258902, 41258901)

c. Acute Toxicity to Freshwater Fish

Species	% A.I.	LC_{50}	MRID
Rainbow trout	95%	1.7 ppb	00113075
Rainbow trout	100%	1.7 ppb	40098001
Rainbow trout	98.6%	6.6 ppb	40473506
Bluegill sunfish	95%	4.8 ppb	00113076
Bluegill sunfish	100%	4.8 ppb	40098001

The acute toxicity tests, listed above, show that fenbutatin-oxide is very highly toxic to freshwater fish, with LC_{50} values ranging from 1.7 to 6.6 ppb. (MRID's 00113075, 40098001, 40473506, 00113076, and 40098001)

In addition to testing on the technical product, formulated product testing on fish was also required because the LC_{50} of the technical fenbutatin-oxide was lower than the Expected Environmental Concentration (EEC) in the aquatic environment. These data, listed below, show that the formulated products of fenbutatin-oxide are highly toxic to very highly toxic to freshwater fish. (MRID's 40098001, 40473507, 40473508, and 40098001)

Species	% A.I.	LC_{50}	MRID
Rainbow trout[3]	50%	14 ppb	40098001
Rainbow trout	42%	120 ppb	40473507
Bluegill sunfish	42%	130 ppb	40473508
Fathead minnow[3]	50%	1.9 ppb	40098001
Channel catfish[3]	50%	1.5 ppb	40098001

[3] Studies are Supplemental due to inadequate detail in study reports.

d. Chronic Toxicity to Freshwater Fish

A fish early life stage test was required because fenbutatin-oxide is expected to be transported to aquatic sites, is relatively persistent in water and has laboratory LC_{50} values of less than 1 mg/L.

An early life stage study performed with the rainbow trout shows that growth and survival are impaired at concentrations of greater than 0.31 ppb. The Maximum Allowable Toxicant Concentration (MATC) is between 0.31 ppb and 0.61 ppb. (MRID 40473512)

e. Acute Toxicity to Freshwater Invertebrates

The acute toxicity study performed on Daphnia magna with a 98.6% pure technical product showed that fenbutatin-oxide has an EC_{50} of 31 ppb and is very highly toxic to freshwater aquatic invertebrates. (MRID 40473509)

Formulated product testing on aquatic invertebrates was required for fenbutatin-oxide because the EC_{50} of the technical pesticide was lower than the EEC in the aquatic environment.

The study, performed on a 42% pure formulated product, showed that the formulated product has an EC_{50} of 10 ppb and is very highly toxic to freshwater aquatic invertebrates. (MRID 40473511)

f. Chronic Toxicity to Freshwater Invertebrates

An aquatic invertebrate life cycle test was required because fenbutatin-oxide is expected to be transported to aquatic sites, is relatively persistent in water and has all laboratory EC_{50} values of less than 1 mg/L.

A life-cycle study performed with Daphnia magna shows that survival is impaired at concentrations greater than 0.016 ppm. The MATC is between 0.016 ppm and 0.039 ppm. (MRID 40525901)

g. Acute Toxicity to Estuarine and Marine Organisms

Acute toxicity testing with estuarine/marine organisms was required for fenbutatin-oxide because its use on citrus or apples could result in exposure to the estuarine environment. These tests include an acute LC_{50} for an estuarine fish, an acute LC_{50} for an estuarine shrimp, and either an oyster embryolarvae study or an oyster shell deposition

study.

The information in the following table characterizes fenbutatin-oxide as very highly toxic to estuarine and marine fish and invertebrates. (MRID's 41483301, 40590508, and 40590507)

Species	% A.I.	LC_{50}	MRID
Sheepshead minnow	99%	20.8 ppb	41483301
Mysid shrimp[4]	98%	2.8 ppb	40590508
Eastern oyster[5] (embryolarvae)	98%	0.4 ppb	40590507

h. Chronic Toxicity to Estuarine and Marine Organisms

Since fenbutatin-oxide is relatively persistent in water and has all laboratory EC_{50} values of less than 1 mg/L, data from chronic tests were required. Due to difficulties maintaining the required low concentrations in saltwater, these tests are no longer required. Instead, estimated MATC's will be used.

The MATC for estuarine fish is estimated to be between 0.31 ppb and 0.61 ppb, as determined in the chronic freshwater fish study. The MATC for estuarine invertebrates is estimated to be the same as the MATC in the freshwater invertebrate study (i.e. between 0.016 ppm and 0.039 ppm).

i. Non-Target Insects Data

An acute contact LD_{50} study with technical fenbutatin-oxide to establish the acute toxicity to honey bees resulted in an LD_{50} of 3982 Fg/bee. This study shows that fenbutatin-oxide is practically nontoxic to honey bees. (MRID 00036935)

j. Non-Target Plants Data

Non-target plant testing is not required to support currently

[4] Study is supplemental because analytical detection limit and name of solvent were not reported.

[5] Study is supplemental because analytical detection limit was not reported.

registered uses of fenbutatin-oxide.

k. Other Non-Target Terrestrial Organisms

The available mammalian data indicate that fenbutatin-oxide is practically nontoxic to mammals on an acute basis, since the rat LD_{50} was established at 4400 mg/kg. On a chronic basis, a two-generation reproduction study with rats produced a reproductive NOEL of 75 ppm and a LOEL of 250 ppm.

l. Field Residue Monitoring Studies

The Agency requires field monitoring studies on a case-by-case basis when the use pattern of the chemical, the toxicity to nontarget organisms, and the environmental fate characteristics of the chemical indicate a potential for hazard to nontarget organisms. Fenbutatin-oxide is extremely persistent in terrestrial and aquatic environments, and is very highly toxic to aquatic organisms. The highest application rate is for citrus in Florida. Use on Florida citrus also represents a situation with high potential for contamination of aquatic habitats. For these reasons, monitoring studies measuring residues in citrus groves and adjacent waters were required.

The citrus residue monitoring study was conducted in central and south Florida in 1991. Residues were measured in and around 5 citrus groves that were each treated two times, at 60 day intervals with 2 lb a.i./A (Vendex 4L).

Under the conditions of this study, the major route of transport was within-grove deposition on ditches and spray drift deposition to perimeter/lateral canals. Maximum aquatic residues were 111 Fg/L in perimeter/lateral canals and 1.7 Fg/L in pond water. Sediment residues were generally much greater than those in the water column, and persisted from one year to the next.

For the purposes of calculating risk quotients for freshwater organisms in flowing water, certain residue values from the monitoring study were used. For acute risk quotients, the value used was 10 ppb, the maximum level measured at a discharge point immediately following application. For chronic risk quotients, the value used was 0.77 ppb, the maximum level measured at a discharge point more than 7 days after application. This value is greater than any 21-day average concentration, but its use is justified by the often erratic timing of canal discharges. Monitoring data from the flatwood region were used to

generate a preliminary risk assessment. However, additional studies conducted over multiple years are necessary to study the potential for accumulation over multiple years. Computer model EEC's were used to assess the risks to more static water because the Agency believes that the conditions under which the pond study was conducted were less than high exposure.

Maximum residue in/on citrus leaves was 260 ppm. The foliar dissipation half-life was determined to be 42 days; measured foliar residues as high as 29 ppm were present from the previous year's applications.

The maximum measured soil residue level was 4.1 ppm (within the grove). Very little degradation occurred in soil during the 60 days between applications.

The study provides some usable data for assessing aquatic risks from the use of fenbutatin-oxide in the freshwater to brackish flatwood regions of Florida. However, the data may not reflect expected accumulations over multiple-year use. In addition, the Agency believes that the pond data reflect less than high exposure conditions. (MRID 42872101)

4. 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 combining both 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). The generic risk quotients and their respective LOC's for each risk assessment are provided in the table below. Note that the same risk quotients are used for non-endangered and endangered species, but the acute LOC is lower for endangered species.

Established Levels of Concern (LOC's)

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
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	N/A	N/A	N/A

Non-Endangered Terrestrial Organisms

Exposure of birds and mammals to fenbutatin-oxide is expected through the consumption of insect and plant food material containing fenbutatin-oxide residues and by direct exposure during application.

Acute Effects

No acute hazard to birds or mammals is expected following direct application to vegetation at the maximum use rate. Expected residue levels on terrestrial food items range from 14 to 480 ppm. The risk quotient, using the highest residue level and the avian dietary LC_{50}, is 480/5620 = 0.1, which is well below the LOC of 0.5. The mammalian LD_{50} value of 4400 mg/kg also results in no expected hazard at the highest application rate.

Chronic Effects

Avian reproduction studies showed no adverse effects at 150 ppm, the highest rate tested. The no observed effect level (NOEL), 150 ppm, was used to calculate the chronic risk quotients for birds.

The use of fenbutatin-oxide at current rates presents the potential for chronic hazard to birds and mammals. The following table outlines the expected residue levels at various application rates. These expected

environmental concentrations (EECs) are from the Kenaga nomograph.

Residues (ppm) and Risk Quotients (RQ's) for Avian Species:

Application Rate (lb a.i./A)	Short Grass	Short Grass RQ	Long Grass	Long Grass RQ	Leaves /Leafy Crops	Leaf Crop RQ
1.00	240	1.6	110	0.7	125	0.8
1.25	300	2.0	138	0.9	156	1.0
1.50	360	2.4	165	1.1	188	1.3
2.00	480	3.2	220	1.5	250	1.7

Shaded areas in the above table indicate the use patterns that exceed the avian chronic LOC. These values indicate potential for chronic risk to birds. The potential is increased because fenbutatin-oxide is persistent in aquatic and terrestrial environments and has been shown to accumulate in fish. In addition, many of the registered use sites (citrus, pome fruits, stone fruits, nuts) are high exposure sites for breeding and nesting birds.

The above conclusions are supported by relevant data from the field monitoring study in citrus, where the groves were each treated twice at 60-day intervals with 2 lb a.i./A. Citrus foliage samples were taken from each of 4 groves from the day of first application through sixty days after the second application, with concentrations ranging from 18.0 to 260.0 ppm. Residues in seven (22%) of the 32 composite samples exceeded or were within 10% of the avian chronic LOC. On the basis of the same data set, the authors determined a foliar dissipation half-life of 42 days, which indicates that only partial dissipation will occur between applications 60 days apart.

The chronic hazard assessment for mammals uses the same risk quotient, LOC and EEC values as used in the avian assessment, with the exception that the mammalian NOEL is substituted for the avian NOEL value. Data from a rat reproduction study established a mammalian NOEL of 75 ppm. The table below shows the risk quotient for each of the fenbutatin-oxide use patterns.

Residues (ppm) and Risk Quotients (RQ's) for Mammals:

Application Rate (lb a.i./A)	Short Grass	Short Grass RQ	Long Grass	Long Grass RQ	Leaves /Leafy Crops	Leaf Crop RQ
1.00	240	3.2	110	1.5	125	1.7
1.25	300	4.0	138	1.8	156	2.1
1.50	360	4.8	165	2.2	188	2.5
2.00	480	6.4	220	2.9	250	3.3

Using the 75 ppm NOEL value, all of the risk quotients exceed the established LOC of 1.0. The potential for chronic risk is again increased by the persistence of fenbutatin-oxide and by desirability of many of the use sites as habitat for small mammals.

Data from the field monitoring study support the conclusion of chronic hazard. Based on the same set of foliage samples, residues in 19 of the 32 composite samples (59.4%) exceeded the chronic NOEL for mammals. These residues ranged from 18.0 to 260.0 ppm.

Non-Endangered Aquatic Organisms

Fish and aquatic invertebrates are expected to be exposed to fenbutatin-oxide through drift and runoff from treated areas.

Acute Effects

At current application rates, acute risk to freshwater fish can be expected from all major uses. Acute hazard to freshwater invertebrates can be expected for the citrus use. The major use sites for which estuarine and marine organisms are a concern are citrus and apples. Acute risk to estuarine fish and invertebrates is expected for the citrus use. Acute risk to estuarine invertebrates is expected for the apple use.

The aquatic acute hazard assessment calculates the risk quotient as the EEC/LC_{50} and uses an LOC of 0.5. The assessment also uses eco-toxicity values of the rainbow trout LC_{50} (1.7 ppb) and the Daphnia magna EC_{50} (10 ppb). Computer-estimated instantaneous environmental concentrations (EEC's) are provided in the following table. The EEC's

for citrus, apples and grapes are based on the standard environmental fate surface water models for a 10 hectare field draining into a 1 hectare, 2 meter deep pond using the one in ten-year maximum values modeled over 36 years. The EEC's for almonds and stone fruits are based on the values derived for the other three crops. In addition, actual monitoring data were used to calculate the preliminary risk quotients for flowing water associated with fenbutatin-oxide use on citrus in the flatwood region of Florida.

Since two separate studies were submitted, each showing different K_d values for sandy soil, the Agency has accepted a range of K_d values for sandy soils. Use of the higher K_d values for the citrus EEC calculations results in a lower aquatic EEC, as indicated in the table. The differing K_d values for sandy soils affects the EEC calculations for citrus only. The EEC's for apples, grapes, almonds and stone fruits are static because these crops are generally grown in finer textured soils, for which the K_d values are only addressed in one study. Both modelled EEC values for citrus were used to calculate a range of risk quotients for the citrus use.

Rather than use a calculated EEC value to estimate hazard to aquatic organisms in flowing water, the assessment uses an actual measured value from the citrus monitoring study.

Estimated Environmental Concentrations (Instantaneous):

Crop	Application Rate (lb a.i./A)	EEC Using Lower K_d Value	EEC Using Higher K_d Value (ppb)	Flowing Water EEC (Monitoring Study) (ppb)
Citrus	2.00	12.7	5.4	10.0
Apples	1.50		3.0	
Grapes	1.25		2.5	
Almonds	1.25		3.0	
Stone Fruits	1.00		2.0	

Data from the citrus monitoring study support the above estimates. Maximum residues in nearby aquatic environments ranged from 1.7 ppb (pond) to as high as 111 ppb (lateral and perimeter

canals). The flowing water EEC cited above (10 ppb) is the maximum measured level at a discharge site immediately following application.

The following table shows the risk quotients for freshwater fish/invertebrates using the above EEC's and the rainbow trout/Daphnia magna LC_{50}'s (1.7 ppb/10.0 ppb).

Risk Quotients (RQ's) for Freshwater Fish/Invertebrates:

Crop	Application Rate (lb a.i./A)	RQ in Static H_2O w/ lower K_d*	RQ in Static H_2O w/ higher K_d*	RQ in Flowing H_2O w/ monitor study K_d*
Citrus	2.00	7.5/1.3	3.2/0.5	5.9/1.0
Apples	1.50		1.8/0.3	
Grapes	1.25		1.5/0.3	
Almonds	1.25		1.8/0.3	
Stone Fruits	1.00		1.2/0.2	

* RQ's correspond to the EEC's divided by the rainbow trout/Daphnia magna LC_{50} for each instance

The risk quotients for freshwater fish range from 1.2 for stone fruits to 7.5 for the citrus use. The freshwater fish LOC of 0.5 is exceeded for all major uses. Acute risk to freshwater fish is expected for all major uses at the current application rates. Acute risk to freshwater invertebrates is only expected for the citrus use, where the risk quotients range from 0.5 to 1.3.

The risk quotients calculated for freshwater fish with the citrus use include three values: 3.2 for the modelled static water scenario using the higher K_d value; 5.9 using the flowing water residue value from the monitoring study; and 7.5 for the modelled static water scenario using the lower K_d value. Despite the large differences in K_d values, a risk quotient of 5.9 still results from the monitoring study, causing the Agency to conclude that a significant potential for acute risk to freshwater fish exists.

Since apple orchards and citrus groves are often located close to

estuarine areas, the citrus and apple uses of fenbutatin-oxide generate estuarine concerns. EEC's based on modeling are not yet available for estuarine and marine environments, therefore, the analysis used freshwater EEC's from the previous table to estimate exposure in these environments. For citrus, the flowing water value from the citrus monitoring study (10 ppb) was also used. Acute LC_{50} values for estuarine organisms are:

Sheepshead minnow LC_{50} = 20.8 ppb;
Mysid shrimp LC_{50} = 2.8 ppb;
Oyster embryolarvae LC_{50} = 0.4 ppb.

Risk quotients for each of these organisms are shown in the table below:

Risk Quotients (RQ's) for Sheepshead Minnow/Mysid Shrimp/Oyster

Crop	Application Rate (lb a.i./A)	RQ in Static H_2O w/ lower K_d	RQ in Static H_2O w/ higher K_d	RQ in Flowing H_2O w/ monitor study K_d
Citrus	2.00	0.6/4.5/31.8	0.3/1.9/13.5	0.5/3.6/25.0
Apples	1.50		0.1/1.1/7.5	

Estuarine invertebrates are extremely sensitive to fenbutatin-oxide. Acute risk to these organisms is expected from both the citrus and apple uses. The risk quotients for the oyster range from 7.5 to 31.8 and for the mysid shrimp from 1.1 to 4.5, which far exceed the LOC of 0.5. The results of the citrus residue monitoring study indicate that significant potential for acute risk to estuarine invertebrates exists.

For the estuarine fish, the LOC of 0.5 is exceeded for the citrus use for the risk quotient based on static water modelled with the lower K_d.

Chronic Effects

Chronic risk to freshwater and estuarine fish can be expected from use on citrus, but is not anticipated for other major uses at the current application rates. There is no chronic risk anticipated for freshwater and estuarine invertebrates.

The aquatic chronic hazard assessment uses the geometric mean of the No Observed Effect Level (NOEL) and the Lowest Observed Effect Level (LOEL) to estimate the Lowest Effect Level (LEL). This number is referred to as the Maximum Allowable Toxicant Concentration (MATC). Eco-toxicity values for freshwater organisms used in this assessment are the MATC for rainbow trout (0.435 ppb) and Daphnia magna (24 ppb). Estimated chronic environmental concentrations are provided in the following table. These estimates are based on the standard environmental fate surface water models.

As in the acute assessment, the Agency is using a range of K_d values for sandy soils. Use of the higher K_d values for the citrus EEC calculations results in a lower aquatic EEC, as indicated in the table. Ranges apply only to citrus, since apples, grapes, almonds and stone fruits are generally grown in finer textured soils as discussed earlier. Both modeled EEC values for citrus were used to calculate a range of risk quotients for the citrus use. To estimate hazard to aquatic organisms in flowing water, an actual EEC measured in the citrus monitoring study was used instead of a calculated EEC.

Estimated Environmental Concentrations (Chronic):

Crop	Application Rate (lb ai/A)	21-day (ppb)	60-day (ppb)	90-day (ppb)	Flowing H_2O (Monitoring) (ppb)
Citrus*	2.00	12.7/0.5	12.7/0.5	12.7/0.5	0.77**
Apples	1.50	0.20	0.20	0.20	
Grapes	1.25	0.14	0.10	0.07	

* For the 21-day, 60-day and 90-day intervals in citrus, the EEC's are presented as calculations based on the lower K_d/higher K_d

** Represents the maximum measured level at a discharge site more than 7 days after application

The following table shows the chronic risk quotients, defined as

the EEC divided by the MATC, for freshwater fish. These risk quotients are based on the above EEC's and the MATC for rainbow trout (0.435 ppb). The level of concern is 1.0.

Chronic Risk Quotients for Freshwater Fish:

Crop	Application Rate (lb ai/A)	RQ for lower K_d (21/60/90-days)	RQ for higher K_d (21/60/90-days)	Flowing H_2O (Monitoring Study)
Citrus	2.00	29.2	1.1/1.1/1.1	1.8
Apples	1.50		0.5/0.5/0.5	
Grapes	1.25		0.3/0.2/0.2	

Since EEC's based on modeling were not available for estuarine and marine environments, freshwater EEC's were used to estimate such exposure. Likewise since no estuarine chronic eco-toxicity data were available, the estuarine risk assessments were based on the chronic freshwater values only. The citrus and apple uses of fenbutatin-oxide raise estuarine concerns as they are often closely associated with estuarine areas.

The following table shows the chronic risk quotients for freshwater invertebrates, based on the above EEC's and the MATC for Daphnia magna (24 ppb). The level of concern for freshwater and estuarine invertebrates is 1.0.

Chronic Risk Quotients for Freshwater Invertebrates:

Crop	Application Rate (lb ai/A)	RQ for lower K_d (21/60/90-days)	RQ for higher K_d (21/60/90-days)	Flowing H_2O (Monitoring Study)
Citrus	2.00	0.5	0.02/0.02/0.02	0.03
Apples	1.50		0.01/0.01/0.01	
Grapes	1.25		0.01/0/0	

There is significant potential for chronic risk to freshwater and

estuarine fish from the use of fenbutatin-oxide on citrus. There are no chronic concerns for freshwater and estuarine invertebrates. The potential for chronic risk to fish is increased because fenbutatin-oxide is very persistent in aquatic environments and may accumulate in fish. In addition, citrus use sites are often in close proximity to estuarine environments.

The chronic risk quotients calculated for fish for the citrus use range from 1.1 to 29.2. Despite the large differences in K_d values, a risk quotient of 1.8 results from the monitoring study, supporting the Agency's conclusion that a significant potential for chronic risk to fish exists, regardless of which K_d value is used.

Although the higher K_d values tend to indicate that fenbutatin-oxide is expected to be associated more with the sediment than the water column, it is possible that levels approaching the aqueous solubility of approximately 12 ppb will be maintained in the water after several years of continuous use due to high accumulation in the sediment and slow release into the water. Measured residues in the field residue monitoring study showed some tendency for partitioning into the sediment.

Terrestrial Plants

Hazard to nontarget plants is not anticipated from the use of fenbutatin-oxide.

Nontarget Insects

Hazard to bees is not anticipated from the use of fenbutatin-oxide.

Endangered Terrestrial Organisms

Acute risk to endangered birds and mammals is not expected from any of the current uses. There is a potential for chronic hazard to these organisms from the use of fenbutatin-oxide at current rates.

Endangered Aquatic Organisms

Acute risk to endangered freshwater fish and invertebrates is expected from all major uses. The endangered species LOC is 0.05. The risk quotients for freshwater fish range from 1.2 to 7.5, while those for invertebrates range from 0.2 to 1.3. There is acute hazard to

endangered estuarine fish and invertebrates for both the citrus and the apple uses. For the citrus use the fish risk quotients range from 0.3 to 0.6 and the invertebrate risk quotients range from 1.9 to 31.8. For the apple use the fish risk quotient is 0.1 and the invertebrate risk quotients range from 1.1 to 7.5.

The LOC's for chronic hazard are the same for both endangered and non-endangered species. Fenbutatin-oxide on citrus at current rates presents significant potential for chronic hazard to endangered freshwater and estuarine fish.

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 fenbutatin-oxide as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing fenbutatin-oxide. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of fenbutatin-oxide, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of fenbutatin-oxide and to determine whether fenbutatin-oxide can be used without resulting in unreasonable adverse effects to humans and the environment. To ensure that the potential risks of fenbutatin-oxide are not unreasonable, the Agency is classifying fenbutatin-oxide as a Restricted Use pesticide and requiring the registrant to implement certain risk mitigation measures. Provided these measures are implemented, as discussed below, the Agency finds that all products containing fenbutatin-oxide as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that all uses of fenbutatin-oxide are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing fenbutatin-oxide following review of additional sampling data, if

new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient fenbutatin-oxide, the Agency has sufficient information on the health effects of fenbutatin-oxide and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing fenbutatin-oxide for all uses are eligible for reregistration.

The Agency has determined that fenbutatin-oxide products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

Although the Agency has determined that all uses of fenbutatin-oxide are eligible for reregistration, the Agency is requiring additional risk mitigation measures for the use of fenbutatin-oxide on citrus in Florida. These measures are designed to mitigate the risk to both freshwater and estuarine aquatic organisms that are found near Florida's citrus groves.

B. Regulatory Position

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

1. Risk Mitigation Measures

In order to reregister all uses of fenbutatin-oxide, the Agency is classifying all fenbutatin-oxide products as Restricted Use pesticides for use by certified applicators (or persons under their supervision) only. The Agency has determined that the criteria set forth in 40 CFR 15.170(c)(iii) and 40 CFR 152.170(c)(iv) have been met. The Agency is also requiring additional mitigation measures, including reduced application rates, label amendments with instructions to minimize spray drift, development of more accurate aquatic modeling, and monitoring to determine if fenbutatin-oxide levels accumulate over multiple years of use.

The registrant is reducing the application rates of fenbutatin-oxide on

most crops, including a 50% reduction in the use on citrus from a maximum of 4 pounds of active ingredient per acre, per season, to 2 pounds of active ingredient.

The registrant is also eliminating the aerial application of fenbutatin-oxide in the ecologically-sensitive flatwoods section of Florida and implementing other restrictions on both aerial and airblast applications in Florida. These restrictions are detailed in the Actions Required By Registrants Section.

In addition, the Agency is requiring the registrant to evaluate the mitigation measures through both a modeling and a sediment monitoring program. The registrant will work closely with the Agency to develop a modeling and sampling program that reflects the use of fenbutatin-oxide on Florida citrus.

2. Restricted Use Classification

Because of its very high toxicity to aquatic organisms, the Agency is requiring restricted use status for all uses of fenbutatin-oxide. Applicator training will be required and only certified applicators will be able to apply fenbutatin-oxide.

The Agency believes the Restricted Use classification is appropriate for all uses of fenbutatin-oxide. Many of the use sites are located on or near bodies of water and fenbutatin-oxide has been shown to be very highly toxic to freshwater and estuarine aquatic organisms. In addition, fenbutatin-oxide persists in the environment long after the initial application. The potential for serious contamination of the eco-system is substantial.

The Agency is using the authority of FIFRA section 3(d)(1) to classify fenbutatin-oxide as "Restricted Use". Fenbutatin-oxide meets the criteria for restricted use by certified applicators for hazard to non-target species as stated in CFR 152.170 because of its toxicity to freshwater and estuarine aquatic organisms.

When the Agency classifies a use of a pesticide as Restricted, the pesticide can only be used by or under the direct supervision of a certified applicator who is certified for that use. State Lead Agencies for pesticide programs carry out certification programs under cooperative agreement with the Agency. Each state that conducts a certification program has had a plan approved by the Agency to carry out that program. Within those plans, the states identify categories of certification and standards of competency that must

be met to become certified in each category. As required under FIFRA section 3(d)(1), the Agency will publish a notice of this proposed classification to Restricted Use in the Federal Register. Registrants will need to amend their registrations and product labels to incorporate the Restricted Use Statement, and the other required language in this RED, to coincide with the certification program.

3. Tolerance Reassessment

The tolerance expression for plants should include fenbutatin-oxide only. The tolerance expression for meat, milk, poultry and eggs should include fenbutatin-oxide and its metabolites dihydroxybis(2-methyl-2-phenylpropyl) stannane (SD-31723) and 2-methyl-2-phenylpropylstannoic acid (SD-33608) as well as the parent.

The following discussions address tolerance evaluations for each section in the Code of Federal Regulations. A summary table follows these discussions. A blank under the tolerance reassessment column in the summary table indicates that the current tolerance is adequate.

Tolerances listed under 40 CFR §180.362(a)

The tolerances listed in 40 CFR §180.362(a) are for the residues of fenbutatin-oxide. Sufficient data are available to ascertain the adequacy of the established tolerances listed for: almonds; almonds, hulls; apples; cherries, sour; cherries, sweet; citrus fruits; cucumbers; eggplant; grapes; papayas; peaches; pears; pecans; plums; prunes; strawberries; and walnuts. Certain commodity definitions of the above tolerances are not in accordance with the definitions listed in the Commodity Index Report dated 10/28/92; see the table and discussion below for modifications in commodity definitions.

The individual tolerances for "almonds" (0.5 ppm), "pecans" (0.5 ppm), and "walnuts" (0.5 ppm) should be revoked, and a tolerance for residues in or on "tree nuts group" should be established at 0.5 ppm. The available data from almonds, pecans, and walnuts will support this crop group tolerance.

The separate tolerances for "cherries, sour" (6.0 ppm) and "cherries, sweet" (6.0 ppm) should be combined into a single tolerance for residues in or on "cherries" (6.0 ppm).

The commodity definition for "citrus fruits" should be changed to "citrus fruits group."

The commodity definition for "plums" (4.0 ppm) should be changed to "plums (fresh prunes)," and the separate tolerance for prunes (4.0 ppm) should be revoked.

Tolerances listed under 40 CFR §180.362(b)

The tolerances listed in 40 CFR §180.362(b) are for the combined residues of fenbutatin-oxide and its organotin metabolites calculated as the parent. Sufficient data are available to ascertain the adequacy of the established tolerances for: cattle, fat; cattle, mbyp; cattle, meat; eggs; goats, fat; goats, mbyp; goats, meat; hogs, fat; hogs, mbyp; hogs, meat; horses, fat; horses, meat; horses, mbyp; milk fat; poultry, fat; poultry, mbyp; poultry, meat; sheep, fat; sheep, mbyp; and sheep, meat. Certain commodity definitions of the above tolerances are not in accordance with the definitions listed in the Commodity Index Report dated 10/28/92; see the table and discussion below for modifications in commodity definitions.

The commodity definition for "milk fat" should be changed to "milk, fat."

Tolerances listed under 40 CFR §180.362(c)

The tolerance listed in 40 CFR §180.362(c) is for residues of fenbutatin-oxide. Sufficient data are available to ascertain the adequacy of the established tolerance for: raspberries.

Tolerances listed under 40 CFR §185.3550

The tolerances listed in 40 CFR §185.3550 are for the residues of fenbutatin-oxide. Sufficient data are available to ascertain the adequacy of the established tolerances for: prunes, dried; and raisins. The commodity definitions of the above tolerances are not in accordance with the definitions listed in the Commodity Index Report dated 10/28/92; see the table below for modifications in commodity definitions.

Tolerances listed under 40 CFR §186.3550

The tolerances listed in 40 CFR §186.3550 are for the residues of fenbutatin-oxide. Sufficient data are available to ascertain the adequacy of the established tolerance for: grape pomace, dried.

The commodity definitions of the feed additive tolerances are not in

accordance with the definitions listed in the Commodity Index Report dated 10/28/92; see the table below for modifications in commodity definitions.

A feed additive tolerance has been proposed for "citrus, oil, refined" (140 ppm). The available processing data indicate that fenbutatin-oxide residues concentrate 6.9x in citrus oil.

The tolerance for "citrus pulp, dried" (35.0 ppm) has been proposed to be increased to 100 ppm; available processing data indicate that fenbutatin-oxide residues concentrate 4.8x in dried pulp.

The tolerance for "raisin waste" (20 ppm) has been proposed to be increased to 80 ppm; available processing data indicate that fenbutatin-oxide residues concentrate 1.7x in grape stems and 16.1x in stem waste.

Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 180.362(a)			
Almonds Pecans Walnuts	0.5 0.5 0.5	Revoke and establish at 0.5 ppm	*Tree nuts group*
Almonds, hulls	80.0		
Apples	15.0		
Cherries, sour Cherries, sweet	6.0 6.0	Combine into one tolerance at 6 ppm	*Cherries*
Citrus fruits	20.0		*Citrus fruits group*
Cucumbers	4.0		
Eggplant	6.0		
Grapes	5.0		
Papayas	2.0		
Peaches	10.0		
Pears	15.0		
Plums	4.0		*Plums (fresh prunes)*
Prunes	4.0	Revoke	Covered under "Plums (fresh prunes)"

TABLE B. *(Continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Strawberries	10.0		
Tolerances listed under 180.362(b)			
Cattle, fat	0.5		
Cattle, mbyp	0.5		
Cattle, meat	0.5		
Eggs	0.1		
Goats, fat	0.5		
Goats, mbyp	0.5		
Goats, meat	0.5		
Hogs, fat	0.5		
Hogs, mbyp	0.5		
Hogs, meat	0.5		
Horses, fat	0.5		
Horses, mbyp	0.5		
Horses, meat	0.5		
Milk fat	0.1		*Milk, fat*
Poultry, fat	0.1		
Poultry, mbyp	0.1		
Poultry, meat	0.1		
Sheep, fat	0.5		
Sheep, mbyp	0.5		
Sheep, meat	0.5		
Tolerances listed under 180.362(c)			
Raspberries	10.0		
Tolerances listed under 185.3550			
Prunes, dried	20.0		*Prunes*

TABLE B. *(Continued)*.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Raisins	20.0		*Grapes, raisins*
Tolerances listed under 186.3550			
Apple pomace, dried	75	30	*Apples, pomace, wet*
Citrus oil	--	140	*Citrus, oil, refined*
Citrus pulp, dried	35.0	100	*Citrus, pulp, dried*
Grape pomace, dried	100.0		*Grapes, pomace, wet and dried*
Raisin waste	20.0	80	*Grapes, raisin, waste*

Codex Harmonization

Several maximum residue limits (MRLs) for fenbutatin-oxide have been established by Codex in various commodities. The Codex MRLs (currently expressed in terms of fenbutatin-oxide) and applicable U.S. tolerances (currently expressed in terms of the combined residues of fenbutatin-oxide and its organotin metabolites) are listed in the table below. The tolerance expression for plants should include fenbutatin-oxide only. The tolerance expression for meat, milk, poultry and eggs should include metabolites dihydroxybis(2-methyl-2-phenylpropyl)stannane (SD-31723) and 2-methyl-2-phenylpropyl stannoic acid (SD-33608) as well as the parent.

Because of the differences between the Codex and the current and recommended U.S. tolerance expressions for animal commodities, compatibility is not achievable. Furthermore, with the exception of the tolerance levels for grapes (5 ppm and 5 mg/kg), U.S. tolerance levels are higher than the corresponding Codex MRLs. The established or reassessed U.S. tolerances for citrus pulp, dried; eggplant; and meat of cattle, goats, hogs, horses, and sheep exceed the corresponding codex MRLs by factors greater than 5x. Available data indicate that U.S. agricultural practices involving applications of fenbutatin-oxide can result in residues that exceed the Codex MRLs, making it unlikely that U.S. tolerance levels could be lowered to achieve compatibility with Codex MRLs.

No questions of compatibility exist with respect to commodities where:

(i) no codex MRL's have been established but U.S. tolerances exist; and (ii) Codex MRLs have been established but U.S. tolerances do not exist.

Codex MRL's and Applicable U.S. Tolerances

Commodity	Codex MRL (mg/kg)	Reassessed U.S. Tolerance (ppm)
Apple	5	15 (Apples)
Apple pomace, wet	20	30 (Apples, pomace, wet)
Cherries	5	6 (Cherries)
Citrus fruits	5	20 (Citrus fruits group)
Citrus pulp, dry	7	100 (Citrus, pulp, dried)
Cucumber	1	4 (Cucumbers)
Eggplant	1	6 (Eggplant)
Gherkin	1	4 (Cucumbers)
Grapes	5	5 (Grapes)
Horse kidney	0.2	0.5 (Horses, mbyp)
Horse liver	0.2	0.5 (Horses, mbyp)
Kidney of cattle, goats, pigs, and sheep Liver of cattle, goats, pigs, and sheep	0.2 0.2	0.5 (Cattle, mbyp) 0.5 (Goats, mbyp) 0.5 (Hogs, mbyp) 0.5 (Sheep, mbyp)
Meat of cattle, goats, horses, pigs, and sheep	0.02	0.5 (Cattle, meat) 0.5 (Goats, meat) 0.5 (Horses, meat) 0.5 (Hogs, meat) 0.5 (Sheep, meat)
Melons, except Watermelon	1	N/A
Milks	0.02	0.1 (Milk, fat)
Peach	7	10 (Peaches)
Pear	5	15 (Pears)
Peppers, Sweet	1	N/A
Plums (including Prunes)	3	4 [Plums (fresh prunes)] 20 (Prunes)
Strawberry	3	10 (Strawberries)
Tomato	1	N/A

4. Endangered Species Statement

Acute hazard to endangered birds and mammals is not expected from any current use. There is significant potential for chronic hazard to these organisms from the use of fenbutatin-oxide at current rates.

There is significant acute hazard to endangered freshwater aquatic organisms from all major uses at current application rates. For the two use sites, citrus and apples, that raise estuarine concerns due to their close proximity to estuarine areas, there is significant acute hazard to endangered aquatic organisms. There is also significant potential for chronic hazard to freshwater and estuarine fish from the citrus use.

EPA is currently working with the U.S. Fish and Wildlife Service and other federal and state agencies to develop a program to avoid jeopardizing the continued existence of listed species from the use of pesticides. When this program goes into effect, endangered species precautionary labeling will be required.

5. Labeling Rationale

Due to fenbutatin-oxide's toxicity to aquatic organisms, all manufacturing-use products are required to bear a statement on the toxicity of the pesticide to fish and aquatic invertebrates. Please see the Actions Required by Registrants section for further details.

Due to the potential for chronic hazard to birds, mammals and aquatic organisms, all labels for end-use products containing fenbutatin-oxide must be amended to bear a statement on the toxicity of the pesticide and some application mitigation measures. Please see the Actions Required by Registrants section for further details.

Worker Protection Requirements

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 93-11, "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) for Handlers

For each 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.

There are no special toxicological concerns about fenbutatin-oxide that warrant the establishment of active-ingredient-based PPE requirements for handlers.

Early Entry PPE Requirements

The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval 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, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

For products containing fenbutatin-oxide, the PPE required for early entry is coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

Entry Restrictions for non-WPS Uses

Some registered uses of fenbutatin-oxide are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency has determined that, at this time, the entry restrictions discussed in this section need not apply to uses of fenbutatin-oxide outside the scope of the Worker Protection Standard for Agricultural Chemicals, including out-of-scope commercial uses. The predicted frequency, duration and degree of post-application exposure from these uses do not warrant the risk mitigation measures being required for persons engaged in the production of agricultural plants for commercial or research purposes.

All non-WPS occupational uses of fenbutatin-oxide end-use products must bear the following entry restriction, "Do not enter or allow others to enter the treated area until sprays have dried."

Entry Restrictions for Residential Products

The Agency is concerned about post-application exposures to homeowners following application of fenbutatin-oxide, therefore, residential products must contain the following requirement, "Do not allow persons or pets to enter the treated area until sprays have dried."

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.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of fenbutatin-oxide for the above eligible uses has been reviewed and determined to be substantially complete. However, the following additional generic data are required at this time:

61-2(b)	Discussion of formation impurities
63-12	pH
165-4	Bioaccumulation in fish
201-1	Droplet size spectrum
202-1	Drift field evaluation

2. Labeling Requirements for Manufacturing-Use Products

Toxicity Statement

Due to the toxicity of fenbutatin-oxide to birds, mammals and aquatic organisms, all manufacturing-use products must bear the following statement:

"This pesticide is toxic to birds, mammals, fish, and aquatic invertebrates."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA requires 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

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

Use Directions

In this RED document, all the uses of fenbutatin-oxide are being declared Restricted. For products being reregistered under this RED document, a restricted use legend must appear at the top of the front panel of the label. No other wording or symbols may appear above the legend and it must begin with the heading "RESTRICTED USE PESTICIDE," followed by a brief statement of the reason for the restricted use classification (i.e., "DUE TO VERY HIGH TOXICITY TO AQUATIC ORGANISMS"). Following this, the terms of the restriction must be stated as, "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."

Worker Protection Standard

Personal Protective Equipment for Handlers

There are no special toxicological concerns about fenbutatin-oxide that warrant the establishment of active-ingredient-based PPE requirements for handlers. The PPE for pesticide handlers will be based on the acute toxicity of the end-use product.

Entry Restrictions

For occupational end-use products containing fenbutatin-oxide as an active ingredient, the Agency is establishing a 48-hour restricted-entry interval for each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). For products containing fenbutatin-oxide, the PPE required for early entry permitted by the WPS is coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

All non-WPS occupational uses of fenbutatin-oxide end-use products must bear the following entry restriction: "Do not enter or allow others to enter the treated area until sprays have dried."

All residential products must bear the following entry restriction: "Do not allow persons or pets to enter the treated area until sprays have dried."

Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing fenbutatin-oxide that are intended primarily for occupational use:

Application Restrictions:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions 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."

Type of Respirator: If the acute inhalation toxicity of the end-use product is in category I or II, then a respirator is required for pesticide handlers. A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) is the only type of respirator that is appropriate to mitigate fenbutatin-oxide inhalation concerns.

Toxicity Statement

Due to the toxicity of fenbutatin-oxide to birds, mammals and aquatic organisms, all end-use product labels must bear the following statement:

"This pesticide is toxic to birds, mammals, fish, 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. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."

Drift Reductions

To mitigate the risks posed by fenbutatin-oxide's high toxicity to aquatic organisms, all end-use product labels with aerial applications must bear the following statements for citrus use in Florida:

1) Do not apply within 125 feet of bodies of water such as lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries.
2) Do not apply when gusts or sustained winds exceed 8 mph.
3) The boom length must not exceed 3/4 of the wing or rotor length (i.e. The distance of the outer-most nozzles on the boom must not exceed 3/4 of the length of the wingspan or rotor).
4) Do not apply at a height greater than 10 feet above the top of the

target plants unless a greater height is required for aircraft safety.

5) Nozzles must always point backward and never be pointed downwards more than 45 degrees.
6) Do not apply in less than 10 gallons of final spray per acre.
7) Do not apply east of US Highway #1, south and east of State Road #846 or south of West Palm Beach Canal.

All end-use products using airblast applications must bear the following statements for citrus use in Florida:

1) Citrus groves may be planted close to bodies of water. Do not apply within 25 feet of bodies of water such as lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries.
2) For all plantings within 75 feet of bodies of water as described above, spray trees only from outside the planting away from the bodies of water.
3) Shut off the sprayer when turning at row ends.
4) Do not apply when gusts or sustained winds exceed 12 mph.

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 fenbutatin-oxide 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 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													
FOOD/FEED USES													
ALMOND				Use Group: TERRESTRIAL FOOD+FEED CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
APPLE				Use Group: TERRESTRIAL FOOD+FEED CROP									
High volume spray (dilute)., Prebloom through foliar., High volume ground.	EC	NA	1.5 lb A	*	4	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.5 lb A	*	4	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Prebloom through foliar., Low volume ground.	EC	NA	1.5 lb A	*	4	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.5 lb A	*	4	NS	NS	NS	AN	1			C46, G20, H01(14)
CHERRY				Use Group: TERRESTRIAL FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1.5 lb A	*	NS	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.5 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1.5 lb A	*	NS	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.5 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
CITRUS FRUITS				Use Group: TERRESTRIAL FOOD+FEED CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	4 lb A	*	NS	2/1 yr	NS	NS	60	1			C46, G06, H01(7)
	WP	NA	4 lb A	*	NS	2/1 yr	NS	NS	60	1			C46, G20, H01(7)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	2 lb A	*	NS	2/1 yr	NS	NS	60	1			C46, G06, H01(7)
	WP	NA	2 lb A	*	NS	2/1 yr	NS	NS	60	1			C46, G20, H01(7)

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 Max. /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													
FOOD/FEED USES (con't)													
EGGPLANT			Use Group: TERRESTRIAL FOOD CROP										
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	2 lb A	*	3	NS	NS	6 lb	AN	1			C46, G06, H01(3)
	WP	NA	2 lb A	*	3	NS	NS	6 lb	AN	1			C46, G20, H01(3)
GRAPES			Use Group: TERRESTRIAL FOOD+FEED CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1.25 lb A	*	2	NS	NS	NS	21	1			C46, G06, H01(28)
	WP	NA	1.25 lb A	*	2	NS	NS	NS	21	1			C46, G20, H01(28)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1.25 lb A	*	2	NS	NS	NS	21	1			C46, G06, H01(28)
	WP	NA	1.25 lb A	*	2	NS	NS	NS	21	1			C46, G20, H01(28)
NECTARINE			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
PAPAYA			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	WP	NA	1 lb A	*	9	NS	NS	NS	30	1	CA		C46, G20, H01(7)
PEACH			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)

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													
FOOD/FEED USES (con't)													
PEAR			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Prebloom through foliar., High volume ground.	EC	NA	1.5 lb A	*	4	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.5 lb A	*	4	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Prebloom through foliar., Low volume ground.	EC	NA	1.5 lb A	*	4	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.5 lb A	*	4	NS	NS	NS	AN	1			C46, G20, H01(14)
PECAN			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
PLUM			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
PRUNE			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)

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													
FOOD/FEED USES (con't)													
RASPBERRY (BLACK, RED)			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Postharvest., High volume ground.	EC	NA	1 lb A	*	2	NS	NS	NS	21	NS	OR		C46, H01(7)
	EC	NA	1 lb A	*	2	NS	NS	NS	21	NS	WA		C46, H01(7)
	WP	NA	1 lb A	*	2	NS	NS	NS	21	NS	OR		C46, H01(7)
	WP	NA	1 lb A	*	2	NS	NS	NS	21	NS	WA		C46, H01(7)
High volume spray (dilute)., Preharvest., High volume ground.	EC	NA	1 lb A	*	3	NS	NS	NS	21	NS	OR		C46, H01(7)
	EC	NA	1 lb A	*	3	NS	NS	NS	21	NS	WA		C46, H01(7)
	WP	NA	1 lb A	*	3	NS	NS	NS	21	NS	OR		C46, H01(7)
	WP	NA	1 lb A	*	3	NS	NS	NS	21	NS	WA		C46, H01(7)
STRAWBERRY			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1 lb A	*	4	NS	NS	NS	AN	1			C46, G06, H01(1)
	WP	NA	1 lb A	*	4	NS	NS	NS	AN	1			C46, G20, H01(1)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1 lb A	*	4	NS	NS	NS	AN	1			C46, G06, H01(1)
	WP	NA	1 lb A	*	4	NS	NS	NS	AN	1			C46, G20, H01(1)
WALNUT (ENGLISH/BLACK)			Use Group: TERRESTRIAL FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
Low volume spray (concentrate)., Foliar., Low volume ground.	EC	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G06, H01(14)
	WP	NA	1.25 lb A	*	2	NS	NS	NS	AN	1			C46, G20, H01(14)
NON-FOOD/NON-FEED													

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)													
CHRISTMAS TREE PLANTATIONS			Use Group: TERRESTRIAL NON-FOOD CROP										
Low volume spray (concentrate)., Foliar., Aircraft.	EC	NA	1 lb A	*	1	NS	NS	NS	NS	NS	OR		C46
	EC	NA	1 lb A	*	1	NS	NS	NS	NS	NS	WA		C46
Spray., Foliar., Airblast.	EC	NA	1 lb A	*	1	NS	NS	NS	NS	NS	OR		C46
	EC	NA	1 lb A	*	1	NS	NS	NS	NS	NS	WA		C46
ORNAMENTAL AND/OR SHADE TREES			Use Group: GREENHOUSE NON-FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	UC	*	NS	NS	NS	NS	AN	1			C46, G06
High volume spray (dilute)., Nurserystock., High volume ground.	EC	NA	UC	*	NS	NS	NS	NS	AN	1			C46, G06
			Use Group: TERRESTRIAL NON-FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	EC	NA	UC	*	NS	NS	NS	NS	AN	1			C46, G06
	WP	NA	UC	*	NS	4/1 yr	NS	NS	AN	1			C46, G20
High volume spray (dilute)., Nurserystock., High volume ground.	EC	NA	UC	*	NS	NS	NS	NS	AN	1			C46, G06
			Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL										
Soil treatment., Foliar., Hose-end sprayer.	EC	NA	UC	*	NS	NS	NS	NS	21	NS			
Soil treatment., Foliar., Power sprayer.	EC	NA	UC	*	NS	NS	NS	NS	21	NS			
Soil treatment., Foliar., Tank-type sprayer.	EC	NA	UC	*	NS	NS	NS	NS	21	NS			
Spray., Foliar., Hose-end sprayer.	EC	NA	UC	*	NS	NS	NS	NS	7	NS			
Spray., Foliar., Power sprayer.	EC	NA	UC	*	NS	NS	NS	NS	7	NS			
Spray., Foliar., Tank-type sprayer.	EC	NA	UC	*	NS	NS	NS	NS	7	NS			
			Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP										
High volume spray (dilute)., Foliar., High volume ground.	WP	NA	UC	*	NS	NS	NS	NS	AN	1			C46, G20

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)									
High volume spray (dilute)., Nurserystock., High volume ground.	WP	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G20
ORNAMENTAL HERBACEOUS PLANTS				Use Group: GREENHOUSE NON-FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
High volume spray (dilute)., Nurserystock., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
				Use Group: TERRESTRIAL NON-FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
	WP	NA		UC	*	NS	4/1 yr	NS	NS	AN	1		C46, G20
High volume spray (dilute)., Nurserystock., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Soil treatment., Foliar., Hose-end sprayer.	EC	NA		UC	*	NS	NS	NS	NS	21	NS		
Soil treatment., Foliar., Power sprayer.	EC	NA		UC	*	NS	NS	NS	NS	21	NS		
Soil treatment., Foliar., Tank-type sprayer.	EC	NA		UC	*	NS	NS	NS	NS	21	NS		
Spray., Foliar., Hose-end sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	NS		
	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spray., Foliar., Power sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	NS		
	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spray., Foliar., Tank-type sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	NS		
	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	WP	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G20

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 HERBACEOUS PLANTS (con't)				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP (con't)									
High volume spray (dilute)., Nurserystock., High volume ground.	WP	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G20
ORNAMENTAL NONFLOWERING PLANTS				Use Group: GREENHOUSE NON-FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
High volume spray (dilute)., Nurserystock., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
				Use Group: TERRESTRIAL NON-FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
	WP	NA		UC	*	NS	4/1 yr	NS	NS	AN	1		C46, G20
High volume spray (dilute)., Nurserystock., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Soil treatment., Foliar., Hose-end sprayer.	EC	NA		UC	*	NS	NS	NS	NS	21	NS		
Soil treatment., Foliar., Power sprayer.	EC	NA		UC	*	NS	NS	NS	NS	21	NS		
Soil treatment., Foliar., Tank-type sprayer.	EC	NA		UC	*	NS	NS	NS	NS	21	NS		
Spray., Foliar., Hose-end sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	NS		
	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spray., Foliar., Power sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	NS		
	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
Spray., Foliar., Tank-type sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	NS		
	EC	NA		UC	*	NS	NS	NS	NS	AN	NS		
				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	WP	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G20

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 NONFLOWERING PLANTS (con't)				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP (con't)									
High volume spray (dilute)., Nurserystock., High volume ground.	WP	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G20
ORNAMENTAL WOODY SHRUBS AND VINES				Use Group: GREENHOUSE NON-FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
High volume spray (dilute)., Nurserystock., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
				Use Group: TERRESTRIAL NON-FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
	WP	NA		UC	*	NS	4/1 yr	NS	NS	AN	1		C46, G20
High volume spray (dilute)., Nurserystock., High volume ground.	EC	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G06
				Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL									
Soil treatment., Foliar., Hose-end sprayer.	EC	NA		UC	*	NS	NS	NS	NS	21	NS		
Soil treatment., Foliar., Power sprayer.	EC	NA		UC	*	NS	NS	NS	NS	21	NS		
Soil treatment., Foliar., Tank-type sprayer.	EC	NA		UC	*	NS	NS	NS	NS	21	NS		
Spray., Foliar., Hose-end sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	NS		
Spray., Foliar., Power sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	NS		
Spray., Foliar., Tank-type sprayer.	EC	NA		UC	*	NS	NS	NS	NS	7	NS		
				Use Group: TERRESTRIAL+GREENHOUSE NON-FOOD CROP									
High volume spray (dilute)., Foliar., High volume ground.	WP	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G20
High volume spray (dilute)., Nurserystock., High volume ground.	WP	NA		UC	*	NS	NS	NS	NS	AN	1		C46, G20

LEGEND

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)

SOIL TEXTURE FOR MAX APP. RATE

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

FORMULATION CODES

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
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.
G06 : Do not feed or graze livestock on cover crops in treated areas.
G20 : Do not feed or graze animals on cover crops in treated areas.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

CA	California
OR	Oregon
WA	Washington

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 Fenbutatin-oxide covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Fenbutatin-oxide 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 Fenbutatin-Oxide

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	40365801
61-2A	**Start. Mat. & Mnfg. Process**	All	00113071, 40365801, 40843601
61-2B	**Formation of Impurities**	All	00113071, 40365801
62-1	**Preliminary Analysis**	All	40590501
62-2	**Certification of limits**	All	40590501
62-3	**Analytical Method**	All	00053791, 00113071, 00113078, 40590501
63-2	**Color**	All	00113071, 40365801
63-3	**Physical State**	All	00113071, 40365801, 40560901
63-4	**Odor**	All	00113071, 40365801
63-5	**Melting Point**	All	00113071, 40365801
63-6	**Boiling Point**	All	N/A
63-7	**Density**	All	40365801
63-8	**Solubility**	All	00113071, 40365801, 40696401
63-9	**Vapor Pressure**	All	40365801
63-10	**Dissociation Constant**	All	N/A
63-11	**Octanol/Water Partition**	All	40696402
63-12	**pH**	All	40365801
63-13	**Stability**	All	00113071, 40365801

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	A, B, C, I, K	00113073
71-2A	**Avian Dietary - Quail**	A, B, C, I, K	40473505
71-2B	**Avian Dietary - Duck**	A, B, C, K	00113074
71-4A	**Avian Reproduction - Quail**	A, B, C	41258901
71-4B	**Avian Reproduction - Duck**	A, B, C	41258902
72-1A	**Fish Toxicity Bluegill**	A, B, C, K	00113076, 40098001
72-1B	**Fish Toxicity Bluegill - TEP**	A, B, C	40473508
72-1C	**Fish Toxicity Rainbow Trout**	A, B, C, I, K	00113075; 40098001; 40473506
72-1D	**Fish Toxicity Rainbow Trout- TEP**	A, B, C, K	40473507
72-2A	**Invertebrate Toxicity**	A, B, C, I, K	40473509
72-2B	**Invertebrate Toxicity - TEP**	A, B, C, K	40473511
72-3A	**Estuarine/Marine Toxicity - Fish**	A, B, C	41483301
72-3B	**Estuarine/Marine Toxicity - Mollusk**	A, B, C	40590507
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A, B, C	40590508
72-4A	**Early Life Stage Fish**	A, B, C	40473512
72-4B	**Life Cycle Invertebrate**	A, B, C	41551401
72-5	**Life Cycle Fish**	A, B, C	40525901
72-6	**Aquatic Organism Accumulation**	A, B, C	41551402
72-7B	**Actual Field - Aquatic Organisms**	A, B	42872101

Data Supporting Guideline Requirements for the Reregistration of Fenbutatin-Oxide

REQUIREMENT		USE PATTERN	CITATION(S)
141-1	**Honey Bee Acute Contact**	A, B, C	00036935
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A	40709901
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A	40709902
81-3	**Acute Inhalation Toxicity - Rat**	A	40473502, 40473503
81-4	**Primary Eye Irritation - Rabbit**	A	40709803, 40709805
81-5	**Primary Dermal Irritation - Rabbit**	A	40709803, 40709905
81-6	**Dermal Sensitization - Guinea Pig**	A	40709804, 40709806
82-1A	**90-Day Feeding - Rodent**	A	00037582, 00067049, 00113001
82-1B	**90-Day Feeding - Non-rodent**	A	00113002, 40977001, 41192401
82-2	**21-Day Dermal - Rabbit/Rat**	A	40641201
83-1A	**Chronic Feeding Toxicity - Rodent**	A	00037582, 00067049, 00113001
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A	00113002, 40977001, 41192401
83-2A	**Oncogenicity - Rat**	A	00037582, 00067049, 00113001
83-2B	**Oncogenicity - Mouse**	A	00037581, 00067048, 00113000
83-3A	**Developmental Toxicity - Rat**	A	00072693
83-3B	**Developmental Toxicity - Rabbit**	A	00049230, 00069880, 00079319
83-4	**2-Generation Reproduction - Rat**	A	41540601
84-2A	**Gene Mutation (Ames Test)**	A	40473501, 40770601

Data Supporting Guideline Requirements for the Reregistration of Fenbutatin-Oxide

REQUIREMENT		USE PATTERN	CITATION(S)
84-2B	**Structural Chromosomal Aberration**	A	40590502, 40590504
84-4	**Other Genotoxic Effects**	A	40590503, 40590505
85-1	**General Metabolism**	A	41069101
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	A	40083802
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A, C, I, K	40790901
161-2	**Photodegradation - Water**	A, C	40790902
161-3	**Photodegradation - Soil**	A, C	40790903
162-1	**Aerobic Soil Metabolism**	A, C, I, K	40257001
162-2	**Anaerobic Soil Metabolism**	A, C	40257002
163-1	**Leaching/Adsorption/Desorption**	A, C, I, K	40257003, 40257004
164-1	**Terrestrial Field Dissipation**	A, C, K	41608501, 42074501
164-5	**Long Term Soil Dissipation**	A, C, K	42896801
165-1	**Confined Rotational Crop**	A	41520702
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	A	00113018
171-4B	**Nature of Residue - Livestock**	A	00113018, 00113020, 00113029, 00113078, 41183801

Data Supporting Guideline Requirements for the Reregistration of Fenbutatin-Oxide

REQUIREMENT		USE PATTERN	CITATION(S)
171-4C	**Residue Analytical Methods - Plants/Livestock**	A	00026038, 00030349, 00045869, 00045870, 00069881, 00070506, 00077245, 00093721, 00105161, 00105203, 00105204, 00109280, 00112902, 00113018, 00113063, 00113078, 00130837, 00143694, 00145444, 00146038, 00148257, 00148733, 40750601, 40750602, 40750603, 40750604, 41110801, 41110802, 41110803, 41110804, 41110901, 41110902, 41520701, 42106801
171-4E	**Storage Stability**	A	00113063, 00113078, 00146308, 41110801, 41110901, 41520701, 42568701
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A	00113078
171-4K	**Crop Field Trials**	A	00026038, 00030349, 00045869, 00069881, 00071183, 00077245, 00093721, 00105161, 00105203, 00105204, 00109280, 00112902, 00113018, 00113063, 00145444, 00146038, 00148257, 00148733, 00109280, 41110801, 41110802, 41110803, 41110804, 41110902

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Fenbutatin-oxide

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.

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41110804 Eble, J. (1989) Magnitude of Residues of Fenbutatin Oxide and Two Metabolites in Grapes…after Application of Vendex Miticide: Project No. AMR-1126-88. Unpublished study prepared by The National Food Laboratory, Inc. in cooperation with McKenzie Laboratories, Inc. 54 p.

41110901 Barber, G. (1989) Freezer Storage Stability Study of Fenbutatin Oxide and Metabolites in Strawberries, Eggplants, and Almonds: Proj. ID AMR-991-87. Unpublished study prepared by McKenzie Laboratory. 41 p.

41110902 Marxmiller, R. (1989) Magnitude of Residues of Fenbutatin Oxide and Metabolites in Cocumbers Treated with Vendex Miticide: Proj. ID AMR-1138-88. Unpublished study prepared by E.I. du Pont de Nemours & Co., Inc. 104 p.

BIBLIOGRAPHY

MRID **CITATION**

41183801 Hawkins, D.; Mayo, B.; Jackson, A.; et al (1989) The Metabolism of Mass 119 Sn^{o}- Fenbutatin Oxide in Laying Hens: Project ID HRC/-DPT 185/89231 and AMR-922-87. Unpublished study prepared by Huntingdon Research Centre. 63 p.

41183802 Ravitz, S.; Baugher, D. (1989) Dislodgeable Foliar Residues of Vendex Miticide Applied to Citrus in California and Florida, 1988: OAI Project No. 26587: Du Pont Study No. AMR-981-87-I. Unpublished study prepared by Orius Associates in association with McKenzie Research. 107 p.

41192401 Smith, R. (1989) Toxicity Studies on the Pesticide SD14114: Two Year Oral Toxicity Test in Dogs: Supplement 2: Laboratory Project ID TLGR 0035.73. Unpublished study prepared by Shell Research Ltd. 33 p.

41258901 Beavers, J.; Hoxter, K.; Corbitt, A.; et al. (1989) Vendex Technical: A One-generation Reproduction Study with the Bobwhite (Colinus virginianus): Wildlife International Ltd. Project No. 112-201. Unpublished study prepared by Dupont Haskell Laboratory. 155 p.

41258902 Beavers, J.; Hoxter, K.; Corbitt, A.; et al. (1989) Vendex Technical: A One-generation Reproduction Study with the Mallard (Anas platyrhynchos): Wildlife International Ltd. Project No. 112-202. Unpublished study prepared by Dupont Haskell Laboratory. 152 p.

41483301 Boeri, R.; Ward, T. (1990) Acute Flow-through Toxicity of Vendex to the Sheepshead Minnow, Cyprinodon variegatus: Lab Project No.: HLO-78-90. Unpublished study prepared by Resource Analysts, Inc., EnviroSystems Div. 30 p.

41520701 McClory, J. (1990) Freezer Storage Stability Study of Fenbutatin Oxide in Cucumbers, Oranges, Plums, Apples, and Grapes: Lab Project I.D.: AMR-1495-89. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. in association with McKenzie Laboratories, Inc. 22 p.

41520702 Horne, P. (1990) Confined Accumulation Study of ¢119mSn-Fenbutatin Oxide on Rotational Crops: Lab Project I.D.: AMR-926-87. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 41 p.

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MRID	CITATION
41540601	Bentley, K. (1990) Reproductive and Fertility Effects with Vendex Technical (IN Y4332-5) Multigeneration Reproduction Study in Rats: Lab Project Number: 128-90: 8388-001. Unpublished study prepared by E. I. du Pont de Nemours and Co./Haskell Laboratory. 1262 p.
41551401	Boeri, R.; Ward, T. (1990) Early Life Stage Toxicity of Vendex to the Sheepshead Minnow, Cyprinodon variegatus: Lab Project No.: HLO 303-90. Unpublished study prepared by EnviroSystems Div. 182 p.
41551402	Boeri, R.; Ward, T. (1990) Life-cycle Toxicity of Vendex Technical to the Mysid, Mysidopsis bahia: Lab Project Number: HLO 304-90. Unpublished study prepared by EnviroSystems Div. 318 p.
41608501	Marxmiller, R.; McClory, J. (1990) Field Soil Dissipation of Vendex Miticide: Lab Project Number: AMR-1152-88. Unpublished study prepared by McKenzie Laboratories, Inc. 97 p.
42074501	Marxmiller, R.; McClory, J.; Stanley, B. (1991) Field Soil Dissipation of Vendex Miticide: Lab Project Number: AMR 1152-88. Unpulished study prepared by McKenzie Laboratories, Inc. 136 p.
42106801	Barber, G. (1990) Method Validation Study for Fenbutatin-Oxide and Metabolites in Agricultural Crops: Lab Project No: AMR/992/87. Unpublished study prepared by McKenzie Labs. 75 p.
42568701	McClory, J. (1992) Freezer Storage Stability Study of Fenbutatin Oxide and Metabolites in Strawberries, Eggplants, and Almonds: Supplement No. 1: Lab Project Number: AMR 991-88. Unpublished study prepared by E.I. DuPont de Nemours and Co. 37 p.
42721001	Amoo, J.; Walker, D. (1993) Solubility of Fenbutatin Oxide in n-Octanol and Dimethylformamide: Lab Project Number: AMR 2605-93. Unpublished study prepared by E.I. du Pont de Nemours and Co. 22 p.
42872101	Wallace, M.; Jenkins, J.; Sutherland, C.; et al. (1993) An Aquatic Residue Monitoring Study of Vendex 4L in Florida Citrus Groves: Amended Report I: Lab Project Number: 112-194: AMR 1165-88. Unpublished study prepared by McKenzie Labs, Inc. and Wildlife International Ltd. 764 p.

BIBLIOGRAPHY

MRID	CITATION
42896801	McClory, J.; Freeman, C.; Wetherington, J. (1993) Field Soil Dissipation of Vendex Miticide: Fenbutatin-Oxide: Lab Project Number: AMR 1152-88. Unpublished study prepared by E. I. du Pont de Nemours and Co.; Mckenzie Lab., Inc. 222 p.
43336401	Goodyear, A. (1993) (Carbon 14) Fenbutatin-Oxide: Adsorption/Desorption in Three Soils: FInal Report: Lab Project Number: 579/127/1015: 579/127. Unpublished study prepared by Hazelton UK. 83 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Fenbutatin-oxide. 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 Fenbutatin-oxide 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. Fenbutatin-oxide RED Fact Sheet

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 pet-

itions 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 REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
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_____

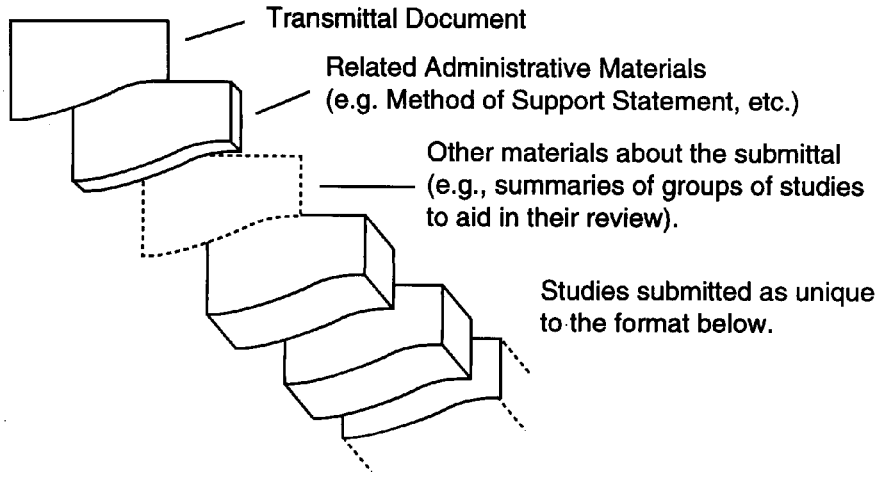
Example 3.

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.

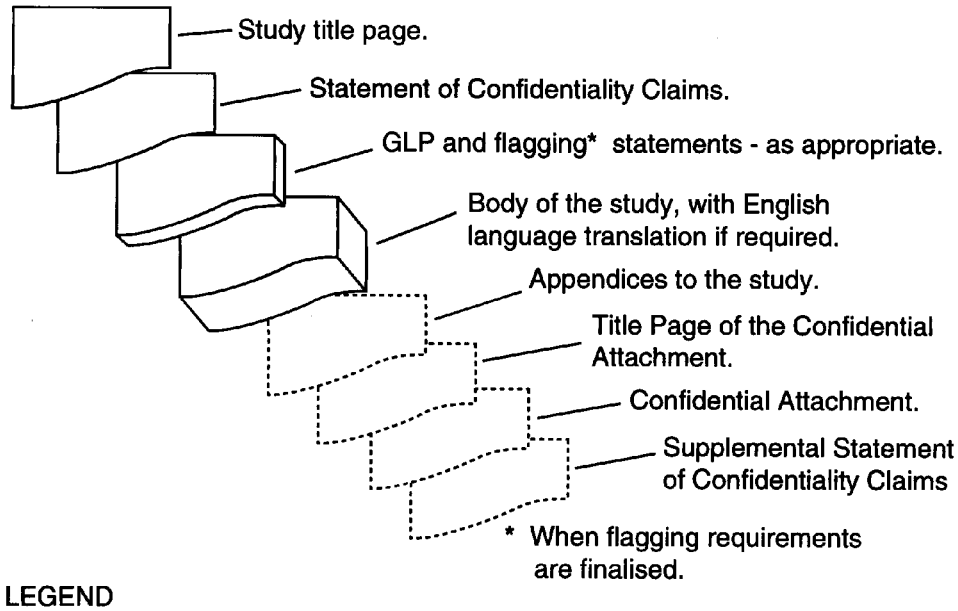
Submitter_____

ATTACHMENT 7.

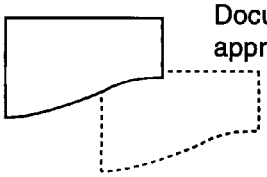
FORMAT OF THE SUBMITTAL PACKAGE



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

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 Reqistrant'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 Reqistrant'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 Reqistrant'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 Reqistrant'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 Reqistrant'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 Reqistrant'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 after 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, unless 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. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

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. INQUIRIES AND RESPONSES TO THIS NOTICE

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

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (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,

Louis P. True, Jr., Acting 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

Fenbutatin-oxide DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Fenbutatin-oxide. 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 Fenbutatin-oxide 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 Fenbutatin-oxide are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Fenbutatin-oxide are needed. These data are needed to fully complete the reregistration of all eligible Fenbutatin-oxide 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 Susan Jennings at (703) 308-8021.

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

Susan Jennings, 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: Fenbutatin-oxide

FENBUTATIN-OXIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Fenbutatin-oxide. 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 Fenbutatin-oxide 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 Fenbutatin-oxide are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Fenbutatin-oxide 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 Fenbutatin-oxide products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Fenbutatin-oxide, please contact Susan Jennings at (703) 308-8021.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008. (703) 308-8583.

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

Emily Mitchell
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Fenbutatin-oxide**

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.

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 agree 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

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.

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 Reqistrant'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 Indredient 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 lowvolume 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 product. For these cases, please supply all relevant details so that the Agency can ensure that its records are correct.

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

EPA'S BATCHING OF FENBUTATIN-OXIDE 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 the active ingredient fenbutatin-oxide, 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. Notwithstanding 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.

The table below shows the two EPA registrations and six Special Local Need (SLN) registrations which were placed into two batches.

BATCH NO.	EPA REG. NO. & SLN REG. No.	% of Fenbutatin-Oxide	Formulation Type
1	352-480	50.00% - Fenbutatin-Oxide	Wettable Powder
	OR880005	50.00% - Fenbutatin-Oxide	Wettable Powder
	WA880009	50.00% - Fenbutatin Oxide	Wettable Powder
2	352-493	42.00% - Fenbutatin-Oxide	Emulsifiable Concentrate
	OR880004	42.00% - Fenbutatin-Oxide	Emulsifiable Concentrate
	OR910001	42.00% - Fenbutatin-Oxide	Emulsifiable Concentrate
	WA880010	42.00% - Fenbutatin-Oxide	Emulsifiable Concentrate
	WA910001	42.00% - Fenbutatin-Oxide	Emulsifiable Concentrate

The table below shows three EPA registrations which were not batched for various reasons such as additional active ingredients, significant differences in the inert ingredients, and significant differences in the concentrations of active and inert ingredients.

EPA REG. NO.	% of Fenbutatin-Oxide & Other Active Ingredients	Formulation Type
239-2594	0.75% - Fenbutatin-Oxide 4.00% - Acephate 3.25% - Triforine	Soluble Concentrate
239-2595	0.50% - Fenbutatin-Oxide 8.00% - Acephate	Soluble Concentrate
352-479	98.40% - Fenbutatin-Oxide	Technical

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 $\geq$ 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).

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 $\underline{<}2$ or $\underline{>}11.5$.
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	b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-96

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 reregistration 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)(D) 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)(D) 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 sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-90)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-94-021 September 1994

R.E.D. FACTS

Fenbutatin-oxide

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 0245, fenbutatin-oxide or Vendex.

Use Profile

Fenbutatin-oxide is a miticide or acaricide used to control mites, aphids, thrips, mealybugs, whiteflies and scale on citrus, apples, stone fruits, nut trees, several other food crops and ornamentals. Marketed under the trade name Vendex, fenbutatin-oxide is used in the U.S. primarily on orange and grapefruit crops.

Fenbutatin-oxide is formulated as a wettable powder, emulsifiable concentrate and soluble concentrate. It is applied aerially or through airblast or groundboom equipment two to nine times per year, depending on the site.

Regulatory History

Fenbutatin-oxide was first registered as a pesticide in the U.S. in 1974. The first end-use product was registered in August 1975. EPA issued a Registration Standard for fenbutatin-oxide in March 1987 (NTIS #PB87-190690). Currently, 10 pesticide products containing this active ingredient are registered.

Human Health Assessment

Toxicity

Fenbutatin-oxide generally is of low acute toxicity. However, it is a severe eye irritant in rabbits and has been placed in Toxicity Category I, indicating the highest degree of acute toxicity, for eye irritation effects.

In a subchronic dermal toxicity study using rabbits, fenbutatin-oxide caused redness of the skin and swelling at a low dosage but did not cause systemic toxicity.

Fenbutatin-oxide does not cause chronic toxicity and has been classified as a "Group E" carcinogen--a chemical showing evidence of non-carcinogenicity for humans.

In a developmental toxicity study using rats, fenbutatin-oxide caused no compound-related effects in treated dams. A similar study using rabbits resulted in anorexia, gastric lesions and abortions. In a reproductive toxicity study using rats, decreased body weight and food consumption were observed in parents, and pup body weights also were reduced during lactation. Fenbutatin-oxide is not mutagenic.

Metabolism studies indicate that the potential for bioaccumulation of fenbutatin-oxide is minimal. Approximately 1% of the pesticide is absorbed from the gastrointestinal tract when it is administered orally.

A reference dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime, has been established for fenbutatin-oxide at 0.05 mg/kg/day (milligrams per kilogram per day). This RfD is based on the reproductive toxicity study which caused reduced body weight and food consumption in both generations of rats.

Dietary Exposure

People may be exposed to residues of fenbutatin-oxide through the diet. Tolerances or maximum residue limits have been established for citrus, apples, many stone and other fruits, tree nuts and several vegetables (please see 40 CFR 180.362(a) and (c)); for milk fat, eggs and the meat, fat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep (please see 40 CFR 180.362(b); for dried prunes and raisins (please see 40 CFR 185.3550); and for apple and grape pommace, citrus oil and pulp, and raisin waste (please see 40 CFR 186.3550). EPA has reassessed these fenbutatin-oxide tolerances and found that a number of changes are needed, as detailed in the RED document.

International maximum residue limits (MRLs) have been established by Codex for many food commodities. However, because of the differences in tolerance expression between the MRLs and U.S tolerances, compatibility between the two is not achievable. In addition, the U.S. tolerances are higher than the corresponding Codex MRLs. Established U.S. agricultural practices for application of fenbutatin-oxide are unlikely to be changed. Therefore, U.S. tolerance levels probably cannot be lowered to achieve compatibility with Codex MRLs.

EPA has assessed the dietary risk posed by fenbutatin-oxide. For the overall U.S. population, exposure from all current tolerances represents 136% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. This value likely overstates the risk, however, because it assumes all crops have tolerance-level residues and 100% of all crops with tolerances are treated.

Information on actual anticipated residue levels and percent of crop treated with fenbutatin-oxide was included to more accurately estimate dietary exposure. The resulting Anticipated Residue Contribution (ARC) for the overall U.S. population represents 4% of the RfD, and the ARC for the most highly exposed subgroup, children age one to six, is 8% of the RfD. Chronic dietary risk from exposure to fenbutatin-oxide is believed to be minimal.

Occupational and Residential Exposure

Occupational and residential exposure can be expected based on the use patterns of currently registered products containing fenbutatin-oxide. The Worker Protection Standard for Agricultural Pesticides (WPS) established an interim 48-hour restricted entry interval (REI) based on fenbutatin-oxide's Toxicity Category I eye irritation potential. EPA has determined that the 48-hour REI should be retained for all WPS sites as a prudent measure to mitigate risk to workers entering treated areas after application. The personal protective equipment (PPE) required for early entry includes coveralls, chemical-resistant gloves, shoes, socks and protective eyewear.

Uses of fenbutatin-oxide that are outside the scope of the WPS including occupational and residential use products are required to add strengthened entry restrictions to their labels.

Human Risk Assessment

Fenbutatin-oxide generally is of low acute toxicity but is a severe eye irritant. It poses no significant chronic health risks and is classified as a Group E carcinogen, indicating that it poses no known cancer risk for humans.

Although people may be exposed to residues of fenbutatin-oxide in many fruits and other foods, the chronic dietary risk from such exposure is minimal. Workers and other users may be exposed to fenbutatin-oxide during and after application to food crops and ornamentals. To mitigate the risk of eye irritation during these activities, EPA is requiring a 48-hour REI and use of PPE including protective eyewear for all agricultural uses within the scope of the WPS, and more stringent entry restrictions for non-WPS occupational and residential uses.

Environmental Assessment

Environmental Fate

Fenbutatin-oxide is persistent in the environment, with no major route of dissipation. It is relatively unsusceptible to hydrolysis or photodegradation in water or on soil. Microbial degradation of fenbutatin-oxide in soil also is very slow.

Fenbutatin-oxide is relatively immobile in the environment. It is slightly soluble in water, has a low vapor pressure and binds strongly to soil. Therefore, it is not expected to leach.

Although fenbutatin-oxide is persistent, residues do not tend to accumulate in crops planted in previously treated soil. Fenbutatin-oxide does accumulate in fish tissues.

In the field, fenbutatin-oxide exhibits the same characteristics of persistence and immobility as in the laboratory. Calculated half-lives range from 271 days to 1367 days in different States and soils. This long half-life causes residue levels to increase with each successive application.

Ecological Effects

Fenbutatin-oxide is practically nontoxic to birds on an acute and subacute dietary basis, and has no effect on their reproduction. It also is practically nontoxic to mammals and honey bees. However, fenbutatin-oxide is very highly toxic to freshwater, estuarine and marine fish and invertebrates.

Ecological Effects Risk Assessment

Although no acute hazard is expected, use of fenbutatin-oxide at current rates does present the potential for chronic hazard to birds and mammals. Hazards to bees and nontarget plants are not anticipated.

Acute risk to freshwater fish is expected for all major uses of fenbutatin-oxide at current application rates. Acute risk to freshwater invertebrates is only expected for the citrus use, and acute risk to estuarine invertebrates is expected from both the citrus and the apple uses.

A significant potential for chronic risk to fish exists from the use of fenbutatin-oxide on citrus. No chronic risk is anticipated for freshwater and estuarine invertebrates.

Acute risk to endangered birds and mammals is not expected, but there is a potential for chronic hazard to these organisms. Acute risk to endangered freshwater fish and invertebrates is expected from all major uses. Use of fenbutatin-oxide on citrus presents significant potential for chronic hazard to endangered freshwater and estuarine fish.

Additional Data Required

EPA is requiring the following additional generic data for fenbutatin-oxide to confirm its regulatory assessments and conclusions: Discussion of formation impurities, Ph, bioaccumulation in fish, droplet size spectrum, and drift field evaluation.

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 fenbutatin-oxide end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Use Directions (Restricted Use Classification)

All uses of fenbutatin-oxide are declared Restricted, and products reregistered under this RED must bear a restricted use legend at the top of the front panel of the label. No other wording or symbols may appear above the legend and it must begin with the heading,"RESTRICTED USE PESTICIDE," followed by a brief statement of the reason for the restricted use classification (ie, "DUE TO VERY HIGH TOXICITY TO AQUATIC ORGANISMS"). Following this, the terms of the restriction must be stated as, "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."

Entry Restrictions and Personal Protective Equipment (PPE)

For occupational end-use products, EPA is establishing a 48-hour restricted entry interval (REI) for each use that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The PPE required for early entry permitted by the WPS is coveralls, chemical-resistant gloves, shoes plus socks, and protective eyewear.

All end-use products with non-WPS occupational uses must bear the following entry restriction:

> "Do not enter or allow others to enter the treated area until sprays have dried."

All residential use products must bear the following entry restriction:

> "Do not allow persons or pets to enter the treated area until sprays have dried."

Other Labeling Restrictions

EPA is requiring the following labeling statements on all end-use products intended primarily for occupational use:

> Application Restrictions: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."
>
> Engineering Controls: "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements: "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."

Type of Respirator: If the acute inhalation toxicity of the end-use product is in category I or II, then a respirator is required for pesticide handlers. A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) is the only type of respirator that is appropriate to mitigate fenbutatin-oxide inhalation concerns.

Toxicity Statement

Due to the toxicity of fenbutatin-oxide to birds, mammals and aquatic organisms, all end-use product labels must bear the following statement:

"This pesticide is toxic to birds, mammals, fish, 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. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."

Drift Reductions

To mitigate risks posed due to fenbutatin-oxide's high toxicity to aquatic organisms, all end-use product labels with aerial applications must bear the following statements for citrus use in Florida:

1) Do not apply within 125 feet of bodies of water such as lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries.

2) Do not apply when gusts or sustained winds exceed 8 mph.

3) The boom length must not exceed 3/4 of the wing or rotor length (ie, the distance of the outer-most nozzles on the boom must not exceed 3/4 or the length of the wingspan or rotor).

4) Do not apply at a height greater than 10 feet above the top of the target plants unless a greater height is required for aircraft safety.

5) Nozzles must always point backward and never be pointed downwards more than 45 degrees.

6) Do not apply in less than 10 gallons of final spray per acre.

7) Do not apply east of US Highway #1, south and east of State Road #846 or south of West Palm Beach Canal.

All end-use products using airblast applications must bear the following statements for citrus use in Florida:

1) Citrus groves may be planted close to bodies of water. Do not apply within 25 feet of bodies of water such as lakes, reservoirs, rivers, permanent streams, natural ponds, marshes or estuaries.

2) For all plantings within 75 feet of bodies of water as described above, spray trees only form outside the planting away form the bodies of water.

3) Shut off the sprayer when turning at row ends.

4) Do not apply when gusts or sustained winds exceed 12 mph.

Regulatory Conclusion

To ensure that the potential risks of this pesticide are not unreasonable, EPA is classifying fenbutatin-oxide as a Restricted Use Pesticide and is requiring the registrant to implement certain risk mitigation measures. Provided that these measures are implemented, all products containing fenbutatin-oxide as an active ingredient are eligible for reregistration.

The Restricted Use Pesticide classification is appropriate for all uses of fenbutatin-oxide because many of its use sites are located on or near bodies of water, and this pesticide is very highly toxic to freshwater and estuarine aquatic organisms. Fenbutatin-oxide persists in the environment long after initial application. The potential for serious contamination of the ecosystem is substantial.

The required risk mitigation measures are designed to reduce the risk to freshwater and estuarine aquatic organisms found near Florida's citrus groves. Measures include reduced application rates, label amendments with instructions to minimize spray drift, development of more accurate aquatic modeling, and monitoring to determine if fenbutatin-oxide levels accumulate over multiple years of use.

Fenbutatin-oxide products will be reregistered once the confirmatory generic data, product-specific data, revised Confidential Statements of Formula and revised labeling (including the Restricted Use Pesticide classification) are received and accepted by EPA, assuming that the required risk mitigation measures also are implemented.

For More

EPA is requesting public comments on the Reregistration Eligibility

Information

Decision (RED) document for fenbutatin-oxide 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.

Following the comment period, the fenbutatin-oxide RED document 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 fenbutatin-oxide RED, or reregistration of individual products containing fenbutatin-oxide, 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 6:00 pm Central Time, Monday through Friday.