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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

SUBJECT: Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides

FROM: Debra Edwards, Director
Special Review and Reregistration Division
Office of Pesticide Programs

TO: Jim Jones, Director
Office of Pesticide Programs

As you know, EPA has completed its assessment of the cumulative risks from the organophosphate (OP) class of pesticides as required by the Food Quality Protection Act of 1996. In addition, the individual OPs have also been subject to review through the individual-chemical review process. The Agency's review of individual OPs has resulted in the issuance of Interim Reregistration Eligibility Decisions (IREDs) for 22 OPs, interim Tolerance Reassessment and Risk Management Decisions (TREDs) for 8 OPs, and a Reregistration Eligibility Decision (RED) for one OP, malathion.[1] These 31 OPs are listed in Appendix A.

EPA has concluded, after completing its assessment of the cumulative risks associated with exposures to all of the OPs, that:

(1) the pesticides covered by the IREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) are indeed eligible for reregistration; and

[1] Malathion is included in the OP cumulative assessment. However, the Agency has issued a RED for malathion, rather than an IRED, because the decision was signed on the same day as the completion of the OP cumulative assessment.

(2) the pesticide tolerances covered by the IREDs and TREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) meet the safety standard under Section 408(b)(2) of the FFDCA.

Thus, with regard to the OPs, EPA has fulfilled its obligations as to FFDCA tolerance reassessment and FIFRA reregistration, other than product-specific reregistration.

The Special Review and Reregistration Division will be issuing data call-in notices for confirmatory data on two OPs, methidathion and phorate, for the reasons described in detail in the OP cumulative assessment. The specific studies that will be required are:

- 28-day repeated-dose toxicity study with methidathion oxon; and
- Drinking water monitoring study for phorate, phorate sulfoxide, and phorate sulfone in both source water (at the intake) and treated water for five community water systems in Palm Beach County, Florida and two near Lake Okechobee, Florida.

The cumulative risk assessment and supporting documents are available on the Agency's website at www.epa.gov/pesticides/cumulative and in the docket (EPA-HQ-OPP-2006-0618).

Attachment A:

Organophosphates included in the OP Cumulative Assessment

Chemical	Decision Document	Status
Acephate	IRED	IRED completed 9/2001
Azinphos-methyl (AZM)	IRED	IRED completed 10/2001
Bensulide	IRED	IRED completed 9/2000
Cadusafos	TRED	TRED completed 9/2000
Chlorethoxyphos	TRED	TRED completed 9/2000
Chlorpyrifos	IRED	IRED completed 9/2001
Coumaphos	TRED	TRED completed 2/2000
DDVP (Dichlorvos)	IRED	IRED completed 6/2006
Diazinon	IRED	IRED completed 7/2002
Dicrotophos	IRED	IRED completed 4/2002
Dimethoate	IRED	IRED completed 6/2006
Disulfoton	IRED	IRED completed 3/2002
Ethoprop	IRED	IRED completed 9/2001 IRED addendum completed 2/2006
Fenitrothion	TRED	TRED completed 10/2000
Malathion	RED	RED completed 8/2006
Methamidophos	IRED	IRED completed 4/2002
Methidathion	IRED	IRED completed 4/2002
Methyl Parathion	IRED	IRED completed 5/2003
Naled	IRED	IRED completed 1/2002
Oxydemeton-methyl	IRED	IRED completed 8/2002
Phorate	IRED	IRED completed 3/2001
Phosalone	TRED	TRED completed 1/2001
Phosmet	IRED	IRED completed 10/2001
Phostebupirim	TRED	TRED completed 12/2000
Pirimiphos-methyl	IRED	IRED completed 6/2001
Profenofos	IRED	IRED completed 9/2000
Propetamphos	IRED	IRED completed 12/2000
Terbufos	IRED	IRED completed 9/2001
Tetrachlorvinphos	TRED	TRED completed 12/2002
Tribufos	IRED	IRED completed 12/2000
Trichlorfon	TRED	TRED completed 9/2001

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-00-006
August 2000

Interim Reregistration Eligibility Decision (IRED)

Profenofos

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data, as well as the public comments received on the preliminary and revised risk assessment(s), for the organophosphate (OP) pesticide profenofos. In reaching this decision point on profenofos, EPA has employed a pilot public participation process developed by the Tolerance Reassessment Advisory Committee (TRAC) to increase public involvement and improve the transparency of the reregistration and tolerance reassessment processes.

The Agency successfully implemented the six phase pilot process during its review of profenofos. The pilot public participation process afforded multiple opportunities for public comment on the Agency's risk assessments, including a Technical Briefing presentation to the general public on June 16, 1999. The final formal comment period, which closed on August 16, 1999, invited interested parties to participate and provide suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments.

After reviewing the comments received during the public comment periods and reviewing the available data received from the registrant and other sources, a number of risk mitigation measures were identified that the Agency believes are necessary to address the human health and environmental risks associated with the current use of profenofos. EPA is now publishing its interim reregistration eligibility and risk management decision for the current uses of profenofos and the associated human health and environmental risks. The tolerance reassessment decision for profenofos will be finalized once the cumulative assessment for all of the organophosphate pesticides is complete. The Agency's decision on the individual chemical profenofos can be found in the attached document entitled, "Interim Reregistration Eligibility Decision for Profenofos.

A Notice of Availability for this interim Reregistration Eligibility Decision for Profenofos is published in the *Federal Register*. To obtain a copy of the interim RED document, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the interim RED and all supporting documents are available on the Internet. See http://www.epa.gov/oppsrrd1/op/.

The interim RED is based on the updated technical information found in the profenofos public docket. The docket not only includes background information and comments on the Agency's

preliminary risk assessments, it also now includes the Agency's revised risk assessments for profenofos (revised as of June 16, 1999 and updated in March 2000), teleconference notes, and documents summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5.

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

Please note that the profenofos risk assessment and the attached interim RED concern only this particular organophosphate. This interim RED is the Agency's final reregistration decision except for the decision on tolerance reassessment. Because the FQPA directs the Agency to consider available information on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with cholinesterase enzyme, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after completing the risk assessments for the individual organophosphates. The Agency is working towards completion of a methodology to assess cumulative risk and the individual risk assessments for each organophosphate are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks that have already been attributed to current uses of profenofos. The Agency will issue the final tolerance reassessment decision for profenofos once the cumulative assessment for all of the organophosphates is complete.

End-use product labels must be revised by the manufacturer to adopt the changes set forth in Section IV. of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Carmelita White at (703) 308-7038.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosure

Interim Reregistration Eligibility

Decision

for

Profenofos

Case No. 2540

TABLE OF CONTENTS

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Glossary of Terms and Abbreviations

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

Glossary of Terms and Abbreviations

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

Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for profenofos. The decisions outlined in this document do not include the final tolerance reassessment decision for profenofos. However, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. One tolerance will be modified and nine other tolerances will be revoked. The final tolerance reassessment decision for this chemical will be issued once the cumulative assessment for all of the organophosphates is complete. The Agency may need to pursue further risk management measures for profenofos once the cumulative assessment is finalized.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued this risk mitigation decision on profenofos. After considering the revised risks, as well as consultation with Novartis Crop Protection, Inc., the technical registrant of profenofos, and comments and mitigation suggestions from other interested parties including the National Cotton Council, National Alliance of Independent Crop Consultants, and several certified crop advisors, EPA developed its risk management decision for uses of profenofos that pose risks of concern. This document details these activities and discusses the actions necessary to reduce the risks identified in the risk assessment for the purpose of reregistration.

Profenofos is an organophosphate insecticide/miticide used solely on cotton. It was first registered in the United States in 1982. There are about 775,000 pounds (lbs.) active ingredient (ai) applied to cotton each year. Profenofos, a "restricted use" pesticide, is used to control tobacco budworm, cotton bollworm, armyworm, cotton aphid, whiteflies, spider mites, plant bugs, and fleahoppers. An estimated 85% of all profenofos is used for the control of lepidopteran species (the worm complex) at varying rates. About 30% of this use is aimed at controlling the worm complex at the current maximum label rate of 1 lb. ai/Acre. Other pests are usually controlled at lower rates.

Human Health Risk

The profenofos risk assessments are based on its potential to cause cholinesterase inhibition. The Agency's human health risk assessment for profenofos indicates that there are no concerns for dietary risk from food and water. Dietary risks (food) do not exceed 8% of the acute PAD while chronic risks (food) do not exceed 20% of the chronic PAD. Neither acute nor chronic drinking water risk exceed the Agency's level of concern based on a drinking water level of comparison assessment (DWLOC). Because there are no residential uses of profenofos, aggregate risk is based only on dietary (food and water) exposures. In short, aggregate risk does not exceed the Agency's level of concern.

The human health risk assessment for profenofos indicates that there are concerns for occupational mixers/loaders and applicators and flaggers involved in groundboom and aerial applications and for reentry personnel following application. Margins of Exposure (MOE) of less than 100 for dermal and less than 300 for inhalation are of concern for occupational exposures. All inhalation exposure MOEs greatly exceed 300 and therefore do not contribute appreciably to occupational risks. Two of five occupational dermal handler scenarios produce MOEs less than 100 even when assuming the use of engineering controls (closed systems for mixer/loaders for aerial application, and enclosed cockpits for aerial applicators). The MOEs for aerial mixers/loaders and applicators were 23 and 40, respectively, even with the use of engineering controls for short and intermediate term dermal exposure. MOEs for mixers/loaders and applicators involved in groundboom applications and for flaggers supporting aerial applications ranged from 101 to over 1,000 and, therefore, do not exceed the Agency's level of concern.

Postapplication worker risk estimates were calculated from registrant submitted studies on dislodgeable foliar residue dissipation and scout and hoer monitoring exposure. The studies measured both inhalation and dermal exposure. Using these data, the Agency calculates that under the present assumptions and use rates, the restricted entry interval (REI) for workers who reenter treated fields to perform routine hand labor activities should be 48 hours, and 72 hours in arid regions that receive less than 25" of annual rainfall. Certified crop advisors and their employees currently have an exemption from the WPS requirements. The Agency is concerned that crop advisors performing scouting activities could be at risk when spending extended periods in treated cotton fields during the REI. The Agency is requiring an advisory on the label to alert handlers of the protective measures that should be taken when reentering treated fields to perform scouting and hoeing tasks to minimize risks.

Environmental Fate and Ecological Risk

In addition to considering the human health effects associated with exposure to profenofos, the Agency assessed the environmental fate and ecological risks that could result from the use of profenofos on cotton. Available environmental fate studies show that profenofos is not persistent in neutral and alkaline soils. Profenofos breaks down rapidly in aerobic and anaerobic conditions and dissipates in neutral to alkaline soils with a half-life of several days. Acidic conditions typical of the areas where most profenofos use occurs favor a slower breakdown. Although not highly mobile, profenofos may reach surface waters through spray drift or runoff.

Data were available to assess the hazard profenofos poses to nontarget terrestrial and aquatic organisms. Profenofos is moderately to highly toxic to birds, moderately toxic to small mammals, highly toxic to bees, and highly to very highly toxic to fish and aquatic invertebrates. Thirteen separate fish kill incidents were reported to the Agency between 1994 and 1996 in which profenofos was implicated as the probable to highly probable cause. The kills were generally attributable to runoff, although spray drift during application killed several hundred fish in one incident. These incident reports support the results of the Agency's comparison of estimated environmental concentrations to affect levels in fish and

suggest fish may be at significant risk. Unlike fish, incident reports are not normally collected for aquatic invertebrates; however, the ecological assessment suggests profenofos will pose an even greater hazard for aquatic invertebrates than for fish.

Risk Mitigation

The registrant has agreed to immediately modify the profenofos label to address human health and ecological risks. For occupational risks, the label will be modified to: (1) reduce the maximum application rate to 0.75 lb. ai/A; (2) allow a 1 lb. ai/A rate for use only on lepidopteran pests up to twice per season; (3) require closed mixing/loading systems and enclosed cockpits and cabs; and (4) prohibit pilots from mixing and loading on the same day of application. While these measures will not reduce the risks to below the Agency's level of concern based on the current risk assessment, the Agency believes these measures will significantly reduce exposure.

As indicated above, the Agency is requiring changes to the profenofos label to address worker risk from aerial application where large quantities of the chemical are handled. Mixer, loader and applicator risks are not of concern for groundboom applications given the smaller number of acres treated and amount of pesticide handled once closed systems are employed. For aerial application, the registrant has agreed to only market the product in an advanced mixing/loading system and allow application using enclosed cockpits beginning with the 2001 growing season. The seasonal maximum application rate is being reduced from 6 to 5 lbs ai/A/season. Application at the 1 lb ai/A rate will be limited to twice per year and may be used only for severe lepidopteran infestations. Use under all other conditions will be limited to 0.75 lbs ai/A/application. Information reported by USDA indicates that growers frequently use even lower application rates generally ranging from 0.46 to 0.62 lb ai/A and have used rates as low as 0.25 lb ai/A. At this lowest application rate, risks are not of concern based on the current assessment.

The registrant is undertaking an exposure study using the advanced mixing/loading system that will be commercially available next year. This advanced system is expected to perform better than the older closed mixing/loading systems currently reflected in the PHED database. Use of this improved system and the aforementioned risk mitigation measures are expected to confirm the Agency’s belief that actual exposures and concomitant risks are not of concern.

To address risk to aquatic animals, the registrant has agreed to require a 300' buffer zone around water bodies for aerial applications and a 100' buffer zone around water bodies for groundboom applications. Although the mitigation measures focus on minimizing risk to fish, the Agency believes they will have a secondary benefit in mitigating risks to nontarget aquatic invertebrates and may mitigate some risks to terrestrial species. The Agency is also requiring the registrant to reduce the application rate which should also reduce exposure.

The decisions in this document are specific to profenofos; a cumulative risk assessment of all organophosphate pesticides has not been completed. The cumulative assessment may result in further risk mitigation measures for profenofos.

The Agency is issuing this Interim Reregistration Eligibility Document (IRED) for profenofos, as announced in a Notice of Availability published in the *Federal Register*. This interim RED document includes guidance and time frames for making label changes for products containing profenofos. This document is not the final reregistration eligibility decision because the Agency has not completed the final tolerance reassessment. The IRED outlines the risks of profenofos (when considering profenofos individually) and provides the necessary label modifications which must be implemented to make any future eligibility findings.

Note that there is no comment period for this document**,** and that the time frames for compliance with the necessary changes outlined in this document are shorter than those given in previous REDs. As part of the process discussed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessments for profenofos have already been subject to numerous public comment periods, and a further comment period for profenofos was deemed unnecessary. The Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period, depending on the content of the risk management decision. With regard to complying with the requirements in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for profenofos can be considered final, however, until the cumulative risk assessment for all organophosphate pesticides is complete. The cumulative assessment may result in further risk mitigation measures for profenofos.

I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment during reregistration. FQPA also amends the Federal Food, Drug and Cosmetic Act (FFDCA), to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Profenofos belongs to a group of pesticides called organophosphates which share a common mechanism of toxicity. They all affect the nervous system by inhibiting cholinesterase. Therefore, tolerance reassessment requires that the Agency consider, among other things, the cumulative effects of exposures to all organophosphates.

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

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

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

- Aggregating Exposure from all Non-Occupational Sources
- How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- Whether and How to Use Data Derived from Human Studies

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

In addition to the policy issues that resulted from the TRAC process, the Agency published in the *Federal Register* on August12, 1999, a draft Pesticide Registration Notice that presents EPA's proposed approach for managing risk from organophosphate pesticides to occupational users. This notice describes the Agency's baseline approach to managing risks to handlers and workers of organophosphate pesticides. Generally, basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased reentry intervals are needed for most uses where current risk assessments indicate a risk and such protective measures are feasible. The draft guidance policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this interim RED are consistent with that draft Pesticide Registration Notice.

This document consists of six sections. Section I contains the regulatory framework for reregistration tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticide and the worker risk management PR Notice. Section II provides a profile of the use and usage of profenofos. Section III gives a summary of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV discusses the Agency's interim decision regarding measures necessary for the interim reregistration eligibility and risk management decisions. Section V summarizes label changes needed to meet the Agency's interim reregistration eligibility decision set forth in Section IV. Finally, the Appendices list Data Call-In (DCI) information, related documents and how to access them. The revised risk assessments [and addenda] are not included in this document, but are available on the Agency's web page (www.epa.gov/oppsrrd1/op), and in the Public Docket.

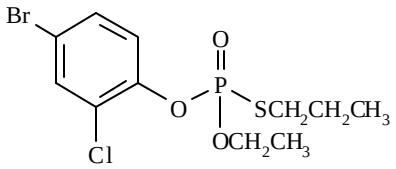
II. Chemical Overview

A. Regulatory History

Profenofos was first registered by the Agency in 1982 for use as an insecticide/miticide. This interim reregistration eligibility review is the Agency's first reevaluation of profenofos since its initial registration in 1982. A Registration Standard was not issued for profenofos, nor was profenofos ever the subject of a Special Review.

B. Chemical Identification

Profenofos:



O-(4-bromo-2-chlorophenyl)-O-ethyl-S-propyl phosphorothioate

- **Common Name:** Profenofos
- **Chemical Name:** O-(4-bromo-2-chlorophenyl) O-ethyl S-propyl phosphorothioate
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 41198-08-7
- **OPP Chemical Code:** 111401
- **Empirical Formula:** $C_{11}H_{15}O_3PSBrCl$
- **Molecular Weight:** 373.65 g/mole
- **Trade and Other Names:** Curacron 8E, CGA-15324
- **Basic Manufacturer:** Novartis Crop Protection, Inc.

Technical profenofos is a pale yellow liquid with a boiling point of 100°C (1.8 Pa) and a density of 1.46 g/cm^3 at 20°C. Pure profenofos is an amber-colored oily liquid with a boiling point of 110°C (0.13 Pa). Profenofos has limited solubility in water (20 ppm), but is completely soluble in organic solvents (ethanol, acetone, toluene, n-octanol, and n-hexane) at 25°C. (See "Human Health Risk Assessment, Profenofos, June 16, 1999".)

C. Use Profile

The following information is based on the currently registered use of profenofos.

Type of Pesticide: Insecticide/miticide

Summary of Use:

Sites: Terrestrial food and feed crop - cotton.

Food: Cottonseed is processed into cottonseed oil; meal and gin trash are used as ruminant feed.

Residential: No residential uses.

Other Nonfood: None. Registered for use on cotton only.

Target Pests: Profenofos is used to control tobacco budworm, cotton bollworm, armyworms (fall, beet), cotton aphid, spider mites, plant bugs, fleahoppers, and whiteflies.

Formulation Types:

Registered: Novartis Crop Protection, Inc., has registered a technical grade (89% ai) and an emulsifiable concentrate (73% ai).

Method and Rates of Application:

Equipment - Aircraft (fixed wing and helicopter) and groundboom.

Method and Rate - Foliar spray applied at up to 1.0 lb ai/A (maximum)

Timing - From planting through defoliation; six treatments per season (maximum).

Trend - According to USDA's National Agricultural Statistics Service and other sources, profenofos use has declined markedly over the last five years. USDA reports that growers are using lower rates (0.46 to 0.62 lb ai/A) and applying the pesticide less frequently (about twice per year).

Use Classification: Profenofos is a restricted use pesticide.

D. Estimated Usage of Pesticide

Based on information available to the Agency and from consultation with the USDA, the Agency estimates that on average approximately 775,000 pounds of profenofos are applied to an estimated average of 5% of the approximately 13,818,000 acres of cotton grown in the US per year. The Agency estimates the maximum percent cotton treated to be about 10%. Although some profenofos is used in nearly every state where cotton is grown, approximately 80% of the yearly use of profenofos is in the mid-South states of Arkansas, Georgia, Texas, Louisiana, and Mississippi.

III. Summary of Profenofos Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide profenofos, as fully presented in the documents, "Human Health Risk Assessment, Profenofos, June 16, 1999," and "Reregistration Eligibility Decision Environmental Risk Assessment for Profenofos, June 16, 1999." The purpose of this summary is to assist the reader by identifying the key features, findings and conclusions reached in these risk assessments.

Using relevant data submitted under section 4(g)(2)(A) of FIFRA, published scientific literature, and available surrogate data, the Agency assessed the human health and ecological risks associated with using profenofos on cotton. For more detail, see "Human Health Risk Assessment, Profenofos, June 16, 1999," and "Reregistration Eligibility Decision Environmental Risk Assessment for Profenofos, June 16, 1999," The endpoint of concern is cholinesterase inhibition as measured in plasma, red blood cells, and brain following exposure to profenofos. The Agency calculated human health risks from food, water, and occupational exposures. Potential dietary (food) exposure to profenofos residues may occur through the consumption of cottonseed oil, milk, meat and meat by-products, and through drinking water. There are no residential, recreational, or other non-occupational sources of exposure to profenofos. Therefore, in quantifying aggregate risks, the Agency only considered exposures from food and drinking water. The results of the individual food and drinking water analysis indicate that dietary risk is not of concern for profenofos (as stated previously this assessment considers profenofos alone and does not consider cumulative risks).

The occupational risk assessment for profenofos considered exposures that could result from aerial and groundboom application methods based on maximum application rates. Postapplication data

were submitted by the registrant and were considered by the Agency in its postapplication risk assessment. The results of the occupational risk assessment indicate that risks for both handlers and postapplication workers are a concern.

The Agency considered the toxicity and environmental fate characteristics of profenofos in its assessment of the potential adverse effects on nontarget aquatic and terrestrial organisms. Using exposure estimates derived from environmental fate studies that were conducted under conditions that favor rapid dissipation of profenofos, the Agency identified potential risks to nontarget species, particularly aquatic organisms. Additional information on reported fish kill incidents that identified profenofos as the probable cause confirm that the use of profenofos under typical use conditions can pose adverse risk to aquatic organisms.

These risk assessments for profenofos were presented at a June 16, 1999, Technical Briefing, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's risk management decision for profenofos only; the Agency must complete a cumulative assessment of the risks of all organophosphate pesticides before any final decisions can be made.

A. Human Health Risk Assessment

The Agency issued its preliminary risk assessment for profenofos in August 1998 (Phase 3 of the TRAC process). Since that time, the preliminary risk assessment has been revised to address stakeholder comments and refined to the extent practicable using currently available information. These updates or refinements include:

- Refined the dietary risk assessment using DEEM (an updated exposure model). (Previous assessment was based on DRES to assess the dietary risk.)

- Reevaluated the postapplication risks to determine reentry requirements.

- Calculated DWLOCs.

- Compared the estimates of profenofos levels in drinking water to the DWLOC estimates.

The following table summarizes the toxicological endpoints selected by the Agency to assess human health risks for profenofos:

Table 1. Summary of Toxicological Endpoints for Profenofos

TYPE OF EXPOSURE (duration and route)	ENDPOINT AND DOSE	STUDY
Acute Dietary (one day)	aPAD of 0.005 mg/kg /day [NOEL 0.5 mg/kg/day inhibition of cholinesterase activities in plasma (males) and RBC's (females)]. UF: 100	Non-guideline acute single-dose oral toxicity study in rats (MRID 43213302).
Chronic Dietary	cPAD of 0.00005 mg/kg/day [NOEL 0.005 mg/kg/day / inhibition of cholinesterase activity in plasma and RBC's]. UF: 100	Six-month dog study (MRID 00081687).
Short-Term Occupational (one to seven days)	NOEL of 1.0 mg/kg/day [NOEL for significant decreases in cholinesterase activities in RBC's, plasma, and brain]. UF: 100	21-day dermal toxicity study in rabbit (MRID 41644501).
Intermediate-Term Occupational (one week to several months)		
Inhalation (any duration)	LOEL of 9.7 mg/kg/day. Dose calculated for route-to-route extrapolation based on the LOEL of 0.068 mg/L, which inhibited brain, RBC, and plasma cholinesterase activities]. UF: 300	21-day inhalation toxicity study in rat (MRID 00082079).

1. Dietary Risk (food)

Dietary Exposure Assumptions

The Agency's dietary risk assessment for profenofos uses the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. Acute dietary risk is calculated considering maximum, or high end, single day exposure to pesticide residues in food. Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year life time. The Agency uses the estimated maximum percent crop treated for acute risk and the average estimated percent crop treated for chronic risk. The no-observed-effect-level (NOEL) and uncertainty factors (UF) are used to establish the "allowable" exposures to a pesticide, which is referred to as the reference dose (RfD). The RfD is divided by the FQPA Safety Factor, which results in the Population Adjusted Dose (PAD). The FQPA safety factor is intended to provide up to an additional 10-fold factor to safeguard against a special sensitivity in infants and children to specific pesticide residues in food or to account for an incomplete database. The PAD is the value used for regulatory decisions rather than the RfD following FQPA considerations.

Estimated acute and chronic dietary exposures to profenofos result in risk estimates that are significantly below the Agency's level of concern using reassessed tolerances, and incorporating anticipated residues and percent crop treated. For the acute dietary risk assessment, the entire

distribution for each food item of single day food consumption was combined with a single residue level to obtain a distribution of exposure. For the chronic dietary risk assessment, the three-day average consumption for the U.S. and sub-populations was combined with average residues in commodities to determine average exposure. Limited monitoring data have been generated for profenofos by the USDA Pesticide Data Program (PDP) and the U.S. Food and Drug Administration (FDA).

FQPA Safety Factor

The FQPA Safety Factor was reduced to 1X. The reduction was based on the completeness of the toxicity and exposure databases, and on the assessment of the following studies: (1) a developmental toxicity study in rats; (2) a supplemental developmental study in rabbits; (3) a two-generation reproduction study in rats; (4) an acute delayed neurotoxicity study in hens (and two supplementary studies); (5) an acute neurotoxicity study in rats; and (6) a subchronic neurotoxicity study in rats.

Based on these data, the Agency concluded that the additional 10X FQPA Safety Factor to account for enhanced sensitivity of infants and children, as required by FQPA, should be reduced to 1X since there was no indication of increased sensitivity to young animals following pre-and/or post-natal exposure to profenofos. Specifically, there was no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in prenatal developmental toxicity studies, 2) no offspring toxicity was seen at the highest dose tested in the two-generation reproduction toxicity study and there was no evidence of abnormalities in the development of the fetal nervous system in these studies and 3) adequate data and modeling outputs are available to satisfactorily assess dietary exposure and to provide a screening level drinking water exposure assessment. The Agency believes that the assumptions and models used in the assessments do not underestimate the potential risk for infants and children. Therefore, the additional 10X factor as required by FQPA was reduced to 1X.

a. Dietary Risk from Food (Acute)

As previously stated, the acute dietary risk (food) of profenofos does not exceed the Agency's level of concern (i.e., less than 100% of the acute PAD is utilized). The endpoint is cholinesterase inhibition in plasma and red blood cells from a single-dose oral toxicity rat study with a NOEL of 0.5 mg/kg (MRID 43213302). The Agency applied the conventional uncertainty factor (UF) of 100 to account for both interspecies extrapolation (10X) and intraspecies variability (10X). The 10X FQPA safety factor was reduced to 1X (removed). The acute dietary assessment is based on cholinesterase inhibition observed in an acute oral toxicity study in rats with a NOEL of 0.5 mg/kg/day (MRID 43213302). An uncertainty factor of 100 was applied to account for interspecies extrapolation (10X) and intraspecies variability (10X).

As a result, the acute PAD is calculated to be 0.005 mg/kg/day. The Agency conducted a deterministic analysis which resulted in a dietary exposure <8% of the aPAD at the 95th exposure

percentile for the most highly exposed subpopulation (children 1 - 6 years). No additional data were available for the Agency to further refine the risk assessment. The results of field trials indicate residue on cotton seed was below the level of detection. In contrast, gin trash residues contained substantial residues. Therefore, a tolerance must be established. The acute dietary risk assessment was based on residue values of ½ the limit of quantitation (LOQ) for cottonseed oil, milk, meat and meat byproducts, and the Agency's estimate of maximum percent crop treated (10%).

b. Dietary Risk from Food (Chronic)

The chronic dietary risk assessment is based on cholinesterase inhibition in plasma and red blood cells from a six-month dog feeding study with a NOEL of 0.005 mg/kg (MRID 00081687). As above, the Agency applied an UF of 100 for both interspecies extrapolation (10X) and intraspecies variability (10X). The FQPA 10X safety factor was reduced to 1X (removed) as in the acute dietary assessment. Therefore, the cPAD is calculated to be 0.00005 mg/kg/day. For the most highly exposed subgroup, children (1 - 6 years), less than 20% of the cPAD is utilized.

The chronic dietary risk assessment was conducted using a 5% weighted average crop treated estimate and anticipated residue values based on one-half the limit of quantitation for cottonseed oil, milk, meat and meat byproducts. This approach allows the Agency to put emphasis on the most recent data, which results in a more accurate account of the current use patterns. The chronic dietary risk (food) of profenofos does not exceed the Agency's level of risk concern (i.e., less than 100% chronic PAD is utilized).

2. Dietary Risk (Drinking Water)

Drinking water exposure to pesticides can occur through ground water and surface water contamination. The Agency considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available. The Agency did not have representative drinking water monitoring data available for profenofos; therefore, the surface and ground water assessments were based on modeling predictions. Based on laboratory studies and limited field data, the Agency assessed the potential of profenofos to reach surface- or ground-water sources of drinking water (see Section E, Environmental Risk Assessment, June 16, 1999, for details).

The Agency performed surface and groundwater modeling to estimate drinking water concentrations, which were then compared to the Drinking Water Level of Comparison (DWLOC). The GENEEC and PRZM-EXAMS models were used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. All of these are considered to be screening models, with the PRZM-EXAMS, model being somewhat more refined than the other two. The models are discussed below.

a. Surface Water

Tier II PRZM-EXAMS modeling provides upper-bound predictions of profenofos concentrations in surface water. This model is based on more refined data and less conservative assumptions than the GENEEC model. The modeling was performed assuming profenofos was applied at the maximum label rate of 1 lb ai/A, 6 times per season to a cotton site in Mississippi, a major cotton-growing state. Based on the modeling, concentrations of profenofos in surface water are not likely to exceed 6 ppb profenofos equivalents for peak (acute) exposure and 0.1 ppb profenofos equivalents for mean (chronic) exposure. Profenofos concentrations in water were measured in eleven of the thirteen fish kill incidents reported between 1994 and 1996. Although the surface water concentrations were generally below the modeled estimates, actual measured concentrations ranged from a low of 0.08 ppb to 36.4 ppb.

b. Ground Water

Profenofos is not expected to leach to ground water based on limited laboratory mobility data. The SCI-GROW model was used to estimate ground water concentrations using the same site, soil, and application rate input data used for PRZM/EXAMS. The model resulted in a screening-level concentration of 0.03 ppb. The Agency also has limited data from wells monitored in Texas that show no detection. However, these data were not of sufficient quantity or representative of profenofos use under various geographical conditions to be used for risk assessment.

c. Drinking Water Levels of Comparison

To determine the maximum allowable contribution of water containing pesticide residues permitted in the diet, the Agency first looks at how much of the overall allowable risk is contributed by food and then determines a drinking water level of comparison (DWLOC) to ascertain whether modeled levels exceed this value. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. As mentioned above, the Agency modeled the drinking water exposure values because of limited monitoring data. The Agency compared the DWLOCs and the estimated concentrations of profenofos in surface water and ground water generated by modeling with PRZM/EXAMS and SCI-GROW, respectively.

As seen in the table below, neither surface water or ground water modeled concentrations for profenofos exceed the DWLOC for acute or chronic exposures. Consequently, the Agency has no concern for exposure to profenofos in drinking water.

Table 2. Drinking Water Level of Comparison and Modeled concentrations

Population Subgroup	PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	DWLOC (µg/L)	PRZM-EXAM (µg/L) EECs	SCI-GROW (µg/L) EECs
Acute Exposure						
Adult Male	0.005	0.000114	0.004886	171	6	0.03
Adult Female	0.005	0.000108	0.004892	146	6	0.03
Infants <1 yr	0.005	0.000394	0.004606	46	6	0.03
Children 1-6	0.005	0.000400	0.0046	46	6	0.03
Children 7-12	0.005	0.000237	0.004763	48	6	0.03
Chronic Exposure						
Adult Male	0.00005	0.000003	0.000047	2	0.1	0.03
Adult Female	0.00005	0.000003	0.000047	1.41	0.1	0.03
Infants <1 yr	0.00005	0.000004	0.000046	0.46	0.1	0.03
Children 1-6	0.00005	0.000009	0.000041	0.41	0.1	0.03
Children 7-12	0.00005	0.000005	0.000045	1.57	0.1	0.03

B. Residential Risk

There are no residential uses of profenofos. It is registered as a restricted use pesticide for use only on cotton.

C. Aggregate Risk

Aggregate risk considers combined exposures from food, drinking water, and non-occupational uses of a pesticide. As stated previously, there are no residential or other non-occupational (e.g., use on a golf course) uses of profenofos to consider in an acute or chronic aggregate assessment. Therefore, as discussed above, acute and chronic drinking water levels of comparison (DWLOCs) were calculated and compared to estimated environmental concentrations (EECs) that were generated using the PRZM-EXAMS model for surface water and the SCI-GROW model for ground water sources of drinking water. The EECs for surface and ground water were less than the acute and chronic DWLOCs indicating that aggregate risk is less than the level of concern, based on current use.

D. Occupational Risk

The Agency considers the tasks (e.g., mixing/loading, applying); pesticide formulation (e.g., liquid, granular); application method (e.g., aerial, groundboom); application rate and similar activities in assessing occupational exposure. The Agency considers both direct and indirect or secondary

exposure and risks that may result from the use of the pesticide, such as handlers not directly involved in mixing/loading or applying the chemical. The Agency also reviews any incident data that may be available and applicable.

The Pesticide Handlers Exposure Database (PHED) was used to estimate occupational exposure. PHED is a comprehensive generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposures for pesticide workers (e.g., mixers, loaders, and applicators) involved in the handling or application of pesticides. The database currently contains data for over 2000 monitored exposure events.

The Agency's first step in performing a handler exposure assessment is to complete a baseline exposure assessment. The baseline scenario generally represents a handler wearing long pants, a long-sleeved shirt, shoes and socks. If the level of concern is met or exceeded, then additional protective measures, such as PPE (personal protective equipment) and engineering controls, are used to recalculate the Margin of Exposure (MOE) until exposure is sufficiently reduced. A MOE is a measure of how close the handlers' exposure comes to the No-Observed-Effect- Level (NOEL) taken from animal studies. The Agency uses the MOE as an expression of risk. The levels of protection used as the basis for calculating exposure from profenofos activities include:

- **Baseline:** Long-sleeved shirt and long pants and socks and shoes (no respiratory protection).
- **Maximum available PPE:** Baseline scenario + coveralls and chemical resistant gloves.
- **Engineering controls:** Closed cab, enclosed cockpit or closed loading system.

The current label requires the following PPE for “applicators and other handlers”: coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks, protective eyewear, and chemical-resistant apron when cleaning equipment, mixing, or loading.

In addition to factors captured in PHED, the toxicity of a chemical is integral to assessing risk to handlers. The endpoints (i.e., NOEL) and uncertainty factors used in the assessment of risk to occupational and post-application handlers are summarized below.

Mixer/Loader and Applicator Risk

Inhalation and dermal exposure to profenofos can result from occupational use. The Agency assessed dermal and inhalation risks for mixers/loaders and applicators during aerial and groundboom applications and for flaggers during aerial application. Profenofos is not expected to be used on a continuous long-term basis (greater than 6-months a year) resulting in chronic exposure. Therefore, only short- (1-7 days) and intermediate- (one week-several months) term occupational risk assessments were conducted.

For profenofos, the Agency assessed dermal exposures using a NOEL from a 21-day dermal toxicity study in the rabbit. This study serves as the endpoint for both short-term and intermediate-term exposures. Significant decreases in cholinesterase activity in red blood cells, plasma, and brain were observed. A NOEL of 1.0 mg/kg/day was established and the LOEL was 10 mg/kg/day (MRID 41644501). An uncertainty factor of 100 was applied to account for interspecies extrapolation (10X) and intraspecies variability. MOEs that are greater than 100 do not exceed the Agency's level of concern.

The risk assessment for inhalation short-term and intermediate term exposure is based on a 21-day inhalation toxicity study in the rat (MRID 00082079). Brain, red blood cell, and plasma cholinesterase activities were significantly depressed at the lowest dose tested, 0.068 mg/L. In order to quantify inhalation risk, the Agency converted the inhalation endpoint to an oral dose equivalent of 9.7 mg/kg/day, because of the need to calculate dermal and inhalation risks together. A NOEL for cholinesterase inhibition was not established. The Agency applied an UF of 300 for the inhalation risks to account for interspecies extrapolation (10X), intraspecies variability (10X), and the use of a LOEL (3X) rather than a NOEL for short and intermediate term risk estimates. An inhalation MOE that is greater than 300 is above the Agency's level of concern.

In reviewing the use patterns of profenofos, the Agency identified four major exposure scenarios: (1) mixing/loading liquid formulations for aerial and groundboom equipment; (2) aerial application (3) groundboom application; and (4) flagging during aerial spray applications. Absent chemical specific data, the Agency assessed the aerial and ground scenarios using surrogate data from PHED version 1.1. The Agency also assumed that an applicator applies profenofos to 350 acres/day (aerial) and 80 acres/day (groundboom) at the maximum label rate of 1 lb ai/acre. Mixing/loading and application are assumed to be performed by different individuals.

The results of these assessments indicate that dermal exposure is a significant source of exposure and that inhalation exposure does not contribute measurably to overall exposure. The dermal exposure component resulted in MOEs <100 for aerial mixers/loaders (MOE 23) and aerial applicators (MOE 40), based on exposure estimates assuming the use of engineering controls (i.e., closed mixing/loading systems and enclosed cockpits). The MOE for aerial flaggers was 1000 when assuming the use of engineering controls (enclosed cabs). If engineering controls are used, the MOE for groundboom mixers/loaders is 101 and for groundboom applicators the MOE is 180. The Agency continues to be concerned about mixer/loaders and applicators involved in aerial spray operations even after considering the use of engineering controls. Reducing the aerial application rate to 0.75 lb. ai/A results in increased MOEs for aerial mixers/loaders (MOE 29) and aerial applicators (MOE 50).

The Agency assumed 350 acres per day as a representative treatment day for handlers supporting cotton treatment, rather than using the 1200 default maximum treatment value. Based on information provided by the registrant and the use practices associated with profenofos, the Agency considers 350 acres to be a reasonable assumption. In the case of profenofos, the Agency believes that the conventional maximum default values, which expresses the total cotton acreage per day under

ideal weather conditions, would overestimate exposure. Typically, profenofos would not be applied at the maximum rate to the entire cotton acreage on a given farm. Entire fields may not need to be treated because pest pressure is often localized.

Postapplication Risk

The Agency also assessed risks to postapplication workers. Postapplication workers who enter previously treated fields may be exposed to profenofos because their skin contacts treated surfaces. Exposures are directly related to the kind of tasks performed. The Agency examines the amount of pesticide residue found on the workers over time from various studies. The Agency evaluates this information to determine the number of hours/days following application that must elapse before the pesticide residues dissipate to a level where worker MOEs equal or exceed 100 while wearing baseline attire. Baseline attire is defined as long-sleeved shirt, long pants, shoes and socks. Based on the results of the postapplication worker assessment, the Agency decides whether to establish early entry restrictions for worker reentry into treated fields for nonroutine hand labor activities using a specified set of PPE or to prohibit entry for a period of time.

For profenofos, the Agency also reviewed dislodgeable foliar residue (DFR) studies (MRID 428513-04 and 428513-03) and postapplication worker exposure studies (MRID 428513-02) that were conducted at several sites in various states. These studies measured the average dislodgeable foliar residues and postapplication exposure to workers during scouting and hoeing activities. The results of these studies showed that the major exposure was from the dermal route and exposure via the inhalation route is not a concern. Using the data from these studies, the Agency determined that the MOEs for dermal risks were above the level of concern (MOE greater than 100) at days two to three following pesticide application. These data support the current reentry interval (REI) of 48 to 72 hours (for non-arid conditions). Table 3 below summarizes the MOEs for scouts and hoers who may enter fields treated with profenofos. As shown in the table, dermal risk for both scouts and hoers for a period of time (48-72 hrs) after treatment exceed the Agency's level of concern.

Table 3. Risks for Cotton Scouting and Hoeing in Profenofos-Treated Fields

Margins of Exposure (MOEs)*						
	Cotton Scouting			**Cotton Hoeing**		
Days after treatment	**North Carolina & South Carolina (avg of 3 sites)**	**Texas**	**California**	**North Carolina & South Carolina (avg of 3 sites)**	**Texas**	**California**
0	15	9	13	38	22	32
1	43	48	40	**110**	**120**	99
2	**200**	**140**	78	not needed	not needed	**195**
3	not needed	not needed	**110**	not needed	not needed	not needed

*MOE = NOEL ÷ Calculated Average Daily Dermal Dose; where the NOEL = 1 mg/kg/day and the Calculated Average Daily Dermal Dose = DFR (µg/cm^2) x TC (cm^2/hr) x conversion factor (1 mg/1,000 µg) x exposure time (8 hrs) ÷ body weight (70 kg). See table 1 in amended postapplication risk assessment dated August 13, 1999, in docket.

Human Incident Reports

The Agency reviewed the Incident Data System (IDS) to determine whether profenofos cases had been reported. The database contains over 17,000 pesticide-related reports of incidents involving adverse effects to humans and approximately 9,000 reports involving domestic animals since 1992. Of the reported incidents, profenofos was identified in only seven human cases with minor symptoms and one lawsuit alleging death.

The Agency also reviewed the Poison Control Center's data which compiles data reported from 1985 through 1992. This database covered 28 organophosphate and carbamate chemicals. Additional data on all pesticide exposures were obtained for the years 1993-1996. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System, which obtains data from about 70 centers at hospitals and universities. There were only three occupational cases and four non-occupational cases involving exposure to profenofos alone reported from 1985 through1992. Two occupational and six non-occupational cases were reported for profenofos from 1993 through 1996. Non-occupational cases are likely to involve bystanders or workers exposed to spray drift. Profenofos had a lower ratio of symptomatic cases reported per pounds used than did other organophosphate or carbamate insecticides.

E. Environmental Risk Assessment

1. Environmental Fate and Transport

Available environmental fate studies show that profenofos is not persistent, particularly in neutral and alkaline soils. Hydrolysis is the major route of dissipation in neutral to alkaline environments. Photolysis is not a major pathway while biotic processes -- aerobic and anaerobic metabolism -- become important after the initial hydrolysis. Profenofos metabolizes rapidly in aerobic and anaerobic conditions and dissipates in neutral to alkaline soils with a half-life of several days. Little data exists for acid soils, although it can be inferred that profenofos dissipates at a slower rate. One of the major degradates, 4-bromo-2-chlorophenol, is persistent in the environment while the fate of another degradate, O-ethyl-S-propyl phosphorthioate, is not well known. Profenofos is not highly mobile and is not expected to leach to ground water under normal use. Because field dissipation studies were conducted under conditions that resulted in a moisture deficit, the leaching potential could not be reliably assessed in the studies. The mobility and leaching potential of the degradates is unknown. The chemical may reach surface waters through spray drift or runoff.

The available environmental fate database is relatively complete but contains substantial gaps related to profenofos' degradates. However, the Agency does not expect the degradates to pose any toxicological concerns. While the guideline requirements have been met, our understanding of the fate of profenofos is confined primarily to neutral and alkaline environments (which are more prevalent in the Southwest and Western cotton-growing regions). The fate of profenofos under acidic conditions

(common to the Southeast and Mid South regions) is not well understood. (See Reregistration Eligibility Decision Environmental Risk Assessment for Profenofos, June 16, 1999, for a detailed discussion.)

2. Ecological Risk Assessment Analysis

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics, pesticide use, and/or monitoring data. To evaluate the potential risk to nontarget organisms from the use of profenofos products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the estimated exposure concentration to the toxicity endpoint values, such as a LD50 or LC50. These RQ values represent the level of concern the particular pesticide and/or use may pose for nontarget organisms. Use, toxicity, fate, and exposure are combined to characterize the risk as well as the level of certainty and uncertainty in the assessment.

For profenofos, laboratory data showed that it is highly to very highly toxic to fish and aquatic invertebrates. The Agency also assessed fish kill incident reports and testing to determine potential risk to aquatic species.

The acute toxicity data for nonterrestrial animals showed moderate toxicity using a single-dose oral study on mallard ducks. Subacute studies on mallard duck and northern bobwhite quail showed slight to high toxicity to these species, respectively (MRID 43107302). A chronic toxicity study for avian species showed that profenofos significantly affects egg production due to parental toxicity (MRID 92148004 and 92148006). The results of acute and subacute studies on small mammals indicated that profenofos is moderately toxic (MRID 00105226 and 001052281). Profenofos is highly toxic to honey bees (MRID 41627308).

a. Nontarget Terrestrial Animal Risk

The Agency has adequate data to assess the hazard of profenofos to nontarget terrestrial organisms. On an acute basis, profenofos is moderately to highly toxic to birds, moderately toxic to small mammals, and highly toxic to bees.

Results of acute toxicity studies do not represent all species of bird, mammal, or aquatic organisms. Only one or two surrogate species for birds are used to represent all bird (680+) species in the United States. For mammals, acute studies are usually limited to a Norway rat or house mouse. Neither reptiles nor amphibians are tested. The assessment of risk or hazard makes the assumption that avian and reptilian toxicity are similar. The results of these studies indicate that profenofos is more toxic to some bird species (MRID 416273-01) than others. Also, avian reproduction studies showed the profenofos affects egg production due to parental toxicity (MRID 92148004, 92148006).

A single application of profenofos at maximum label rates poses some acute and chronic risk to birds (acute RQs range from .21- 4.21 and chronic RQs range from 1.2 - 24) and small mammals (acute RQs range from 0.01 - 0.76). Since profenofos can be applied up to 6 times per season (at the maximum label rate), profenofos levels in the environment and on avian and mammalian food and feed items from its use could be as much as 2 times higher than those associated with a single application.

b. Nontarget Aquatic Animal Risk

Toxicity data for profenofos show that the chemical is highly to very highly toxic to fish and aquatic invertebrates. In calculating toxicity to nontarget aquatic animals, the Agency typically uses one or two surrogate species to represent all freshwater fish (2000+) species in the United States. Estuarine/marine testing is usually limited to a crustacean, a mollusk, and a fish. The assessment of risk or hazard assumes that fish and amphibian toxicity are similar.

Since profenofos can be applied up to 6 times per season (at the maximum application rate), the Agency assumed this frequency and rate of application in conducting its aquatic risk assessment, and, assumed that the compound would degrade fairly rapidly between applications. The resulting acute RQs range between 0.24 and 0.77 for fish, between 2.5 - 6.4 for aquatic invertebrates, and the RQ is 0.02 for shellfish. The chronic RQ for fish is 0.58; the chronic RQ for aquatic invertebrates is between 5.2 and 5.8. This suggests that the use of profenofos poses some acute risk to fish and aquatic invertebrates and some chronic risk to aquatic invertebrates. The magnitude of the actual risks posed to aquatic species may be somewhat greater in certain locations (e.g., the Southeast and Mid-South cotton growing regions) than is suggested by these RQs. This is because in certain surface water systems (i.e., systems which are more acidic), profenofos will not degrade as rapidly as was assumed in the calculation of the above RQs. In fact, there have been 13 documented, significant fish kill incidents between 1994 and 1996 attributed to profenofos use in Louisiana and Mississippi. These fish kills were generally attributed to runoff of profenofos - suggesting that the Agency's aquatic risk assessment and acute RQs accurately reflect the fact that the use of this compound poses some acute risk to fish.

As noted earlier, the Agency estimated acute profenofos concentrations in surface water using modeling (6 ppb for peak). The profenofos concentrations reportedly found in surface water associated with the fish kill incidents were generally below the modeled acute peak concentration. The measured concentration levels of profenofos ranged from 0.08 ppb - 36.4 ppb in surface water where the fish kill incidents occurred.

In the majority of the incidents, water samples were taken and analyzed for profenofos. While measured concentrations were below the fish LC_{50}, initial profenofos concentrations were likely higher prior to dilution in the water bodies and dissipation prior to sampling (post incident). Profenofos was detected in fish tissue in the four incidents in which it was analyzed. Profenofos was the only pesticide detected in 3 incidents. Of the remaining 10 incidents, methyl parathion and atrazine and/or cyanazine

were believed to be a co-contributor in two separate incidents, while other pesticides were considered unlikely contributors due to the toxicity, concentration, or lack of detection in fish tissues.

The Agency considers these reports reliable because samples collected by States and analyzed by universities confirmed the presence of profenofos in either fish tissues or water. Records indicate the Curacron 8E product used at the time of these incidents had the label statement prohibiting aerial application "within 300 feet upwind of impounded water" and that label directions and precautions were followed by certified applicators. None of the reported incidents were attributed to misuse. Therefore, the Agency has concern for the acute risks posed to freshwater and marine/estuarine fish from the labeled use of profenofos.

The Agency assessed the results from an early fish life cycle study (MRID 92148014) to establish the chronic toxicity of profenofos. The results indicate that profenofos is very highly toxic on a chronic basis. However, the Agency needs more data to adequately assess the chronic risk for aquatic animals. Additional data are needed because the estimated environmental concentration (EEC) (5.9 ppb) is equal to or greater than one-tenth of the NOEC (2.0 ppb) in the early fish life cycle study and studies from other organisms indicate that the reproductive

physiology of fish may be affected which could adversely impact the ecological system. The full fish life cycle study is needed for the Agency to confirm the chronic risks to aquatic life.

F. Assessment of the Use of Profenofos

1. Use Patterns

On average, approximately 775,000 pounds of profenofos are applied to 5% of the estimated 13.8 million acres of cotton grown annually in the United States. Profenofos is used in three regions: the South (AL, AR, FL, GA, LA, MS, MO, SC, and TN), Southwest (NM, OK, TX), and the Far West (AZ, CA). Almost 90% of the estimated profenofos use occurs in the Southern region. However, profenofos accounts for only 6% of the total insecticide use on cotton in this region. Use of profenofos in the Far West and Southwest accounts for less than 5% of the total insecticide use in those regions on cotton. (EPA proprietary data, 1995-1997) Application rates vary by pest species and infestation level, but typical application rates range from 0.125 to 0.5 lb. a.i. per acre early season to 0.25 to 1.0 lb a.i. per acre mid-to-late season.

The primary and most critical targeted pests of profenofos applications are the worm complex: tobacco budworm, cotton bollworm, and fall and beet armyworms. It is estimated that greater than 50% of all insecticide treatments applied to cotton are targeted at worm complex pests. The worm complex attacks developing bolls directly impacting yield and quality of the cotton. Yield losses attributable to this complex can be as high as 90% in untreated cotton fields (Crop Profile for Cotton in North Carolina, 1999, USDA/OPMP). Profenofos also has usage targeted at the cotton aphid, spider

mites, plant bugs, leafhoppers, and whiteflies, which all occur at varying levels in the different cotton production regions. Profenofos use, as a percent of the total insecticide use on each pest, is estimated to be 10% or less for all six pest groups. An estimated 85% of all profenofos usage is for the control of the worm complex. Profenofos is not used for boll weevil control or as a component of any eradication program, but is currently an important component of a systems approach to control the targeted pests.

Profenofos is one of only a few registered pesticides that has both larvicidal and ovicidal activity on the worm complex. This is important because worm pressure often increases dramatically towards the end of the growing season with an associated increase in the amount of egg laying. This is one reason profenofos usage is highest from mid-to-late season. Ovicidal activity is important against the worm complex because of the intense pest pressure that can build very quickly late in the season. With activity against both stages of the worm complex, profenofos continues to be an important component of a systems approach to the control of these important pests. Growers typically vary the application rate as a function of pest pressure. Although the worm complex is the most targeted pest, early season applications are usually at rates below the maximum label rate.

2. Alternatives

When the Agency reviews alternatives to a pesticide, it considers efficacy against target pests, costs, ease of use, potential resistance development to the pesticide, impacts on existing integrated pest management (IPM) programs, and several other characteristics. The Agency recognizes that there are several alternatives potentially available to control the pests targeted by profenofos on cotton (see, "Analysis of the Use of Profenofos Insecticide (Curacron 8E) on Cotton", November 2, 1999); however, none are exact replacements.

One of the newer and more novel alternatives is Bt cotton (cotton containing the Bt gene (*Bacillus thuringiensis*) (Bollgard™), a Monsanto Corp. product, which was introduced for commercial use in 1996. Bt cotton provides excellent control of pink bollworm and tobacco budworm, moderate control of bollworm, and some control of armyworms. Other potential alternatives include synthetic pyrethroids (lambda-cyhalothrin, zetamethrin, cypermethrin, cyfluthrin, esvenfalerate, and tralomethrin) and other organophosphates and carbamates. There are several recently registered insecticides (i.e, spinosad, tebufenozide, and pymetrozine) for use on cotton and several more under review. Some of these pesticides, used in combination with other existing control techniques (Bt cotton, pyrethroids, other OPs, and carbamates), may achieve efficacious control for the pests targeted by profenofos.

The Agency also considers the cost of potential alternatives when evaluating how appropriate substitute pest control measures are to an existing technique, in this case profenofos. Several of the potential alternatives identified (the synthetic pyrethroids, the organophosphates, and the carbamates - except aldicarb) are estimated to cost the same or less than profenofos per acre. Although Bt cotton may be more expensive to produce and growers also pay a premium (technology fee) on the seed (that

makes the overall cost of the seed substantially more than non-Bt cotton seed), the costs are offset by the reduced amount of treatments needed and the potential increase in yield (Crop Profile for Cotton in Texas, 1999, USDA/OPMP). However, Bt cotton and the other alternatives are not used alone because of the potential for target pests to build up resistance to the pesticide.

Profenofos is an important component of current resistance management strategies. Its efficacy in controlling high worm complex infestation periods is consistent with the interim reregistration eligibility decision and risk management decisions stated below.

IV. Interim Risk Management Reregistration Eligibility Decision

A. Interim Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing an active ingredient are eligible for reregistration. For profenofos, the Agency assessed the dietary, ecological and occupational risks associated with its use on cotton. There are no residential uses. The Agency has determined that the organophosphates share a common mechanism of toxicity, the inhibition of cholinesterase levels. As required by FQPA, a cumulative assessment will need to be conducted to evaluate the risk from food, water and non-occupational exposure resulting from all uses of OPs. Currently, the Agency is developing the methodology needed to conduct such an assessment with guidance/advise provided by the Science Advisory Panel. Consequently, the risks and decisions presented in this document are only for profenofos.

For the individual assessment of profenofos, the Agency considered (1) dietary, occupational, and ecological risks, (2) the availability of efficacious alternatives, (3) scope of use, and (4) human and wildlife incident data. The Agency previously identified and required the submission of generic (i.e., active ingredient specific) data to support reregistration of products containing profenofos as an active ingredient.

The Agency has completed its review of these generic data (Appendix B identifies the generic data the Agency reviewed as part of its interim determination of reregistration eligibility of profenofos). During this review, the Agency determined that MOEs for handlers involved in aerial applications (mixers/loaders and pilots) exceed the Agency's level of concern even after engineering controls are considered. As discussed in Section IV.D., the Agency believes these risks could be overstated. Additionally, the Agency believes that chemical-specific data from field studies would more accurately reflect the actual exposure to profenofos during aerial application than currently estimated using surrogate data. The Agency is, therefore, calling in confirmatory chemical-specific exposure data on aerial mixers/loaders and applicators in order to refine the occupational risk assessment. The Data-Call-In (DCI) will require a handler dermal exposure study (using engineering controls). This chemical-specific exposure study should be conducted using an advanced closed mixing and loading system that

is not currently represented in the PHED database. The Agency expects that this study will more accurately reflect actual exposure and that the associated risk will likely be of less concern than currently projected using PHED. (As described in Section IV, the registrant has agreed to manufacture profenofos in a particular performance-based, closed mixing and loading system.) Once the handler dermal exposure study is received and reviewed, the Agency may refine the risk assessment based on the findings. If the results of the study are not consistent with the Agency's expectations, the Agency may reconsider this reregistration decision.

As a result of its assessment of the risks of profenofos alone, EPA has determined that certain uses of profenofos, unless amended as set forth in this document, may present risks inconsistent with FIFRA. Accordingly, EPA may commence cancellation proceedings unless the registrant agrees to label changes implementing the risk reduction measures discussed in this reregistration eligibility decision. At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. The Agency also expects that new data from the pending exposure study will result in MOEs below the Agency's level of concern. Also, because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for profenofos after assessing the results of the exposure study or the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

The Agency therefore finds, based on the results of the risk assessments and the expected timely receipt of confirmatory exposure data, that products containing profenofos as an active ingredient are eligible for reregistration as long as the registrant fulfills the label modifications and the data requirements outlined in this document. As stated previously, this reregistration eligibility decision does not include the cumulative assessment with other organophosphates.

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

1. Summary of Phase 5 Comments and Responses

A 60-day public comment period for the revised risk assessments was initiated on June 16, 1999. The Agency invited the public to submit risk mitigation recommendations at the technical briefing held on June 16, 1999, and in a FR notice (64 FR 32229, dated June 16, 1999) which opened the public docket. No comments or risk mitigation options were submitted to the Agency during the public comment period.

2. Basis for Interim Eligibility Determination

This interim decision presents the Agency's current position on reregistration eligibility of pesticides containing the active ingredient profenofos. An incremental approach to the reregistration process (assessing available information and making risk mitigation decisions on the specific chemical prior to a cumulative assessment) is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By initially evaluating each organophosphate one at a time and taking appropriate risk reduction measures on that basis, the Agency is addressing the risks of the organophosphates in as timely a manner as possible. If the Agency receives any additional information that calls the basic findings of this assessment into question, this decision may be modified.

"Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment was for this individual organophosphate, and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of organophosphates once the methodology is developed and the policy concerning cumulative assessments is resolved.

EPA has determined that risk from exposure to profenofos is within its own "risk cup." In other words, if profenofos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for profenofos meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food and drinking water (there were no residential uses). Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to profenofos "fit" within the individual risk cup. Therefore, the profenofos tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is completed.

B. Tolerance Summary

In the individual assessment, tolerances for residues of profenofos in/on plant commodities [40 CFR §180.241] are presently expressed in terms of profenofos and its metabolites converted to 4-bromo-2-chlorophenol and calculated as profenofos. The Agency has concluded that profenofos *per se* is the compound of toxicological concern. The tolerance expression will be revised to reflect that profenofos *per se* is the only regulated residue. Sufficient field trial data reflecting the maximum registered use patterns are available to reassess the established tolerance for cottonseed; data indicate that the existing cottonseed tolerance should be lowered from 3.0 ppm to 2.0 ppm.

Ruminant metabolism and feeding studies indicate that the established tolerances for the fat, meat, and meat byproducts of cattle, goats, horses, and sheep (0.05 ppm), and for milk (0.01 ppm) are adequate. Poultry metabolism and feeding studies indicate that there is presently no need for tolerances for residues of profenofos *per se* in poultry tissues and eggs; the established tolerances should be revoked. The Agency is revoking the tolerance for hogs based on feeding studies.

Tolerances To Be Proposed Under 40 CFR 180.404

A tolerance for cotton gin byproducts is needed. The registrant should submit a petition to establish a new tolerance for cotton gin byproducts at 55 ppm.

Tolerances Listed Under 40 CFR 186.4975

Based on the results of an acceptable cottonseed processing study and the revision to the tolerance expression, the established feed additive tolerance for cottonseed hulls should be revoked. The Agency no longer recognizes soapstock as a significant feed item. The established feed additive tolerance should be revoked. A tolerance summary of profenofos' tolerance reassessments is presented in Table 4.

Table 4. Tolerance Summary for Profenofos

COMMODITY	CURRENT TOLERANCE (ppm)[a]	TOLERANCE REASSESSMENT (ppm)[b]*	COMMENT/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR 180.404:			
Cattle, fat	0.05	0.05	
Cattle, mbyp	0.05	0.05	
Cattle, meat	0.05	0.05	
Cottonseed	3.0	2.0	Field trial data suggest that the established tolerance for cottonseed should be lowered. *[Cotton, undelinted seed]*
Eggs	0.05	Revoke	Poultry metabolism and feeding studies indicate that tolerances are not needed for poultry commodities. [Category 40 CFR 180.6(a)(3)]
Goats, fat	0.05	0.05	

COMMODITY	CURRENT TOLERANCE (ppm)[a]	TOLERANCE REASSESSMENT (ppm)[b]*	COMMENT/ *[Correct Commodity Definition]*
Goats, mbyp	0.05	0.05	
Goats, meat	0.05	0.05	
Hogs, fat	0.05	Revoke	Feeding studies indicate that tolerances are not needed for hog commodities. [Category 40 CFR 180.6(a)(3)]
Hogs, mbyp	0.05	Revoke	
Hogs, meat	0.05	Revoke	
Horses, fat	0.05	0.05	
Horses, mbyp	0.05	0.05	
Horses, meat	0.05	0.05	
Milk	0.01	0.01	
Poultry, fat	0.05	Revoke	Poultry metabolism and feeding studies indicate that tolerances are not needed for poultry commodities. [Category 40 CFR 180.6(a)(3)]
Poultry, mbyp	0.05	Revoke	
Poultry, meat	0.05	Revoke	
Sheep, fat	0.05	0.05	
Sheep, mbyp	0.05	0.05	
Sheep, meat	0.05	0.05	
Tolerances To Be Proposed Under 40 CFR 180.404:			
Cotton, gin byproducts	None	55.0	New RAC according to the 860 Residue Chemistry Guidelines, 860.1000, Table 1 (August 1996).
Tolerances Previously Listed Under 40 CFR 186.4975:			
Cottonseed hulls	6.0	Revoke	Not warranted based on the results of an acceptable cottonseed processing study and the revision to the tolerance expression.
Soapstock	15.0	Revoke	No longer considered a feed item by the Agency (860 Residue Chemistry Guidelines, 860.1000, Table 1; August 1996).

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

The Agency will commence proceedings to revoke, modify the existing tolerances, and correct commodity definitions. The establishment of a new tolerance will be deferred, pending the outcome of the cumulative assessment.

C. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that EPA

include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and FFDCA authority to require wildlife evaluations to the extent that effects in wildlife may help determine whether a substance may have an effect in humans. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

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

D. Regulatory Position

Section IV.D-F outlines the specific risk mitigation measures established in this decision document. Where labeling revisions are necessary, specific language is set forth in the summary tables of Section V. The Agency believes the measures identified in this document will adequately mitigate the risks associated with the use of profenofos. In particular, the Agency has determined the measures discussed below will reduce risks to mixers/loaders and applicators involved in groundboom and aerial applications, flaggers supporting aerial applications, postapplication handlers and workers, and mitigate exposure to nontarget organisms. The registrant has agreed to amend the label incorporating all the changes by the 2001 growing season.

The Agency has determined that profenofos must be used in closed systems to mitigate handler and worker risks. Requiring closed systems resolves much of the worker risks associated with both groundboom and aerial application. (Aerial application usually involves handling larger quantities of the chemical than groundboom application, resulting in higher risk). The registrant has agreed to market the product only in an advanced mixing/loading system. Enclosed cockpits must also be used for aerial application. When closed loading systems are employed, mixer/loader and applicator risks are not of concern for groundboom applications (given the smaller number of acres treated and the amount of pesticide handled). Using enclosed cabs, restricted entry intervals and appropriate personal protective equipment the risks to flaggers supporting aerial applications and the risk to postapplication workers and handlers are also not of concern.

Although the current risk assessment indicates a concern for handlers involved in aerial applications, the Agency believes that such risks do not raise a concern when all of the uncertainties and mitigation measures outlined in this document are considered. To confirm this position, the Agency is requiring the registrant to undertake an exposure study using the advanced mixing/loading technology that will be marketed next year. This advanced system is expected to perform better than the older closed mixing/loading systems currently reflected in the PHED database. The Agency believes that the exposure study will confirm that the refined MOE's are actually much higher than the current estimates using surrogate data Therefore, actual occupational exposures are expected to be less. The Agency also recognizes that there is uncertainty in the endpoint used for the occupational risk estimates. There is a 10-fold range between the NOEL observed in the rabbit 21-day dermal toxicity study and the

LOEL. If this study were repeated, a higher NOEL might be identified indicating actual toxicity is less than the Agency's current assessment suggests. The use of this improved system combined with the label amendments are expected to confirm the Agency's belief that actual exposures and concomitant risk are not of concern when profenofos is used as specified in this interim reregistration decision document.

To further reduce potential exposure, the Agency is requiring a reduction in the seasonal maximum application rate from 6 to 5 lbs ai/A/season. Application at the 1 lb ai/A rate will be limited to twice per year and may be used only for severe lepidopteran infestations. Use under all other conditions will be limited to 0.75 lbs ai/A/application. Information reported by USDA indicates that growers frequently use even lower application rates generally ranging from 0.46 to 0.62 lb ai/A and have used rates as low as 0.25 lb ai/A. At this lowest application rate, occupational risks are not of concern based on the current assessment.

The Agency is requiring an advisory notice be added to the label to inform crop advisors of the potential risks to workers who reenter the field immediately after application. In particular, this information can assist certified crop advisors [as defined by the Worker Protection Standard (WPS)] who are exempt from the Agency's WPS requirements and allows them to determine the level of protection that should be required for themselves and their employees during scouting activities.

Postapplication residue data indicate worker risks are of concern when cotton is harvested by hand. Mechanical harvesting equipment significantly limits potential handler/harvester exposure. Discussions with stakeholders indicate that virtually all harvesting is currently done mechanically. The Agency is therefore requiring that "mechanical only" harvesting be allowed for profenofos.

To reduce the risks to aquatic animals and other nontargeted terrestrial organisms, the Agency is requiring the use of buffer zones and vegetative strips and a continuation of the registrant's stewardship programs. These measures, coupled with the rate changes, are expected to adequately reduce ecological risk of profenofos.

Profenofos occupies a critical pest control niche for cotton growers in controlling lepidopteran pests as stated earlier. The Agency has determined that the availability of profenofos is most critical during severe pest pressure. In considering the potential alternatives, the Agency considered the potential for pesticide resistance. The alternatives are used in combination with other pesticides, including profenofos, as part of a resistance management strategy to maintain their viability as efficacious materials for the control of the worm complex and several other target pests that profenofos controls. Therefore, profenofos remains an important pest control tool.

E. Human Health Risk Mitigation

The Agency has determined that the dietary aggregate exposure (food and water) is less than the Agency's level of concern. However, risks to certain occupational workers and handlers is of concern.

The Agency has also determined engineering controls are warranted to reduce short and intermediate term occupational exposures. Additionally, the registrant has initiated a mammalian pharmacokinetics study in preparation of a mixer/loader and applicator exposure study that may refine the occupational exposure assessment.

1. Mitigation Measures

Dietary risk from food and water sources is less than the level of concern determined by the Agency.

a. Dietary (food)

(i.) Acute

The acute dietary exposure estimate is below the Agency's level of concern for the general U.S. population and all population subgroups. Infants and Children (1-6 years) are exposed to profenofos at a level less than or equal to 8% of the aPAD (0.005 mg/kg/day) at the 95th exposure percentile. No additional mitigation for acute dietary food risk is needed.

(ii.) Chronic

The chronic dietary risk estimate is below the Agency's level of concern for the general population and all population subgroups. The risk is estimated to be less than 20% of the cPAD for all population subgroups including Infants and Children (1-6 years). No additional mitigation for chronic dietary food risks is needed.

b. Dietary (water)

The Agency's upper bound estimates of acute and chronic drinking water exposure are less than the corresponding DWLOC. Therefore, risks from surface and ground water did not exceed the Agency's level of concern. No mitigation for acute or chronic drinking water risks is required.

c. Residential and Other Non-Occupational Risks

There are no residential or other non-occupational uses of profenofos. Therefore, no mitigation is required.

d. Aggregate (food and water)

For profenofos the aggregate risk is limited to food and water because there are no residential uses. The risk estimates presented do not exceed the Agency's level of concern for the most highly exposed subpopulation, children and infants. No mitigation is required since the aggregate risks are below the Agency's level of concern.

e. Occupational Risk Mitigation

Based on the Agency's revised occupational risk assessment, handlers of profenofos are exposed (dermally) at a level of risk concern. Estimated MOEs for inhalation exposure are well over the target MOE of 300 for all exposure scenarios and do not contribute significantly to the overall risk. Therefore, inhalation risks are not a significant issue for reregistration. Absent dermal risk mitigation measures such as the use of engineering controls, the Agency finds that mixers/loaders and applicators supporting groundboom or aerial applications are subject to risks currently exceeding the Agency's level of concern. To address these exposure concerns, the registrant is proposing to revise the profenofos registration product labeling as specified below. The current label requires the use of coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, and chemical resistant footwear plus socks. The current label also allows up to 6 applications per season at a rate of 1 lb ai/acre. The registrant is prepared to immediately implement the following measures:

- Produce product only in enclosed transfer system container starting with the year 2001 growing season.

- Stipulate the use of enclosed cabs and cockpits for groundboom applicators and flaggers, and aerial applicators, respectively.

- Conduct handler dermal exposure study (with engineering controls).

- Reduce the maximum application rate to 0.75 lb ai/acre for all applications, except applications to control lepidopteran pests.

- Limit use of the maximum application rate of 1 lb ai/A to twice per season and allow the maximum rate only for lepidopteran pests (worm complex, such as caterpillars, etc).

- Prohibit pilots from mixing or loading on the same day.

(i.) Mixers/Loaders

Groundboom: The MOE for mixer/loaders supporting groundboom applications is 101 if engineering controls (i.e., closed mixing/loading systems) are used. Therefore, the Agency is requiring mixers/loaders supporting groundboom applications to use closed mixing/loading systems.

Aerial: The MOE for mixer/loaders supporting aerial applications is 23 if engineering controls (i.e., closed mixing loading system) are used.

As mentioned above, the registrant has agreed to modify the profenofos label immediately, mandating the use of closed mixing/loading systems. The Agency is requiring the registrant to manufacture profenofos in a closed/loading container system. The system must be used to mix/load and enclose the pesticide in a manner to prevent it from contacting handlers. At the connection point, a dry disconnector or dry coupler with not more than 2 ml drippage per disconnect must be installed to ensure worker exposures do not exceed estimated levels. Because closed systems have been commercially available for profenofos users for some time, the Agency does not anticipate that cotton growers or commercial applicators will face difficulties in fully converting to such a use requirement.

The registrant is planning to conduct a biomonitoring study to better determine the level of exposure associated with using the enclosed cockpits and closed mixing/loading systems at the maximum label rate of 1 lb ai/A for handlers (pilots and mixer/loaders) involved in aerial spray applications. At this time the registrant is working on the metabolism study in the monkey to determine the pharmacokinetics. This biomonitoring study may be substituted for a passive dosimetry study, assuming the pharmacokinetics of profenofos are well understood and the study is acceptable.

Furthermore, when considering the recent use trend for profenofos, many mixers/loaders are actually not exposed to profenofos at the levels estimated by the Agency. Use data from 1995-1997 reveal that only about 30% of profenofos applications were at the maximum application rate of 1 lb ai/A. The balance of applications were at rates equal to or less than 0.75 lb ai/A. According to the National Cotton Council, applications made early in the growing season may be as low as 0.25 lb ai/A. This is reportedly a practice common in many profenofos use areas in recent years. When considering the Agency's current risk assessment, the mixers and loaders who work with profenofos at the lowest rates are exposed at levels that are of less concern. It is only the handlers who work with the chemical at the highest rates that have MOEs of the greatest concern to the Agency. Limiting the highest rate to two times per season serves to reduce and limit the potential frequency of such exposures. The Agency further expects that the remaining applications will be made at rates less than 0.75 lb ai/A. Based on information from the USDA, the National Cotton Council, and a review of available marketing information, the Agency believes that these measures will reduce the potential for exposure in a meaningful way.

(ii.) Applicators and Flaggers

Similar to the mixer/loader measures discussed in the previous section, the registrant is also modifying the profenofos label to address risks associated with dermal exposure to applicators and flaggers using profenofos. When using engineering controls as discussed in Section III, the MOEs are as follows: groundboom applicators,180; aerial applicators, 40; and aerial flaggers,1000. Therefore, the registrant has agreed to require the use of enclosed tractor cabs and enclosed cockpits, which are widely available for profenofos users. Mechanical flaggers may also be used. A compliant enclosed cab/cockpit has a nonporous barrier that completely surrounds the occupants of the cab and prevents dermal contact with the pesticide outside of the cab/cockpit. Such new use requirements should not pose any difficulty for cotton growers and commercial applicators because such measures are routinely used (verbal communication with National Cotton Council, 1999).

With the use of enclosed cabs, groundboom applicator and flagger risks are significantly reduced and are not of concern to the Agency. However, the aerial applicator risk is not reduced below the Agency's level of concern at the higher use rates. As stated previously, the Agency believes the proposed interim risk mitigation measures being implemented by the registrant immediately are appropriate and consistent with Agency goals for interim reregistration of the organophosphates. For profenofos, reduction in the seasonal and single application rates, the use of closed systems, and information on decreasing use trends all support the Agency's decision to proceed with the interim reregistration. However, if the results of the worker exposure study show that these measures are not as effective as anticipated, the Agency may revisit this decision. Meanwhile, the Agency is prohibiting pilots from participating in mixing/loading operations on the same day of application. The Agency believes this measure, coupled with the adoption of closed systems and the modified application rate, will reduce exposure levels to aerial applicators.

The Agency is also concerned about applicators/flaggers that must enter or exit contaminated cabs in a treated area. A chemical resistant apron or coveralls, and chemical resistant gloves must be available for flaggers or applicators to use when exiting a cab in the treated area.

(iii.) Other Handlers

In addition to mixers, loaders and applicators, the Agency is concerned about potential exposure to other handlers who participate in tasks where engineering controls are not feasible or may fail (e.g., cleaning, adjusting or repairing equipment; disposing of containers; opening or closing hoses; or cleaning up spills). Secondary exposure and risks may result from profenofos residues that may

remain on the equipment or in the use area. The PPE necessary to protect these handlers include the following:

- double layer of clothing (e.g., coveralls worn over long sleeve shirt and long pants)
- chemical resistant gloves
- socks and chemical resistant footwear
- chemical resistant apron (for use by handlers when cleaning equipment).

(iv.) Postapplication Workers and Handlers

The Agency is also concerned about postapplication exposure and risks to workers performing routine tasks such as hoeing, scouting, or the like in the treated area. The Agency estimated postapplication risks to such individuals from two foliar dissipation studies (MRID 428513-04 and 428513-03) and a worker reentry study that also included a dislodgeable foliar residue (DFR) study (MRID 428513-02).

The DFRs were based on using six applications at the 1 lb ai/A maximum labeled rate. The maximum application rate for profenofos may not be used in all cases and may overestimate risks in instances when a lower application rate is used. However, pest pressures could warrant more than one application at the maximum rate; therefore, the Agency believes the existing data appropriately measures the highest potential dermal exposure. These studies allow the Agency to develop mitigation that is protective for all potential use scenarios. In this case, the mitigation measures are consistent with the requirements outlined under the WPS.

Based on the results of DFR studies that included scouting activities (see Table 3), the Agency is identifying entry restrictions to protect workers that need to reenter a treated field. The Agency is also concerned about the potential risks associated with scouting activities. Generally, scouts work under the supervision of crop advisors. Crop advisors that have been certified or licensed as required in the WPS and employees that work under their direct supervision are exempt from some reentry requirements. Certified crop advisors are authorized to determine the personal protection measures deemed necessary to protect the health of the scouts under their direct supervision.

The Agency believes the requirements discussed below are necessary to protect postapplication workers and scouts. These requirements do not apply to certified crop advisors and persons under their direct supervision at this time. The Agency is including an advisory notice on the label to assist certified crop advisors with determining the proper level of protection that should be required for scouting tasks.

- Early Entry Workers (as defined by WPS): Early-entry personnel must use protective equipment of coveralls; chemical-resistant gloves and shoes and socks. Early-entry personnel in non-arid (areas receiving at least 25" annual rainfall) areas should follow the above requirements for 48-hours after treatment and in arid areas should follow the above requirements for 72-hours after treatment.

- Double notification is required in accordance with WPS due to high dermal toxicity.

- Employees not under the direct supervision of certified crop advisors: Same as early entry workers and handlers per WPS.

- Only mechanical harvesting is allowed.

Postapplication-certified crop advisors and their employees. As mentioned in section IV.D., certified crop advisors and their employees are generally exempt from WPS provisions that address postapplication risks. However, for profenofos, the Agency reviewed field studies submitted by the registrant that indicate potential risks to scouts reentering treated fields. The Agency is committed to providing information and appropriate guidance to the regulated community. Therefore, the Agency is recommending that (1) associations representing certified crop advisors voluntarily inform scouts of the potential risks and the need to be protected during the REI; and (2) the following statement must be placed on the label:

ADVISORY TO CERTIFIED CROP ADVISORS: Users should inform Certified Crop Advisors [as defined by the Worker Protection Standard (WPS)] that people engaged in scouting activities should wear coveralls, shoes and socks, and chemical resistant gloves made of any waterproof material when entering treated areas during the first 48 hours following application (72 hours in areas where the average rainfall is less than 25 inches per year).

F. Ecological Risk Mitigation

1. Aquatic Animals

Some risk quotients for fish and aquatic invertebrate exceed the Agency's level of concern. RQs range from 0.02-6.4 compared to an acceptable RQ of 0.5. The registrant submitted studies on the mobility, hydrolysis, adsorption/desorption, and volatility of profenofos and its degradates in alkaline or neutral soils. Similar data for acidic conditions was not available, therefore, the Agency is not able to fully assess how profenofos acts under all soil conditions. However, the Agency also assessed several fish kill incident reports which did indicate that profenofos was either one of the potential pesticides or the only pesticide implicated in the fish kills. No reports of misuse were associated with any of the fish kill incidents.

Relying upon these fish kill incident reports, the Agency concludes that such incidents were attributable to profenofos use in accordance with the current label requirements. Although the incident reports did not identify site-specific conditions that may have contributed to the fish kills, an evaluation of the incident data and the fate profile suggests that the risk posed to fish from profenofos use is likely to be greater in regions that are susceptible to runoff with neutral to acidic soil conditions. This is more of a concern in the Mid-south and Southeast cotton region than in the Southwest or Texas.

2. Nontarget Terrestrial Organisms

Profenofos is highly toxic to bees, birds, and small mammals based on test results. The RQ values ranged from 0.53-0.76 for terrestrial animals (exceeding the acute risk level of concern of 0.5 or greater). Endangered species levels of concern are exceeded for birds and small mammals from the use of a single application at the maximum rate.

3. Mitigation Measures

a. Aquatic animals

To protect nontarget aquatic animals and reduce risk to nonterrestrial animals:

- Expand all aerial application buffer restrictions to 300 feet for all water bodies (or aquatic habitats) irrespective of wind conditions. (Implementing buffer zones would not limit the ability to plant, but rather restricts the application of the pesticide in the buffer areas.) Under the current label, the 300-foot buffer pertains only to impounded waters upwind of application. Most of the reported fish kill incidents occurred in nonimpounded water bodies.

- Use vegetative buffer strips as a means of protecting water bodies from runoff. The adsorption/desorption characteristics of profenofos suggest that vegetated buffers should be effective at preventing the movement of profenofos into nearby waters. The label should state that buffer width determination should be made in consultation with the local USDA and Natural Resource Conservation Service (NRCS) officials, taking into account the adsorption characteristics of profenofos. The Agency also believes the requirement for vegetative buffer strips will not pose a significant hardship on cotton-growers, because the synthetic pyrethroids which are used on cotton already require vegetative buffers.

- Prohibit application of profenofos in saturated soils. Do not treat while precipitation is occurring, or while conditions favor runoff from the treated area.

- Require 100 foot buffer zone for all waters for groundboom application irrespective of wind direction.

b. Birds and Mammals

Although RQs are exceeded for birds and small mammals, the Agency expects the other proposed mitigation measures will result in lower exposure for terrestrial animals. The proposed measures will reduce drift potential to off-field habitats and, thus, reduce exposure via food sources at and beyond the edge of the field. Also, the reduction in the application rate to mitigate worker risks should reduce the amount of pesticide applied and would have the effect of reducing the level of exposure. The Agency typically receives fewer incident reports for terrestrial organisms unless the exposure involves immediate mortality to large numbers of birds. Such incidents are not usually observed or reported. Should additional information come to the Agency's attention indicating birds or small animals are being adversely impacted, the Agency will take appropriate action at that time.

c. Additional Measures

Even though educational programs are not labeling measures, the registrant supports two voluntary educational programs that are available to growers and provide valuable information on the use of profenofos and potential hazards. The Delta program provides information to growers in Mississippi on a case-by-case basis on what best management practices to implement to avoid runoff into surface waters. The other program known as the Stewardship program is a website sponsored by the National Cotton Council that provides information on how to use profenofos to minimize environmental impacts. The information is important because it includes advice on ways to minimize risks to aquatic life and to avoid future fish kills. The registrant has agreed to expand the Stewardship program and outreach efforts to ensure that all growers are aware of the requirements and the potential impacts of profenofos on aquatic animals. The expansion will require the registrant to take the following steps:

- At routine grower meetings, provide relevant information on ways to minimize runoff or drift, thereby minimizing the potential for fish kill incidents.

- Link the company website to the Cotton Council website for the Stewardship program.

- Include information on the label concerning the website (URL address, information on use practices).

- Coordinate with state agencies, universities and special interest groups to provide outreach programs. Periodically (annually) evaluate the website use to determine the number of users that are accessing the information as a gauge of its utility.

4. Other Options Considered

The Agency requested the public to submit any mitigation proposals or comments to address the potential ecological/environmental risks for profenofos at the technical briefing held on June 16, 1999,(64 FR 32229). None were received.

5. Other Labeling Requirements

a. Endangered Species Statement

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

In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register. EPA is in the process of developing county-specific bulletins that specify measures to protect endangered and threatened species. Although bulletins have not yet been developed for all counties where they will be needed, EPA has completed and distributed over 300 county bulletins.

b. Spray Drift Management

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

"Do not allow this product to drift"

V. What Registrant Must Do

This section specifies the data requirements, responses and labeling changes 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 profenofos for the eligible uses has been reviewed and determined to be substantially complete. Based on a need to further refine the occupational and ecological risk assessments, the Agency is requiring the following additional data.

- Product Use Information. (Guideline 875.1700)

- Dermal Exposure Outdoor. (Guideline 875.1100)

- Full Fish Life Cycle Study for freshwater fish (Guideline 72-5)

The above studies will be used as confirmatory data. If the Agency finds that new studies identify additional risks of concern, the Agency will reconsider the measures established in this Interim RED. The Agency will issue a Data Call-In (DCI) requiring these studies.

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies; due dates are 9/2001. Registrant responses are under review.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current Agency regulations, PR Notices and applicable policies. The MUP labeling must bear the labeling contained in the table at the end of this section.

All registrants must submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all required label amendments outlined in Table 5 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. All amended labels must be submitted within 90 days of receipt of this document. The Registration Division contact for profenofos is Ms. Marilyn Mautz. Her phone number is (703) 308-6785.

B. End-Use Products

To remain in compliance with FIFRA, end-use product (EUP) labeling must be in compliance with all current Agency regulations, PR Notices and applicable policies.

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current Agency acceptance criteria 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

Label changes are necessary to implement mitigation measures outlined in Section IV above. These changes include reduction in application rates, except for lepidopteran pests; additional engineering controls or Personal Protective Equipment; mechanical harvesting requirements; retain the restricted-use classification and add a notation that the classification is due to high toxicity. Specific language to implement these changes is specified in table 5 below. Registrants must submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all required label amendments outlined in Table 5 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. All amended labels must be submitted within 90 days of receipt of this document. The Registration Division contact for profenofos is Ms. Marilyn Mautz. Her phone number is (703) 308-6785.

C. Existing Stocks

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

The Agency has determined that the registrant may distribute and sell profenofos products bearing old labels/labeling for 12 months from the date of issuance of this interim IRED. Persons other than the registrant may distribute or sell such products for 24 months from the date of the issuance of

this IRED. Registrants and persons other than the registrant remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

D. Required Labeling Changes Summary Table

A summary of the required label changes for profenofos is shown in Table 5.

Table 5: Summary of RED Labeling Requirements for Profenofos

Description	Required Labeling	Placement on Label
Manufacturing Use Products		
Formulation Instructions required on all MUPs	"Only for formulation into an insecticide/miticide for use on cotton."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statements	" **Environmental Hazards**" "This chemical is toxic to terrestrial and aquatic plants, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements under Environmental Hazards. Buffer zones also must appear in directions for use.

Description	Required Labeling	Placement on Label
End Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE". "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. Due to high toxicity.	Top of Front Panel
IRED PPE Requirements	**Personal Protective Equipment** "Some materials that are chemical resistant to this product are (registrant inserts correct material as per supplement 3 of PR notice 93-7). If you want more options, follow the instructions for category [registrant inserts A, B, C, D, E, F, G, or H] on an EPA chemical-resistant category selection chart." **Mixers, loaders, applicators, flaggers, and other handlers using engineering controls (see requirements below) must wear:** - long-sleeve shirt and long pants**,** - shoes plus socks - chemical resistant gloves and chemical resistant-apron when mixing and loading." "**Handlers** for which use of an engineering control is not possible and engaged in activities, such as cleaning up a spill or leak and cleaning or repairing contaminated equipment must wear: -- coverall over long-sleeve shirt and long pants, -- chemical-resistant gloves (registrant inserts correct glove types) -- chemical-resistant footwear plus socks -- chemical-resistant apron, NOTE: The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum personal protective equipment, specified above. The more protective PPE must be placed on the product labeling. Fro guidance on which PPE is considered more protective, see PR Notice 93-7.	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Description	Required Labeling	Placement on Label
Engineering Controls	**"Engineering Controls"** "Mixers and loaders must use a mechanical transfer system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for providing dermal protection. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to not more than 2 ml. per disconnect point." "Persons using a closed system that operates under pressure shall wear protective eyewear." "Pilots must: -- use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]; "Ground-equipment applicators and flaggers must use an enclosed cab that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(5)]." "All mixers, loaders, applicators, and flaggers must wear the personal protective equipment specified above for the task they are performing and all (except aerial applicators) must be provided and must have immediately available for use in an emergency, such as a spill, equipment failure or if exiting a cab in a treated area, the PPE specified above for handlers not using engineering controls."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	**"User Safety Recommendations"** "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing." **"ADVISORY TO CERTIFIED CROP ADVISORS**: Users should inform Certified Crop Advisors [as defined by the Worker Protection Standard (WPS)] that people engaged in scouting activities should wear coveralls, shoes and socks, and chemical resistant gloves made of any waterproof material when entering treated areas during the first 48 hours following application (72 hours in areas where the average rainfall is less than 25 inches per year).	Precautionary Statements: Hazards to Humans and Domestic Animals (Must be placed in a box.) (Immediately following Engineering Controls)

Description	Required Labeling	Placement on Label
Environmental Hazards	**"Environmental Hazards:** Due to the hazard to endangered fish, the application of this product is prohibited in Reeves County, TX and within one mile of the Dexter National Fish Hatchery in NM. This pesticide is acutely toxic to fish and wildlife. Do not apply to saturated soil and do not treat while precipitation is occurring, or while conditions favor runoff from the treated area due to the potential for surface water runoff that may cause fish kills. Use with care when applying to areas frequented by wildlife or adjacent to any body of water. For terrestrial uses, do not apply directly to water, or to area where surface water is present, or to intertidal areas below the mean high water mark. Do not apply with aircraft within 300 ft. of any waterbody including impounded waters, rivers, streams, lakes, oceans. Do not apply with aircraft when wind speed is greater than 10 mph. Do not apply with groundboom equipment within 100 ft. of any waterbody including impounded waters, rivers, streams, lakes, oceans. Use vegetative buffers Apply this pesticide only as specified on this label. Do not contaminate water when cleaning equipment or disposing of equipment washwaters." This product is highly toxic to bees exposed to direct treatment or residues on crops or weeds. Do not apply this product or allow it to drift to crops or weeds on which bees are foraging. Additional information may be obtained from your Cooperative Agricultural Extension Service.	Precautionary Statements under Environmental Hazards Buffer zones should be reported in Directions For Use.
Restricted-Entry Interval	"Do not enter or allow workers to enter into treated areas during the restricted entry interval (REI) of 48 hours." "The REI is 72 hours in areas where average rainfall is less than 25 inches a year."	Directions for Use, Agricultural Use Requirements Box
Personal protective equipment required for early entry	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is: - Coveralls - Chemical-resistant gloves made of any waterproof material. - Shoes and socks. Use of protective eyewear will be retained as on the current label for the end-use product. "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas"	
General 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."For any requirements specific to your State or tribe, consult the agency responsible for pesticide regulation. "Cotton treated with this product must be mechanically harvested. Hand harvesting is prohibited." "Pilots are prohibited from participating in mixing or loading on the day of application." "Do not allow this product to drift."	Directions for Use immediately preceding the Agricultural Use Requirements box.
Buffer Zone Restrictions	Do not apply with aircraft within 300 ft. of any waterbody including impounded waters, rivers, streams, lakes, oceans. Do not apply with aircraft when wind speed is greater than 10 mph. Do not apply with groundboom equipment within 100 ft. of any waterbody including impounded waters, rivers, streams, lakes, oceans. Apply this pesticide only as specified on this label. Do not contaminate water when cleaning equipment or disposing of equipment washwaters	Directions For use
Aerial Spray Drift Label Language	"Aerial Spray Drift Management" "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use

Description	Required Labeling	Placement on Label
Continued... Aerial Spray Drift Label Language	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1.The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2.Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use
Continued... Aerial Spray Drift Label Language	"Aerial Drift Reduction Advisory" "This section is advisory in nature and does not supersede the mandatory label requirements." **"INFORMATION ON DROPLET SIZE "** "The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	Directions for Use
Continued... Aerial Spray Drift Label Language (**only required for chemicals that can be applied aerially*)	**"CONTROLLING DROPLET SIZE "** " **!** Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. **!** Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. **!** Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. **!** Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. **!** Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	Directions for Use
Continued... Aerial Spray Drift Label Language (**only required for chemicals applied aerially*)	**"BOOM LENGTH"** "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use

Description	Required Labeling	Placement on Label
Continued... Aerial Spray Drift Label Language (**only required for chemicals that can be applied aerially*)	**"APPLICATION HEIGHT"** "Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use
Continued... Aerial Spray Drift Label Language (**only required for chemicals that can be applied aerially*)	**"SWATH ADJUSTMENT"** "When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use
Continued... Aerial Spray Drift Label Language (**only required for chemicals that can be applied aerially*)	**"WIND"** "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
Continued... Aerial Spray Drift Label Language (**only required for chemicals that can be applied aerially*)	**"TEMPERATURE AND HUMIDITY**" "When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."	Directions for Use
Continued... Aerial Spray Drift Label Language (**only required for chemicals that can be applied aerially*)	**"TEMPERATURE INVERSIONS**" "Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"SENSITIVE AREAS"** "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use

Description	Required Labeling	Placement on Label
Other Applications Restrictions.	Maximum 5 lb ai/A per season: - 0.75 lb ai/A or less per application. - For lepidopteran pests only, you may use 1.0 lb ai/A/ maximum 2x per season. For information on use practices refer to the Cotton Council website: http://www.carefulbynature.org.	Directions for Use under General Precautions and Restriction or Application Instructions.

VI. Related Documents and How to Access Them

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

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

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

The following documents were considered in the risk management assessment and proposal.

Revised HED Assessment
Revised EFED Assessment
Response to Comments (chemical specific)
Response to Generic Comments
Registrant Meeting Minutes

VII. APPENDICES

Appendix A. TABLE OF USE PATTERNS ELIGIBLE FOR REREGISTRATION

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps.	Min. Retreatment Interval	Restrictions/Comments
Cotton					
At-plant, through defoliation Foliar Spray Groundboom Aerial	8 lb/gal EC [100-669]	1*	5*	None	Restricted use Chemical. Not for residential use, or other nonoccupational uses. "Mechanical Harvesting Only"; requires use of closed systems. Do not allow to drift.

EC, emulsifiable concentrate

* 0.75 lb ai/A or less per application; 1.0 lb ai/A 2x per season for lepidopteran allowed. Maximum 5 lb ai/A per season.

Appendix B. TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE REREGISTRATION DECISION

GUIDE TO APPENDIX B

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

The data table is organized in the following formats:

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

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Profenofos

	REQUIREMENT		USE PATTERN	CITATION(S)
875.1700		Product Use Information	All	Data Gap
	61-1	Product Identity and Disclosure of Ingredients	All	40445001, 43665301
	61-2A	Start. Mat. & Mfg. Process	All	40445001, 43665301
	61-2B	Formation of Impurities	All	40445001, 43665301
	62-1	Preliminary Analysis	All	40445002, 43665302
	62-2	Certification of Ingredient Limits	All	40445002
	62-3	Analytical Methods to Verify the Certified Limits	All	40445002, 43665302
830.6302	63-2	Color	All	42030301
830.6303	63-3	Physical State	All	42030301
830.6304	63-4	Odor	All	42030301
830.7200	63-5	Melting Point	N/A	N/A
830.7220	63-6	Boiling Point	All	42030301, 42731401
830.7300	63-7	Density, Bulk Density or Specific Gravity	All	42030301, 42731401
830.7860	63-8	Solubility	All	42030301, 42731401
830.7950	63-9	Vapor Pressure	All	42030301

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Profenofos

	REQUIREMENT		USE PATTERN	CITATION(S)
830.7370	63-10	Dissociation Constant	All	42030301, 42731401
830.7550	63-11	Octanol/Water Partition Coefficient	All	40445003, 42854201
830.7000	63-12	Ph	All	42030301, 42731401
830.6313	63-13	Stability	All	40445003, 42854201, 42968701
ECOLOGICAL EFFECTS				
850.2100	71-1A	Acute Avian Oral - Quail/Duck		41627301,
850.2200	71-2A	Avian Dietary - Quail		43107301
850.2200	71-2B	Avian Dietary - Duck		43107302
850.2300	71-4	Avian Reproduction		92148004, 92148006
850.2300	71-4B	Reproduction toxicity - Mammal		00105226, 00105228
850.1075	72-1B	Fish Toxicity Bluegill		92148008
850.1075	72-1C	Fish Toxicity Rainbow Trout		92148009
850.1010	72-2A	Invertebrate Toxicity		41627304, 41614807
850.1025	72-3A	Estuarine/Marine Acute Toxicity - Pinfish, Mysid		92148010, Acc. 24621
850.1025	72-3B	Estuarine/Marine Acute Toxicity - Mollusk		92148011

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Profenofos

	REQUIREMENT		USE PATTERN	CITATION(S)
850.1035	72-3C	Estuarine/Marine Acute Toxicity - Pink Shrimp		92148012
850.1400	72-4	Fish Early Life Stage Toxicity - Fathead Minnow		92148014
850.1300	72-4B	Aquatic Invertebrate Life Cycle Toxicity - Daphnia Magna		92148013
850.1500	72-5	Full Fish Life Cycle		Data Gap
850.4225 850.4230 850.4250	123-1A	Seed Germination/Seedling Emergence		41627305
850.4250	123-1B	Vegetative Vigor		44735901
	123-2	Aquatic Plant Growth		42265101, 42265102, 42265103, 42265104, 42265105
885.4380	154a-24	Nontarget - Honey Bee Test Tier 1		41627308
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity - Rat		41714801 , 43213302
870.1200	81-2	Acute Dermal Toxicity - Rabbit/Rat		00109427, 00105231
870.1300	81-3	Acute Inhalation Toxicity - Rat		00109428
870.2400	81-4	Primary Eye Irritation - Rabbit		00109429

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Profenofos

	REQUIREMENT		USE PATTERN	CITATION(S)
870.2500	81-5	Primary Dermal Irritation - Rabbit		41714802
870.2600	81-6	Dermal Sensitization - Guinea Pig		00109431
870.6100	81-7	Acute Delayed Neurotoxicity - Hen		00126485, 00082083, 00082085
870.3100	82-1A	90-Day Feeding - Rodent		00105255, 00105226, 00105228
870.3150	82-1B	90-Day Feeding - Non-rodent		00105228
870.3200	82-2	21-Day Dermal - Rabbit/Rat		41644501
870.3465	82-4	90-Day Inhalation - Rat		00143576
	82-5B	90-Day Neurotoxicity - Mammal		42939801, 42939802
870.4100	83-1A	Chronic Feeding Toxicity - Rodent		00081685
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent		00081687, 00108016
870.4200	83-2A	Oncogenicity - Rat		00081685
870.4200	83-2B	Oncogenicity - Mouse		
870.3700	83-3A	Developmental Toxicity - Rat		40033301
870.3700	83-3B	Developmental Toxicity - Rabbit		40033201
870.3800	83-4	2-Generation Reproduction - Rat		43211308, 43213309
870.4300	83-5	Chronic Toxicity/Carcinogenicity - Mice/Rat		00082901, 00081685

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Profenofos

	REQUIREMENT		USE PATTERN	CITATION(S)
870.6300	83-6	Developmental Neurotoxicity		00045031
885.3650	152a-30	Reproductive Toxicity - Rats		43213308, 43213309
870.5250	84-2A	Gene Mutation (Ames Test)		41866901
870.5375	84-2B	Structural Chromosomal Aberration		41945103
	84-4	Other Genotoxic Effects		41945102, 41945101
870.7485	85-1	General Metabolism		42334301
		OCCUPATIONAL EXPOSURE		
875.2100	132-1A	Foliar Residue Dissipation		42851302, 42851303, 42851304
875.2200	132-1B	Soil Residue Dissipation		Waived
875.2400	133-3	Dermal Passive Dosimetry Exposure		Reserved
875.1100	875.1100	Dermal Exposure Outdoor		Data Gap
875.2500	133-4	Inhalation Passive Dosimetry Exposure		00082079
		ENVIRONMENTAL FATE		
	160-5	Chemical Identity		
835.2120	161-1	Hydrolysis		41627309, 41939001
835.2240	161-2	Photodegradation - Water		41879901, 41939002

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Profenofos

	REQUIREMENT		USE PATTERN	CITATION(S)
835.2410	161-3	Photodegradation - Soil		41627310
835.4100	162-1	Aerobic Soil Metabolism		42334302
835.4200	162-2	Anaerobic Soil Metabolism		42334303
835.4400	162-3	Anaerobic Aquatic Metabolism		42218101
835.1230	163-1	Leaching/Adsorption/Desorption		41627311
835.1410	163-2	Volatility - Lab		41905001
835.6100	164-1	Terrestrial Field Dissipation		42851301, 42900901
	165-4	Bioaccumulation in Fish		00085952, 92148059
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue - Plants		00045036, 00045037, 43186801
	171-4B	Nature of Residue - Livestock		00046063, 00046064, 00046085, 00048056, 43301901, 43301902
860.1340	171-4C	Residue Analytical Method - Plants		00086645, 00105244, 43203501
	171-4D	Residue Analytical Method - Animals		00105243,3354801
	171-4E	Storage Stability		42535202, 42928401-42928409, 43430101

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Profenofos

	REQUIREMENT		USE PATTERN	CITATION(S)
860.1500	**171-4K**	**Crop Field Trials - Cottonseed and gin byproducts**		**00045035, 00045038, 00046060, 00105217, 00106649, 42535201, 92148055**
860.1520	**171-4 (l)**	**Magnitude of the Residues in Processed Food/Feed**		**00046060, 00105217, 00106649, 92148057**
860.1480	**171-4 (j)**	**Magnitude of the Residue in Meat, Milk, Poultry, and Eggs: Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep**		**00046061, 00046062, 00046065, 00046067, 00048057, 00105217, 00106649, 92148050-92148051**
860.1480	**171-4 (j)**	**Magnitude of the Residue in Meat, Milk, Poultry, and Eggs Eggs and the Fat, Meat, and Meat Byproducts of Poultry**		**00046061, 00046063, 00046064, 00046067, 00048056, 00105217, 00106649, 92148052-92148053**
860.1400	**171-4 (f)**	**Nature and Magnitude of the Residue in Water**	**N/A**	**N/A**
	171-4 (g)	**Nature and Magnitude of the Residue in Fish**	**N/A**	**N/A**
860.1850	**165-1**	**Rotational Crops (Confined)**		**00086647, 00086650**
860.1900	**165-2**	**Rotational Crops (Field)**	**Reserved**	**N/A**

*These data are required to support a preharvest interval of less than 30 days for tomatoes. To support a plantback harvest interval of less than 4 months, upgraded confined rotational studies or limited field studies (to include seeking metabolites of potential toxicological concern and the parent) must be submitted for all crops, including tomatoes and sugar beets.

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

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 (1999), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

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MRID	CITATION
00045301	Fritz, H. (1974) Reproductive Study–Technical CGA 15324: Rat: Segment II (Test for Teratogenic or Embryotoxic Effects [sic]): Experiment No. 22 74 19 00. (Unpublished study received Mr 4, 1977 under 100-EX-53; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096931-D)
00045035	Houseworth, L.D.; Tweedy, B.G. (1977) Residues of Curacron(R) and Guthion in or on Cottonseed Resulting from Tank Mix Applications to Cotton: Summary: Report No. ABR-77035. (Unpublished study received Jun 1, 1977 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096930-A)
00045036	Fischer, W.C.; Ross, R.D.; Cassidy, J.E. (1975) The Metabolism of Phenyl-14C-CGA-15324 Sprayed on Cotton and the Degradation of this Compound in Soil: Report No. GAAC-75025. (Unpublished study received Jun 1, 1977 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096930-B)
00045037	Simoneaux, B.J.; Thomas, R.D.; Cassidy, J.E. (1976) The Metabolism of Phenyl-14C-CGA-15324 Sprayed on Field Cotton and in Soil: Report No. ABR-76028. (Unpublished study received Jun 1, 1977 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096930-C)
00045038	Holt, B.E.; Thomas, J.; Olney, V.W.; et al. (1977) Residue Report: Cottonseed: Curacron 4EC + Azinphosmethyl: AG-A No. 4372. (Unpublished study including AG-A nos. 4423 and 4466 I, II, received Jun 1, 1977 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096930-D)
00046060	Holt, B.E.; Thomas, J.; Moore, S.; et al. (1976) Residue Report: Cottonseed: AG-A No. 3513. (Compilation; unpublished study including AG-A nos. 3596 A, 3826-I,II-A, 3876..., received Nov 19, 1976 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095614-A)
00046061	Seim, V.W. (1975) Residue Report: Corn Oil: AG-A No. 3883 I, II, III. (Unpublished study including AG-A no. 3889 I, II, III, received Nov 19, 1976 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095614-B)

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MRID	CITATION
00046062	Seim, V. (1976) Residue Report: Milk: AG-A No. 3894 IV,V. (Unpublished study received Nov 19, 1976 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095614-C)
00046063	Seim, V. (1976) Residue Report: Eggs: AG-A No. 3895 III,IV. (Unpublished study received Nov 19, 1976 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095614-D)
00046064	Seim, V. (1976) Residue Report: Chicken Breast, Thigh, Liver, Fat: AG-A No. 3896 III,IV,V. (Unpublished study received Nov 19,1976, under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095614-E)
00046065	Seim, V. (1976) Residue Report: Blood, Loin, Perirenal Fat, Omental Fat, Liver, Kidney, Round Steak: AG-A No. 3915 I,II,III. (Unpublished study received Nov 19, 1976 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095614-F)
00046067	Smith, J.W.; Kahrs, R.A. (1976) Stability of CGA-15324 and Its Metabolites in Frozen Storage: Report No. GAAC-76034. (Unpublished study received Nov 19, 1976 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095614-I)
00046085	Thomas, R.D.; Cassidy, J.E. (1976) Metabolism and Balance Study of Phenyl-14C-CGA-15324 in a Lactating Goat: Report No. GAAC-76024. (Unpublished study received Nov 18, 1976 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 095613-E)
00048056	Seim, V.W. (1975) Biological Report for the Residue Study of CGA-15324 in Poultry and Eggs: Report No. BIOL-2. (Unpublished study received Nov 18, 1976 under 100-EX-53; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095615-O)
00048057	Seim, V.W. (1976) Biological Report for CGA-15324 Residue Test in Lactating Cows: Report No. BIOL-3. (Unpublished study including published data, received Nov 18, 1976 under 100-EX-53; prepared in cooperation with Vero Beach Small Animal Hospital, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095615-P)

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MRID	CITATION
00081685	Burdock, G.A.; Fieser, S.E.; Dudeck, L.E.; et al. (1981) Two-year Chronic Oral Toxicity Study in Albino Rats: CGA-15324 Technical: Project No. 483-134. Final rept. (Unpublished study received Aug 20, 1981 under 100-598; prepared by Hazleton Laboratories America, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:245709-B; 245710; 245715)
00081687	Gfeller, W.; Kobel, W.; Schaeppi, U. (1981) CGA 15'324 Techn.: 6-month Toxicity Study with Dogs: Project No. 790804. (Unpublished study received Aug 20, 1981 under 100-598; prepared by Ciba-Geigy Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:245719-A; 245720; 245721)
00082079	Ullmann, L.; Luetkemeier, H.; Sachsse, K.; et al. (1977) 21-day Inhalation Study on the Rat with Technical CGA 15324: Project No. Siss 5119. (Unpublished study received Feb 14, 1979 under 100-598; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097797-B)
00082085	Reinart, D.; Fletcher, D.; Arceo, R.J.; et al. (1978) Report to Ciba-Geigy Corporation: 42-day Neurotoxicity Study with CGA-15324 Technical in Adult Chickens: IBT No. 8580-11187. (Unpublished study, including letter dated Feb 5, 1979 from J.F. Ellis to The Environmental Protection Agency, received Feb 14, 1979 under 100-598; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 097797-H)
00082901	Hazleton Laboratories (1978) 24-month Carcinogenicity Study of CGA-15324 Technical in Albino Mice: Project No. 483-133. (Unpublished study received Feb 14, 1979 under 100-598; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097800-A)
00085952	Cargile, N.L.; Cassidy, J.E. (1977) The Metabolism of [Phenyl]-14C-CGA-15324 in Bluegill Fish; M12-130-4F: Report No. ABR-77076. (Unpublished study received Nov 6, 1981 under 100-598; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246216-E)

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MRID	CITATION
00086645	Kahrs, R.A.; Smith, J.W.; Ross, J.A. (1978) Gas Chromatographic Method for Assaying Residues of CGA-15324 in Cottonseed Determined as CGA-55960. Method no. AG-322 dated Feb 17, 1978. (Unpublished study received Nov 6, 1981 under 100-598; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246218-H)
00086647	Simoneaux, B.; Cassidy, J.E. (1977) Uptake of the Soil Metabolites of [Phenyl]-14C-CGA-15324 by Rotation Soybeans: Report No. ABR-77005. (Unpublished study received Nov 6, 1981 under 100-598; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 246218-K)
00086650	Simoneaux, B.; Cassidy, J.E. (1978) Uptake of [Phenyl]-14C-CGA-15324 and Its Soil Metabolites by Cotton Grown in a Field Plot in Preparation for Rotation Crops: Report No. ABR-78009. (Unpublished study received Nov 6, 1981 under 100-598; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:246218-N)
00105217	Ciba-Geigy Corp. (1978) The Results of Tests on the Amount of Residues Remaining Including a Description of the Analytical Methods Used: [Curacron]. (Compilation; unpublished study received Mar 3, 1978 under 100-598; CDL:096851-A; 096852; 096853; 096854; 096855)
00105226	Bathe, R. (1974) Acute Oral LD50 of Technical CGA-15324 in the Mouse: Project No. Siss 3647. (Unpublished study received Feb 14, 1979 under 100-598; prepared by Ciba-Geigy, Ltd., Switz., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:097794-F)
00105228	Sachsse, K. (1973) Acute Oral LD50 of Technical CGA-15324 in the Rabbit: Project No. Siss 2850. (Unpublished study received Feb 14, 1979 under 100-598; prepared by Ciba-Geigy, Ltd., Switz., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL: 097794-H)
00105231	Bathe, R. (1973) Acute Dermal LD50 of Technical CGA-15324 in the Rat: Project No. Siss 2850. (Unpublished study received Feb 14, 1979, under 100-598; prepared by Ciba-Geigy, Ltd., Switz., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:097794-M)

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MRID	CITATION
00105243	Smith, J. (1978) A Revised Gas Chromatographic Method for Assaying Residues of CGA-15324 in Animal Tissues and Milk Determined as CGA-55960: Method No. AG-326. (Unpublished study received Apr 26, 1978 under 100-599; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:097036-A)
00105244	Smith, J.; Kahrs, R.; Ross, J. (1978) Gas Chromatographic Method for Assaying Residues of CGA-15324 in Cottonseed Fractions Determined as CGA-55960 (Addendum to AG-322): Method No. AG-327. (Unpublished study received Apr 26, 1978 under 100-599; sub-mitted by Ciba-Geigy Corp., Greensboro, NC; CDL:097036-B)
00105255	Reyna, M.; Arceo, R.; Fischer, C. (1975) Final Report to Ciba-Geigy Corporation: 90-day Subacute Oral Toxicity Study with CGA 15324 Technical in Albino Rats: IBT No. 622-05121 B. (Unpublished study received Nov 19, 1976 under 100-EX-53; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:095610-O)
00106649	Ciba-Geigy Corp. (1976) Summary: [Curacron 4E Insecticide]. Summary of studies 228973-B through 228973-D. (Unpublished study received Jan 17, 1977 under 100-EX-53; CDL:228973-A)
00108016	Nelson, R. (1975) Final Report to ...: 90-day Subacute Oral Toxicity Study with CGA 15324 Technical in Beagle Dogs: IBT No. 611-05122-B. (Unpublished study received Nov 19, 1976 under 100-EX-53; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL: 095610-P)
00109313	Harris, S.; DeFrain, S.; Holson, J.; et al. (1982) A Teratology Study of CGA-15324 Technical in Albino Rats: CGA/SAI 282009. (Unpublished study received Jul 28, 1982 under 100-598; submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:247919-A)

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Appendix D. GENERIC DATA CALL-IN

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

Appendix E. PRODUCT SPECIFIC DATA CALL-IN

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

Appendix F. LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN

Appendix G. LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

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

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

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

Instructions

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

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

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.

8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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

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

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

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

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

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

1. The Office of Pesticide Programs' Web Site

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

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

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

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

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

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

Date of receipt
EPA identifying number
Product Manager assignment

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

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

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

a. Health and Environmental Effects Science Chapters.
b. Detailed Label Usage Information System (LUIS) Report.