US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Dicrotophos

When EPA concluded the organophosphate (OP) cumulative risk assessment in July 2006, all tolerance reassessment and reregistration eligibility decisions for individual OP pesticides were considered complete. OP Interim Reregistration Eligibility Decisions (IREDs), therefore, are considered completed REDs. OP tolerance reassessment decisions (TREDs) also are considered completed.

Combined PDF document consists of the following:

- 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 (July 31, 2006)

- Dicrotophos IRED

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
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate pesticide dicrotophos. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on January 10, 2000. This concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee, and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on June 14, 2000, and closed on August 14, 2000.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of dicrotophos. The EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of dicrotophos and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for dicrotophos will be finalized once the cumulative risks for all of the organophosphate pesticides are considered. The enclosed "Interim Reregistration Eligibility Decision for Dicrotophos," which was approved on April 3, 2002, contains the Agency's decision on the individual chemical dicrotophos.

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

The interim RED is based on the updated technical information found in the dicrotophos 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 dicrotophos (revised as of November 7, 2001), and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. Comments on mitigation or mitigation suggestions were submitted by the American Bird Conservancy, the National Agricultural Aviators Association, a private crop consultant and cotton grower from Louisiana, and Amvac Chemical Company.

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

Please note that the dicrotophos risk assessment and the attached interim RED concern only this particular organophosphate. This interim RED presents the Agency's conclusions on the dietary risks posed by exposure to dicrotophos alone. The Agency has also concluded its assessment of the ecological and worker risks associated with the use of dicrotophos. Because the FQPA directs the Agency to consider available information on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with cholinesterase enzyme, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after considering the risks for the individual organophosphates. The Agency is working towards completion of a methodology to assess cumulative risk and the individual risk assessments for each organophosphate are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address those human health and environmental risks associated with the current uses of dicrotophos. The Agency will issue the final tolerance reassessment decision for dicrotophos and finalize decisions on reregistration eligibility once the cumulative risks for all of the organophophates are considered.

This document contains a generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. Note that a complete DCI, with all pertinent instructions, is being sent to registrants under separate cover. Additionally, for product-specific DCIs, the first set of required responses to is due 90 days from the receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

In this interim RED, the Agency has determined that dicrotophos will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of dicrotophos may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this interim RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this interim RED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this interim RED.

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

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Laura Parsons at (703) 305-5776. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact the Product Reregistration Manager, Karen Jones at (703) 308-8047.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Interim Reregistration Eligibility Decision
for
Dicrotophos

Case No. 0145

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
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.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities

	and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
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.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method

PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. 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.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for dicrotophos. The decisions outlined in this document do not include the final tolerance reassessment decision for dicrotophos; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. A single tolerance for pecans will be revoked now, because there are no currently registered uses. The final tolerance reassessment decision for this chemical will be issued once the cumulative risks for all of the organophosphates are considered. The Agency may need to pursue further risk management measures for dicrotophos once cumulative risks are considered.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on dicrotophos. After considering the revised risks, as well as mitigation proposed by Amvac Chemical Company, the technical registrant of dicrotophos, and comments and mitigation suggestions from other interested parties such as USDA and the US Cotton Council, EPA developed its risk management decision for uses of dicrotophos that pose risks of concern. This decision is discussed fully in this document.

Dicrotophos is an organophosphate acaricide/insecticide used on a variety of insects, first registered in 1964 for use on cotton and various seed crops. Use data from 1987 to 1998 indicate an average domestic use of approximately 502,000 lbs a.i. per year.

Overall Risk Summary

EPA's human health risk assessment for dicrotophos indicates some risk concerns. Food risk, both acute and chronic, is well below the Agency's level of concern. Similarly, drinking water risk estimates based on screening models, from both ground and surface water for acute and chronic exposures, are not of concern. There are, however, concerns for workers who mix, load, and apply dicrotophos to agricultural sites. Also, EPA has identified acute and chronic risks to birds and mammals that are of concern, and some risk to aquatic species.

To mitigate risks of concern posed by the uses of dicrotophos, EPA considered the mitigation proposal submitted by the technical registrant, as well as comments and mitigation ideas from other interested parties, and has decided on a number of label amendments to address the worker and ecological concerns. Results of the risk assessments, and the necessary label amendments to mitigate those risks, are presented in this interim RED.

Dietary Risk

Acute and chronic dietary risk assessments for food and drinking water do not exceed the Agency's level of concern; therefore, no mitigation is warranted at this time for any dietary exposure to dicrotophos.

Occupational Risk

Occupational exposure to dicrotophos is of concern to the Agency, and it has been determined that a number of mitigation measures are necessary. For the agricultural uses of dicrotophos, several mixer/loader/applicator risk scenarios currently exceed the Agency's level of concern (i.e., MOEs are less than the target MOE of 300). EPA believes these risks can be reduced with the following label restrictions: (1) reducing maximum seasonal application to 0.83 lb ai/A from the current 1.5 lb ai/A, (2) prohibiting aerial applications with a phase-out so that no dicrotophos can be applied by air after January 1, 2005, (3) requiring closed mixing loading systems and closed cabs for handlers, and (4) increasing REI to 6 days for postapplication workers.

Therefore, with the addition of the label restrictions and amendments detailed in this document, the Agency has determined that, until the outcome of cumulatives risks for all of the organophosphates has been considered, all currently registered uses of dicrotophos may continue.

Ecological Risk

Ecological risks are also of concern to the Agency.

The mitigation measures of reducing maximum seasonal application rate to 0.83 lb ai/A, and prohibiting aerial applications are expected to lessen, but not eliminate the risk of dicrotophos to wildlife. Further, restricting use to 0.5 lb ai/A prior to August 1 is expected to lessen exposure to birds during the breeding season.

For the uses of dicrotophos the Agency has determined that, with the adoption of all of the label amendments noted in this document, these uses may continue until the outcome of the cumulative risks of all of the organophosphates has been considered.

The Agency is issuing this interim Reregistration Eligibility Document (RED) for dicrotophos, as announced in a Notice of Availability published in the Federal Register. This interim RED document includes guidance and time frames for complying with any necessary label changes for products containing dicrotophos. Note that there is no comment period for this document, and that the time frames for compliance with the label 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 dicrotophos have already been subject to

numerous public comment periods, and a further comment period for dicrotophos was deemed unnecessary. Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period, depending on the content of the risk management decision. With regard to complying with the risk mitigation measures outlined in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for dicrotophos can be considered final, however, until the cumulative risks for all organophosphate pesticides is considered. The cumulative assessment may result in further risk mitigation measures for dicrotophos.

I. Introduction

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

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

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

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

- Applying the FQPA 10-Fold Safety Factor
- Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments
- How to Interpret "No Detectable Residues" in Dietary Exposure Assessments
- Refining Dietary (Food) Exposure Estimates
- Refining Dietary (Drinking Water) Exposure Estimates
- Assessing Residential Exposure
- Aggregating Exposure from all Non-Occupational Sources
- How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- Whether and How to Use Data Derived from Human Studies

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

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

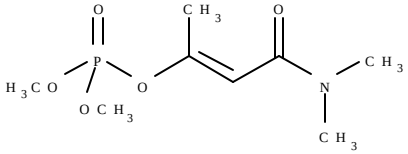
mitigation PR notice. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's interim decision on reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides/op, and in the Public Docket.

II. Chemical Overview

A. Regulatory History

Dicrotophos was first registered in the United States in 1964 by Shell Oil Company as a contact systemic insecticide for use on cotton and various seed crops. In October 1972, a registration was issued for use of an 82% product as a tree injection treatment for systemic suppression of certain insects in ornamental and non-crop trees. In June 1982, dicrotophos was registered for use on ornamentals as a foliar application, but was voluntarily cancelled for this use by the registrant in November 1982. The registration for tree injection treatment is a repackaging of formulated product. This registration is held by J.J. Mauget, Company. In October 1986, the Shell Oil company transferred dicrotophos registrations to DuPont Corporation, and in January 1994, registrations were transferred to Amvac Chemical Company. A Registration Standard was issued for dicrotophos in 1982. A Data-Call-In (DCI) was issued for reregistration in 1991.

B. Chemical Identification



Solubility	1.0×10^{6} ppm
Vapor Pressure	2.2×10^{-5} mm Hg
Henry's Constant	3.1×10^{-11} Atm M^3/Mol (Calculated)
K_{oc}	11 - 187 ml/g

- **Common Name:** Dicrotophos (3-hydroxy-N,N-dimethyl-cis-crotonamide, dimethyl phosphate)
- **Chemical family:** Organophosphate
- **Case number:** 0145
- **CAS registry number:** 141-66-2
- **OPP chemical code:** 035201
- **Empirical formula:** $C_8H_{16}NPO_5$
- **Molecular weight:** 237.19 g/mol
- **Trade and other names:** Bidrin
- **Basic manufacturer:** AMVAC

Dicrotophos is a mixture of the E- and Z-isomers in which the E-isomer is pesticidally active. Technical dicrotophos is a yellow to dark amber liquid at room temperature with a boiling point of 111-112° C at 0.022 mm Hg (399° C at 760 mm Hg). Dicrotophos is miscible (mixable in all proportions) with water, acetone, alcohol, acetonitrile, chloroform, methylene chloride, and xylene. Dicrotophos is only slightly soluble in kerosene and diesel fuel.

C. Use Profile

Dicrotophos is a contact, systemic acaricide/insecticide registered for use on cotton [40 CFR §180.299]. The only dicrotophos end-use formulation currently registered is a water-miscible formulation (Bidrin®) which may be applied foliarly to established cotton plants or used as a tree injection treatment for ornamental and non-food producing trees. At this time products containing dicrotophos are registered for occupational use only. It is classified as Restricted Use and may be purchased and used only by certified applicators or persons under their direct supervision.

Type of Pesticide:	Insecticide
Summary of Use Sites:	Cotton, ornamental and non-food bearing trees
Residential:	There are no homeowner uses of dicrotophos. The tree injection product may be used on residential trees,

but it is applied by certified applicators and is not expected to result in residential exposures.

Target Pests: Formulated for use on cotton. Dicrotophos is used to control: aphids, thrips, spider mites, cotton fleahoppers, stinkbugs, grasshoppers, boll weevils, black fleahoppers, plantbugs (lygus), saltmarsh caterpillars, and leaf perforators.

Formulation Types Registered: The only dicrotophos end-use formulation currently registered is an 82% water-miscible formulation (Bidrin®) which may be applied foliarly to established cotton plants or used as a tree injection for ornamental and non-food bearing trees.

Equipment: Spray applied aerially and by groundboom equipment for cotton. Closed 3-mL ampules with delivery tube for tree-injection

Use Rates: Maximum 3 applications per growing season at a maximum label application rate 0.5 lb ai/A.

Use Classification: Restricted use

D. Estimated Usage of Pesticide

Approximately 502,000 lbs a.i. of dicrotophos are used annually, according to Agency and registrant estimates. The estimated average acres treated are 1,513,000 acres or 10% of cotton. Dicrotophos is primarily used in the Mississippi Valley region.

Table 1. Quantitative Usage Assessment for Dicrotophos

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl/ yr	lb ai/ A/appl	(% of total lb ai used on this site)
Cotton	15,135	1,513	1,986	10%	13%	502	659	0.33	1.4	0.23	TX, MS, AR, LA, TN 85%

NOTES:

Sources: USDA National Agricultural Statistics Service, and US EPA Proprietary Data.

Usage data primarily cover 1994 - 2000. Values are rounded to the nearest 1000 for acres or pounds and the nearest whole % for crop treated.

III. Summary of Dicrotophos Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide dicrotophos, as fully presented in the documents, "HED Risk Assessment for Reregistration Eligibility Document Chemical # 035201," dated 10/28/99 and revised on 11/7/01, and "EFED RED Chapter for Dicrotophos," dated 10/28/98 and "Revised Surface Water EECs (Incorporating the Index Reservoir and Percent Crop Area)" dated 10/24/01. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to better understand the conclusions reached in the assessments.

These risk assessments for dicrotophos were made available to the public allowing for 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 dicrotophos only; the Agency must consider cumulative risks of all the organophosphate pesticides before any final decisions can be made.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for dicrotophos on January 10, 2000 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. Major revisions to the human health risk assessment are listed below: Additional studies were submitted by the registrant, were reviewed by EPA and were incorporated into the risk assessment. These data reduced some uncertainty factors and resulted in new endpoints. The submitted studies are (1) a prenatal developmental toxicity study in rabbits, (2) 14-day and 28-day dermal toxicity studies in rats with ChE determination, and (3) a delayed neurotoxicity study in hens.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is mostly complete, and that it supports an interim reregistration eligibility determination for all currently registered uses. Further details on the toxicity of dicrotophos can be found in the 11/7/01 Human Health Risk Assessment. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 in this document.

b. FQPA Safety Factor

Based on newly submitted studies and reevaluation of existing studies, the FQPA Safety Factor Committee recommended that the FQPA safety factor for dicrotophos be reduced to 3x for all population subgroups when assessing chronic dietary exposure and 1x for acute dietary exposure (HED DOC NO 014699, date 10/24/01, B. Tarplee). This supercedes the previous recommendation

from the FQPA Recommendations for the Organophosphates that 10x be retained for acute and chronic endpoints. The FQPA committee recommended that the safety factor be reduced to 3x for all population subgroups when assessing chronic dietary exposure because there is qualitative evidence of increased susceptibility in the multigeneration reproduction study based on effects on rat pups being more severe than effects on adults. However, there is no quantitative or qualitative evidence of increased susceptibility following in utero exposure to dicrotophos in the prenatal developmental studies in rats or rabbits. The 3x safety factor is required only for chronic dietary exposure since concern for susceptibility seen in the multigeneration reproduction study is not considered to result from an acute exposure. The dietary food exposure assessment does not underestimate potential exposures to infants and children from dicrotophos residues in food. No exposure is expected to infants and children from residential (non-occupational) sources because dicrotophos is registered for use on cotton and for tree-injection and neither use should result in residential exposures.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Dicrotophos

Assessment	Dose	Endpoint	Study	UF	FQPA Safety Factor	PAD
Acute Dietary	LOAEL= 0.5 mg/kg/day	decreased plasma, RBC and brain ChE activity on day 1 was observed (a NOAEL was not established).	Acute Neurotoxicity -Rat MRID 43759801	300	1x	0.0017 mg/kg/day
Chronic Dietary	LOAEL= 0.02 mg/kg/day	decreased plasma, RBC and brain ChE activity in both sexes was observed (a NOAEL was not established).	Chronic Toxicity - Rat MRID 44328402	300	3x	0.00002 mg/kg/day

c. Population Adjusted Dose (PAD)

Acute PAD:

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

A rat acute neurotoxicity study resulted in a LOAEL of 0.5 mg/kg/day based on the decrease in plasma, RBC and brain ChE activity observed on Day 1 (a NOAEL was not established). This dose is appropriate since the effects were observed on Day 1 following a single dose. Also, an additional Uncertainty Factor (UF) of 3 was applied for the use of a LOAEL for risk assessment. Uncertainty Factor (UF): 300 (10 x for inter-species extrapolation, 10 x for intra-species variability and 3 x for lack of a NOAEL).

Acute RfD = 0.5 mg/kg ÷ 300 = 0.0017 mg/kg.

Acute PAD = Acute RfD ÷ FQPA Safety Factor(1) = 0.0017 mg/kg

Chronic PAD:

A rat combined chronic toxicity/carcinogenicity study resulted in an LOAEL of 0.02 mg/kg/day was recommended for the endpoint because at this level decreased plasma, RBC and brain ChE activity in both sexes was observed (a NOAEL was not established). An additional Uncertainty Factor of 3 was applied for the use of a LOAEL for risk assessment. Uncertainty Factor (UF): 300 (10 x for inter-species extrapolation, 10 x for intra-species variability and 3 x for lack of a NOAEL).

Chronic RfD = 0.02 mg/kg/day ÷ 300 = 0.00007 mg/kg/day

Chronic PAD = 0.00007 mg/kg/day ÷ FQPA Safety Factor (3) = 0.00002 mg/kg/day

d. Exposure Assumptions

The revised acute and chronic dietary (food) exposure analyses were conducted using the Dietary Exposure Evaluation Model (DEEM™) and revised toxicity endpoints for dicrotophos. DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-91.

In the acute dietary assessment, exposure was compared to the acute Population Adjusted Dose (aPAD) based on the acute reference dose (RfD) and a 1x FQPA Safety Factor. In the chronic dietary assessment, exposure was compared to the chronic PAD based on the chronic RfD and retention of a 3x FQPA Safety Factor. The Agency considers dietary residue contributions greater than 100% of the PAD to be of concern. The acute and chronic analyses (Tier 3 for each analysis) are refined estimates using anticipated residues from field trial data, and percent of crop treated data from Biological Economic Analysis Division (BEAD). No monitoring data from USDA's Pesticide Data Program (PDP) or FDA's Surveillance Monitoring program were available for dicrotophos.

e. Food Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population

Adjusted Dose does not exceed the Agency's risk concerns. Acute dietary exposures (mg/kg/day) estimates at the 99.9th percentile were below the Agency's level of concern for all subpopulations. The subgroup with the highest estimated exposure was children 1-6 yrs. Their exposure was estimated at 0.000004 mg/kg/day resulting in a risk estimate of 0.27% of the acute population adjusted dose (aPAD). The general U.S. Population's acute dietary exposure and risk estimates were 0.000002 mg/kg/day and 0.12% of the aPAD, respectively.

Chronic dietary exposures (mg/kg/day) estimates are below the Agency's level of concern for all subpopulations. The subgroup with the highest estimated exposure was children 1-6 yrs their estimated exposure was < 0.000001 mg/kg/day resulting in a risk estimate of 0.9% of the chronic population adjusted dose (cPAD.) The general U.S. Population's chronic dietary exposure and risk estimates were <0.000001 mg/kg/day and 0.1% of the cPAD, respectively.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is considered to be an unrefined assessment and provides a high-end estimate of risk. Based on the above-calculated acute exposure from food, an acute Drinking Water Level of Comparison ($DWLOC_{acute}$) was calculated for acute dietary exposures to dicrotophos. The DWLOC is the concentration in drinking water which, when combined or aggregated with exposures through food, would result in an aggregate exposure which is acceptable. In other words, it is the theoretical concentration of a pesticide in drinking water which would be an acceptable upper limit in light of the total aggregate exposure to that pesticide through all pathways. If model-based estimated concentrations in ground and surface waters are less than the $DWLOC_{acute}$, EPA can conclude with reasonable certainty that aggregate exposure through food and drinking water do not exceed EPA's level of concern.

The calculated $DWLOC_{acute}$ is 17 ppb (based on the most highly exposed subgroup, children 1-6). The Agency's model-based estimates for maximum concentrations in surface and ground water are 2.56 ppb and 0.005 ppb, respectively. Surface water concentrations were estimated with the PRZM-EXAMS/IR model and the ground water concentrations were estimated with the SCI-GROW model. Since the model-based estimate for concentrations in surface water and groundwater are below the $DWLOC_{acute}$ (17 ppb), the Agency concludes with reasonable certainty that aggregate exposure to dicrotophos through food and surface water, and food and ground water, will not result in unacceptable exposure and risk.

A DWLOC was also calculated for chronic dietary exposures to dicrotophos. The Agency's revised calculated $DWLOC_{chronic}$ is 0.2 ppb (based on the most exposed subgroup, children 1-6). Model-based estimates for average concentrations of dicrotophos in surface and ground water are 0.2 ppb and 0.005 ppb, respectively. Since the model-based estimate for concentrations in surface water (0.2 ppb) equals the $DWLOC_{chronic}$ of 0.2 ppb and the ground water estimate of 0.005 ppb is well

below the DWLOC, the Agency concludes with reasonable certainty that residues of dicrotophos in food and drinking water do not result in levels of aggregate exposure which exceed the Agency's level of concern. It is important to note that calculated surface water values for dicrotophos are within the range of concentrations recently detected in surface water in the Mississippi River alluvial plane.

3. Occupational and Residential Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of dicrotophos include: individual farmers or growers who mix, load, and/or apply pesticides, and professional or custom agricultural applicators and professional applicators of the tree injection product. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern. However, for dicrotophos, the lack of a NOAEL in the toxicity studies selected for the occupational risk assessment, results in an additional 3x safety factor; therefore, MOEs greater than 300 do not exceed the Agency's risk concern.

a. Toxicity

The toxicity of dicrotophos is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for dicrotophos. The toxicological endpoints and other factors used in the occupational risk assessments for dicrotophos are listed below.

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

Assessment	Dose	Endpoint	Study	Absorption factor
Short-term dermal	LOAEL= 2.0 mg/kg/day MOE=300[a]	Decreased RBC ChE activity in male rats and decreased plasma ChE activity in female rats (a NOAEL was not established).	28 Day Dermal Toxicity- Rat[b] MRID 45378201	NA
Intermediate- term dermal			28 Day Dermal Toxicity- Rat[b] MRID 45378201	NA
Long-term dermal			28 Day Dermal Toxicity- Rat[b] MRID 45378201	NA
Short-term inhalation	LOAEL= 0.5 mg/kg/day MOE=300	The values were recommended for the endpoint because at this level decreased plasma, RBC and/or brain ChE activity was observed (a NOAEL was not established).	Acute Neurotoxicity - Rat; MRID 43759801	100%
Intermediate -term inhalation	LOAEL= 0.04 mg/kg/day MOE=300		Subchronic Neurotoxicity-Rat; MRID 43980201	100%
Long term inhalation	LOAEL= 0.02 mg/kg/day MOE=300		Chronic Toxicity-Rat MRID 44328402	100%

[a] An MOE of 300 applies to occupational exposure/risk assessment due to lack of NOAEL.
[b] 21 day treatment with 1 week follow-up period without treatment

Dicrotophos belongs in acute toxicity category II for dermal and eye irritation and is a strong skin sensitizer.

Table 4. Acute Toxicity Profile for Occupational Exposure for dicrotophos

Route of Exposure	Toxicity Category	MRID	Results
Oral	I	00261098 43893901	LD50 = 11 mg/kg male LD50 = 8 mg/kg female
Dermal	II	00261098	LD50 = 876 mg/kg male LD50 = 476 mg/kg female
Inhalation	data gap	--	--
Eye Irritation	II	00261098	Lesions reversed by 14 days
Dermal Irritation	IV	00261098	No irritation
Dermal Sensitizer	strong sensitizer	00261098	Strong sensitizer

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b. Exposure

It is EPA's policy to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available. PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

A dicrotophos handler exposure study was submitted to PHED (i.e., Bidrin Field Exposure Study in Post-Emergent Application on Cotton, April 7, 1986, Shell Oil Co.). A detailed description and specific results of the study are presented in the Revised Agricultural and Occupational Exposure Assessment Document (D241596, T. Leighton, 10/26/01). The dicrotophos-specific handler data were combined with other data from the PHED Version 1.1 were used to assess handler exposures for dicrotophos.

Anticipated use patterns and application method and range of application rates were derived from current labeling. Application rates specified on dicrotophos labels range from 0.1 to 0.5 pounds of active ingredient per acre in agricultural settings, so scenarios were evaluated at 0.1, 0.2 and 0.5 lbs ai/A. The Agency typically uses acres treated per day values that are thought to represent eight solid hours of work for specific types of application equipment. In this case, the assessment is based on 200 A/day for ground equipment and 1200 A/day for aerial equipment.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimum to maximum levels of protection). The lowest suite of personal protective equipment (PPE) is baseline PPE. If required (i.e., MOEs are less than the target, 300), increasing levels of risk mitigation (PPE) are applied. If MOEs are still less than the target, engineering controls (EC) are applied. In some cases, EPA will conduct an assessment using PPE or ECs taken from a current label. The levels of protection that formed the basis for calculations of exposure from dicrotophos activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical footwear plus socks, and chemical resistant headgear for overhead exposures.
- Maximum PPE: Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical footwear plus socks, chemical resistant headgear for overhead exposures, and a respirator if risk is driven by inhalation.

- Engineering controls: Engineering controls such as a closed cab tractor for application scenarios, and a closed mixing/loading system such as a closed mechanical transfer system for liquids.

Current dicrotophos labels for use on cotton require: Coveralls over short-sleeved shirt and short pants, chemical resistant gloves, chemical footwear plus socks, protective eyewear, chemical resistant headgear for overhead exposures, and a respirator. Chemical resistant aprons are also required when workers are cleaning equipment, mixing or loading.

For dicrotophos, both short term and intermediate term assessments were conducted for handler risks. The short term assessment is based on exposures ranging from 1 to 30 days and the intermediate term assessment is based on exposures ranging from 1 to 6 months. Although information is not available to determine what percentage of applicators apply dicrotophos to cotton continuously for more than 30 days, it is believed to be a very small segment of commercial applicators.

Chemical specific dislodgeable foliar residue (DFR) data were submitted in support of the postapplication assessment, but worker reentry exposure data were not available. Assessments were conducted for short and intermediate term dermal exposures for hand tasks during harvesting as well as early and late season irrigating, scouting and hand weeding activities.

c. Occupational Handler Risk Summary

At this time products containing dicrotophos are intended for occupational use only. It is classified as Restricted Use and may be purchased and used only by certified applicators or persons under their direct supervision. Dicrotophos is applied to cotton during early, middle, and late season using aerial or groundboom equipment.

Dicrotophos may also be used as a tree injection product to control insects in ornamental and non-food bearing trees. This application is completed in a closed system by professional pest control personnel and is not expected to result in unacceptable levels of exposure if the current label restrictions are followed. Therefore, the risk from this use was not assessed.

i) Agricultural Handler Risk

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with dicrotophos. Based on the use patterns, 4 major exposure scenarios (each assessed at 3 different application rates) were identified for dicrotophos:

- (1a) mixing/loading liquid formulation to support aerial applications,
- (1b) mixing/loading liquid formulation to support groundboom applications,
- (2) applying spray with aircraft, and
- (3) applying spray with groundboom equipment.

The results of the short and intermediate term handler assessments are summarized in Table 5 below. Shaded boxes indicate where MOEs are below the target level of 300.

Table 5. Agricultural Uses: Remaining Risk Concerns (combined dermal & inhalation MOEs)

			Total MOEs for Short- Term Risks			
Exposure Scenario[d]	Application Rate[a] (lb ai/acre)	Area Treated[b] A/ day)	Baseline[c]	min PPE (Gloves + Double Layer)	max PPE (Gloves + Double Layer + respirator) +	Engineering controls
Mixer/Loader						
Mixing/Loading Liquid Formulations for Aerial Application (1a)	0.5	1200	0.08	11	13	26
	0.2	1200	0.2	27	32	65
	0.1	1200	0.4	54	65	130
Mixing/Loading Liquid Formulations for Groundboom Application (1b)	0.5	200	0.48	64	78	160
	0.2	200	1.2	160	190	390
	0.1	200	2.4	320	390	780
Applicator						
Applying Sprays with an Airplane (2)	0.5	1200	No Data; see Engineering Controls			44
	0.2	1200				110
	0.1	1200				220
Applying with a Groundboom (3)	0.5	200	83	100	120	270
	0.2	200	210	250	300	680
	0.1	200	410	NA (500)	NA (600)	1,400
			Intermediate - Term Exposures			
Exposure Scenario	Application Rate[a] (lb ai/acre)	Area Treated[b] (A/day)	Baseline	min PPE (Gloves + Double Layer)	max PPE (Gloves + Double Layer + respirator) +	Engineering controls
Mixer/Loader						
Mixing/Loading Liquid Formulations for Aerial Application (1a)	0.5	1200	0.079	3	8	18
	0.2	1200	0.2	7.6	20	46
	0.1	1200	0.39	15	40	92
Mixing/Loading Liquid Formulations for Groundboom Application (1b)	0.5	200	0.47	18	48	110
	0.2	200	1.2	45	120	270
	0.1	200	2.4	91	240	550
Applicator						
Applying Sprays with an Airplane (2)	0.5	1200	No Data; see Engineering Controls			28
	0.2	1200				69
	0.1	1200				140
Applying with a Groundboom (3)	0.5	200	27	29	76	200
	0.2	200	69	73	190	490
	0.1	200	140	150	380	980

Footnotes:

Note: Baseline mitigation = long sleeve shirt, long pants, shoes, and socks.

a Application rate taken from dicrotophos label (EPA 5481-448).

b Amount handled per day values from HED's Science Advisory Council for Exposure, Policy 009.1, "Standard Values for Daily Acres Treated in Agriculture." Health Effects Division, Office of Pesticide Programs, September 2001.

c Total MOE = 1 / dermal MOE + 1 / inhalation MOE

d. Tree injection handlers and applicators were not assessed.

ii) Post-Application Occupational Risk

The post-application occupational risk assessment considered exposures to workers entering treated sites in agriculture. The following potential postapplication exposures scenarios were assessed:

- workers entering treated cotton fields to perform irrigating and hand weeding tasks during the early and late season,
- workers entering treated cotton fields to perform hand harvesting tasks,
- workers entering treated cotton fields to perform mechanical harvesting tasks, and
- handlers entering treated cotton fields to perform scouting and crop-advising tasks during the early season and late season.

Postapplication risks are mitigated for workers using a restricted-entry interval (REI). In general, the REI is established based on the number of days following application that must elapse before the pesticide residues dissipate to a level where estimated worker MOE's equal or exceed 300 while wearing baseline attire (i.e., long-sleeve shirt, long pants, shoes, and socks). Under the Worker Protection Standard for Agricultural Pesticides (WPS) – 40 CFR Part 170, entry to perform routine hand labor tasks is prohibited during an REI and personal protective equipment cannot be considered as a risk reduction measure in establishing the REI.

Postapplication risks are mitigated for crop advisors/scouts using entry restrictions, not restricted-entry intervals. Postapplication risk assessment for crop advisors/scouts for dicrotophos is based on the individual and averaged residue measurements from a dicrotophos dislodgeable foliar residue (DFR) study conducted in two geographical areas (Texas, and Mississippi). Results of the post application assessment for workers and scouts are summarized in Table 6 below.

Table 6. Postapplication Exposure/Risk Estimates

DAT[a]	Short- & Int.-Term MOE[b]		
	hand harvesters late season application	workers and scouts late season	workers and scouts early season
0	40.4	67	5050
1	53.4	89	NA
2	70.7	118	NA
3	93.6	156	NA
4	124	207	NA
5	164	273	NA
6	217	362	NA
7	287	NA	NA
8	380	NA	NA
9	NA	NA	NA

DAT[a]	Short- & Int.-Term MOE[b]		
	hand harvesters late season application	workers and scouts late season	workers and scouts early season

a DAT = days after application
b Short- and Intermediate-term Dermal MOE = Short- and Intermediate-Term Dermal LOAEL (2.0 mg/kg) / dermal dose (mg/kg/day).

Results of the postapplication assessment for short- and intermediate-term dermal exposures indicate that for hand harvesting activities, postapplication MOE's are greater than 300 at day 8; for "late-season" irrigating, scouting, and hand weeding activities, postapplication MOEs are greater than 300 at day 6; and for "early-season" irrigating, scouting, and hand weeding activities, MOEs are greater than 300 on day 0. Although there are no data upon which to assess exposures and risks resulting from mechanical harvesting activities, the Agency believes that significant worker exposure may be possible from [mechanical harvesting cotton] activity. Dicrotophos cannot be applied within 30 days of harvest and; therefore, exposures from hand or mechanical harvesting are not of concern for the postapplication assessment.

Current labels give the REI as 48 hours.

iii) Residential (Homeowner) Handler Risk

Dicrotophos has no homeowner uses. The tree injection product may be used on residential trees, but it is applied by certified applicators and is not expected to result in residential exposures.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated 10/28/98 available in the public docket and at www.epa.gov/pesticides/OP.

The only revision to this publicly available document is a revised drinking water assessment discussed in the dietary risk section above.

1. Environmental Fate and Transport

The environmental fate database for dicrotophos is essentially complete. The major routes of dissipation for dicrotophos in the environment are microbial-mediated degradation in soil and movement into surface and very shallow ground waters.

Laboratory studies showed that hydrolysis and photolysis are not major degradation pathways for dicrotophos.

Laboratory soil metabolism studies showed that dicrotophos degraded rapidly under aerobic and anaerobic conditions. Under aerobic conditions, the soil half-life of dicrotophos was 2.7 days in a Hanford sandy loam soil (pH 5.7). The major soil metabolite was N,N-dimethylacetoacetamide which was present at 20% of applied after 5 days incubation and then declined to 1.0% after 14 days. Under anaerobic conditions, dicrotophos degraded with a half-life of 7 days in a Hanford sandy loam soil. The major degradates were N,N-dimethylacetoacetamide and the hydroxy derivative of N,N-dimethylacetoacetamide, which accounted for 48% and 13% of the applied after 33 days postflooding.

Adsorption/desorption studies showed that dicrotophos was mobile in sand, sandy loam, silt loam and clay soils with Freundlich K_{oc} values ranging from 11-187. The major degradate, N,N-dimethylacetoacetamide, was also highly mobile in both sand and sandy loam soils. Dicrotophos is not expected to be volatile with a vapor pressure of 7.0×10^{-5} mm Hg at 20°C.

In supplemental terrestrial field studies in Mississippi and Georgia, dicrotophos dissipated with a half-life of 2.2 days. The formation and decline of degradates were not addressed in these field studies.

2. Water resource assessment

Water modeling was conducted to determine potential exposure to aquatic animals. The modeling results are summarized here. Refer to the EFED chapter for an in-depth discussion of the water models.

a. Ground water

The SCI-GROW II model was used to estimate a screening concentration of dicrotophos under "worst case" conditions. SCI-GROW provides a screening concentration, an estimate of likely ground water concentrations if the pesticide is used at the maximum allowed label rate in areas with ground water exceptionally vulnerable to contamination. Results from this model indicate that the maximum estimated concentration of dicrotophos in ground water is not expected to exceed 0.0048 ppb for the majority of use sites.

b. Surface Water

The Agency used PRZM-EXAMS to calculate refined Estimated Environmental Concentrations (EECs). The Pesticide Root Zone Model (PRZM, version 3.1) simulates pesticides in field runoff, while the Exposure Analysis Modeling System (EXAMS, version 2.97-5) simulates pesticide fate and transport in an aquatic environment (one hectare body of water, two meters deep). Estimates were generated for dicrotophos from use on cotton grown on a Loring silt loam in the southern Mississippi Valley. These estimates differ from the drinking water EEC's since the maximum possible application rate and minimum interval were used instead of the typical rate and interval used in drinking water assessment. Also, the ecological aquatic EECs were estimated with the farm pond and not the Index Reservoir amendment. EEC's are tabulated below.

Table 7: Estimated Environmental Concentrations (EECs) of Aquatic Exposure for Use of Dicrotophos on Cotton

Analytical Model	Application Method	Application Rate (lbs ai/A)	# of Application (Interval between Applications)	Peak EEC (ppb)	21-day Average EEC (ppb)	60-day Average EEC (ppb)
PRZM/EXAMS	Aerial spray	0.5	3 (5 days)	21.3	8.51	3.46

These values reflect an aerial application of dicrotophos which may result in direct spray drift deposition into surface waters adjoining target use sites. The drift potential for aerial and ground spray is assumed to be equivalent to 5% of applied and 1% of applied, respectively.

The PRZM-EXAMS upper 10th percentile peak EEC was 21.26 ppb, while the yearly upper tenth percentile was 0.614 ppb. Although dicrotophos could reach surface water, it does not appear to persist.

3. Toxicity (Hazard) Assessment

a. Avian/Mammalian Toxicity

Dicrotophos is classified as very highly toxic to birds and to other terrestrial wildlife, particularly mammals on an acute oral basis. Dicrotophos has been shown to be very highly toxic to several species of birds on an acute basis with LD50 values ranging from 2.0 to 9.6 mg/kg. On a subacute basis with dicrotophos mixed in the diet for five days, LD50 values ranged from 13 to 144 ppm. These subacute values are considered to be highly to very highly toxic to several species.

Table 8. Acute Oral Toxicity to Birds

Species	**LD_{50} (mg/kg)**	**Toxicity Category**
Acute Oral (Single dose by gavage)		
Canada Goose (Branta canadensis) (MRID 00160000)	2.28	Very highly toxic
California quail (male) (Callipepla californica) (MRID 00160000)	1.89	Very higly toxic
House sparrow (male) (Passer domesticus) (MRID 00160000)	3.00	Very highly toxic
Subacute dietary[1] (five days of treated feed)		
Japanese quail (Coturnix coturnix japonica) (MRID 00022923)	32	Very highly toxic

[1] Test organisms observed an additional three days while on untreated feed.

Chronic effects to birds measured by avian reproduction studies show reproductive effects at low levels.

Table 9. Reproductive Toxicity to Birds

Species/ Study Duration	NOEC (ppm ai)	LOEC (ppm ai)	LOEC Endpoints
Northern bobwhite (Colinus virginianus) (MRID 44005502)	0.50	1.5	Egg production and food consumption
Mallard duck (Anas platyrhynchos) (MRID 44005501)	1.0	3.0	Female body weight
	3.0	10	Egg production, embryo viability, hatching production and survival, egg shell thickness,and male body weight

Wild mammal testing is not required for dicrotophos. Rat toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. Acute and chronic rat toxicity data relevant to ecological effects show that dicrotophos is very highly toxic to small mammals on an acute oral basis. Dicrotophos appears to be slightly less toxic to mammals than to birds. Dicrotophos affects mammalian reproduction at dietary concentrations of 5 ppm and greater (MRID 00013446). Chronic mammalian effects are body weight gain and fasciculation development, female fertility and offspring survival.

Dicrotophos is also highly toxic to honeybees (MRID 05001991); residues on foliage have been found to remain toxic to bees and other beneficial insects for 2 to 16 days (MRIDs 05009353 and 05013577).

b. Toxicity to Aquatic Animals

Dicrotophos has been shown to be moderately to slightly toxic to fish with 96-hour LC_{50}s ranging from 6-84 ppm (MRID 40098001). Chronic data were not required based on the acute toxicity to freshwater and estuarine fish. Dicrotophos is, however, very toxic to aquatic invertebrates and therefore may indirectly affect fish by reducing the food supply of fish and aquatic animals.

Toxicity of dicrotophos to freshwater and estuarine/marine aquatic invertebrates is presented in the table below. The preferred test species for these tests were more sensitive to dicrotophos than other tested organisms. The Agency notes also that the tests conducted with the scud and stonefly might underestimate toxicity because they were not conducted with the most sensitive life-stage.

Table 10. Acute Toxicity to Aquatic Invertebrates

Species, Study Type	EC_{50} (ppb ai)		Toxicity Category
	48-hr	96-hr	
Freshwater			
Waterflea (Daphnia magna), Flow-through (MRID 43787901)	12.7	--	Very highly toxic
Estuarine/Marine			
Mysid (Americamysis bahia) (MRID 44956501)	--	0.077	Very highly toxic

Chronic data for freshwater invertebrates show that growth was the most sensitive endpoint to dicrotophos testing (MRID 44956501). The NOAEC for growth was 0.99 ppb with a LOAEC of 1.7 ppb. Reproduction NOAEC was 2.8 ppb. Chronic tests show that an estuarine/marine invertebrate is less sensitive than the tested freshwater invertebrate. Based on measured concentrations, dicrotophos inhibited the growth of mysids at concentrations of 6.15 ppb and greater. The NOAEC for growth was 3.09 ppb, reproduction of mysid was impaired at a concentration of 45.4 ppb.

c. Toxicity to Plants

Toxicity to terrestrial and aquatic plants are not required for dicrotophos because it is not a herbicide and there is no information indicating that its use might result in phytotoxicity problems.

4. Exposure and Risk Calculations

a. Levels of Concern

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The Agency calculates risk quotients (RQs) by dividing exposure estimates by acute and chronic ecotoxicity values:

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. Risk presumptions, along with the corresponding LOCs, are given in the table below:

Table 11. Risk Presumptions for Terrestrial and Aquatic Animals		
Risk Presumption	LOC terrestrial animals	LOC aquatic animals
Acute High Risk there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification,	0.5	0.5
Acute Restricted Use -there is potential for acute risk, but may be mitigated through restricted use classification,	0.2	0.1
Acute Endangered Species -endangered species may be adversely affected; regulatory action may be warranted,	0.1	0.05
Chronic Risk -there is potential for chronic risk; regulatory action may be warranted.	1	1

b. Exposure and Risk to Nontarget Terrestrial Animals

i) Avian Risk

Screening Level Acute Avian Risk

The acute risk quotients for broadcast applications of emulsifiable concentrate (EC) products are given in Table 12.

Table 12. Avian Acute Risk Quotients for Single Application of Dicrotophos as an EC Product, Based on a Japanese Quail LC_{50} of 32 ppm.

Site (application method)	Use Rate (lbs ai/A)	No. of Applications	Food Items	Maximum EEC (ppm)	Acute RQ (EEC/LC50)
Cotton	0.5	1	Short grass	120	3.80
			Tall grass	55	1.70
			Broadleaf plants/Insects	68	2.10
			Seeds	7.5	0.23
Cotton	0.5	3	Short grass	160	5.00
			Tall grass	74	2.30
			Broadleaf plants/Insects	92	2.90
			Seeds	11	0.34

The risk quotients for both single and multiple broadcast applications of dicrotophos exceed the avian acute high risk LOC for all wildlife food types except seeds. Therefore, terrestrial residues of dicrotophos are expected to pose a high risk of causing mortality to birds. Acute risk is not predicted

for birds that are strictly seed eaters, but they also could be at risk if they receive significant exposure through other routes. The risk quotients for all food categories exceed the LOCs for consideration of restricted use registration (0.2) and risk to threatened and endangered species (0.1).

Refined avian assessment

Based on the above screen which indicated acute risk to birds and field studies where acute avian effects were seen, a refined risk assessment was conducted for three model species: the Canada goose, the northern bobwhite quail, and the marsh wren.

These species represent large herbivorous waterfowl (Anatidae), medium-sized game birds (Phasianidae), and small insectivorous songbirds (Passeriformes), respectively. The toxicity of the bobwhite was assumed to be equivalent to the California quail (Callipepla californica), and toxicity of the marsh wren was assumed to be equivalent to the house sparrow (Passer domesticus). Food consumption rates for these species were approximated based on information provided in the EPA Wildlife Exposure Handbook (EPA/600/R-93/187a). The diet for the bobwhite was assumed to be composed of 25% insects, which is near the upper bound for adult bird. Risk for bobwhite chicks, however, would be greater since their diet is nearly all insects. Estimates of maximum and average residue levels of dicrotophos on wildlife food was based on the model of Hoerger and Kenega (1972), as modified by Fletcher et al. (1994). Toxicity and exposure data were combined to estimate the number of doses equivalent to the LD_{50} that the bird is predicted to consume in a single day ("LD_{50}/day").

Table 13. Refined Assessment of Avian Acute Risk Quotients Based on LD_{50}s of Three Surrogate Birds

# of Appli-cations	Model Organism	LD_{50} mg/kg	Diet	% BW Consumed per Day	EEC (ppm)		Acute RQ	
					Max.	Ave	Max	Ave
1 app at 0.5 lb ai	Canada goose	2.28	Short grass	3.1	120	43	1.63	0.58
	Quail	1.89	75% seeds & pods 25% small insects	7.3	23	8.3	0.89	0.32
	Small passerine	3.00	Small insects	97.5	68	23	22.10	7.48
3 apps at 0.5 lb ai	Canada goose	2.28	Short grass	3.1	160	58	2.18	0.79
	Quail	1.89	75% seeds & pods 25% small insects	7.3	31	11	1.21	0.42
	Small passerine	3.00	Small insects	97.5	92	30	29.90	9.75

Table 13. Refined Assessment of Avian Acute Risk Quotients Based on LD_{50}s of Three Surrogate Birds

# of Appli-cations	Model Organism	LD_{50} mg/kg	Diet	% BW Consumed per Day	EEC (ppm)		Acute RQ	
					Max.	Ave	Max	Ave
exceeds acute high, acute restricted and acute endangered species LOCs. * exceeds acute restricted and acute endangered species LOCs.								

Refined risk quotients for the Canada goose and a small passerine both exceed the LOC for high (0.5) risk for single and multiple applications, even if average residues are assumed. The refined RQs for quail also exceed the LOC for high risk when maximum residues are used, and is only slightly below the acute risk LOC when average residues are used. All of the RQs exceed the LOCs for consideration of restricted use (0.2) and risk to threatened and endangered species (0.1). These results confirm the first tier assessment in concluding that use of dicrotophos on cotton poses an acute risk of killing many different types of birds, and poses a risk to threatened and endangered birds, even with a single application. These conclusions of acute risk drawn from the refined assessment have high certainty.

Chronic Risks to Birds

Avian chronic risk quotients are given in Table 14. Chronic risk was assessed using two approaches. In the first approach, "maximum" risk quotients were calculated by dividing the bobwhite NOEC by the maximum EECs for wildlife food items. This approach is a conservative screen in which exposure is assumed to be at peak residue levels which occur immediately after the last application. For multiple applications, residues were assumed to dissipate between applications at a half-life of 2.7 days. In the second approach, "30-day mean" risk quotients were calculated by dividing the bobwhite NOEL by the mean EECs for a 30-day period, beginning with the day of the first application. Residues were assumed to dissipate during this 30-day period with a half-life of 2.7 days.

Any risks indicated by 30-day mean risk quotients are highly certain because a 30-day exposure period is long enough to produce chronic effects in birds similar to those observed in the laboratory. Most of the observed chronic effects result in reproduction effects.

Table 14. Avian Chronic Risk Quotients for Use of EC Products of Dicrotophos on Cotton, Based on a Bobwhite NOEC of 0.5 ppm

UseRate (lbs ai/A)	Number of Application	Food Items	EEC (ppm)		Chronic RQ (EEC/NOEC)	
			Maximum	30-Day Mean[1]	Maximum	30-Day Mean[1]
0.5	1	Short grass	120	18	240	36

Table 14. Avian Chronic Risk Quotients for Use of EC Products of Dicrotophos on Cotton, Based on a Bobwhite NOEC of 0.5 ppm

UseRate (lbs ai/A)	Number of Application	Food Items	EEC (ppm)		Chronic RQ (EEC/NOEC)	
			Maximum	30-Day Mean[1]	Maximum	30-Day Mean[1]
		Tall grass	55	8.1	110	16
		Broadleaf plants/Insects	68	10	140	20
		Seeds	7.5	1.1	16	2.2
0.5	3	Short grass	160	53	320	110
		Tall Grass	74	24	150	48
		Broadleaf plants/Insects	92	30	180	60
		Tall Grass	11	3.3	22	6.6

Both the maximum and the 30-day risk quotients indicate that use of dicrotophos on cotton at a rate of 0.5 lb ai/A will result in chronic risk to birds. The risk quotient values, even when 30-day mean EECs were used, suggest that the occurrence of chronic effects is probable, despite the minimal persistence of dicrotophos.

ii) Risks to Mammals

Acute Risk to Mammals

Estimating the potential for adverse effects to wild mammals is based upon EEB's draft 1995 SOP of mammalian risk assessments and methods used by Hoerger and Kenaga (1972) as modified by Fletcher *et al*. (1994). The concentration of dicrotophos in the diet that is expected to be acutely lethal to 50% of the test population (LC50) is determined by dividing the LD50 value (usually rat LD50) by the % (decimal of) body weight consumed. A risk quotient is then determined by dividing the EEC by the derived LC50 value. Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds). The acute risk quotients for the most sensitive mammal, the 15 g animal, are given in Table 15.

Table 15. Mammalian (15 g animal) Acute Risk Quotients for Applications of Dicrotophos, Based on a rat LD_{50} of 9 mg/kg

Site (application method)	Use Rate (lbs ai/A)	#. of Apps	Food Items	% body weight consumed	Maximum EEC (ppm)	Acute RQ (EEC/LC50)
Cotton	0.5	1	Short grass	95	120	12.67
			Broadleaf plants/small insects	95	68	7.18

Table 15. Mammalian (15 g animal) Acute Risk Quotients for Applications of Dicrotophos, Based on a rat LD_{50} of 9 mg/kg

Site (application method)	Use Rate (lbs ai/A)	#. of Apps	Food Items	% body weight consumed	Maximum EEC (ppm)	Acute RQ (EEC/LC50)
			Large insects	95	7.5	0.79
			Seeds	21	7.5	0.18
Cotton	0.5	3	Short grass	95	160	16.89
			Broadleaf plants/small insects	95	92	9.71
			Large insects	95	11	1.16
			Seeds	21	11	0.26

Risk quotients exceed the acute risk LOC (0.5) for most herbivorous and insectivorous mammals (all except larger mammals that feed on larger insects). Risk quotients for granivorous mammals do not exceed the high risk LOC, but do exceed the endangered species LOC (0.1) for small and medium mammals.

For three applications, acute risk quotients exceed the high acute risk LOC (0.5) for most herbivorous and insectivorous mammals (all except larger mammals that feed on larger insects). Risk quotients for granivorous mammals do not exceed the high risk LOC, but do exceed restricted use LOC (0.2) for small mammals, and the endangered species LOC (0.1) for small and medium mammals.

Chronic Risk to Mammals

Chronic risk quotients for mammals are presented in Table 16. These risk quotients are based on the NOAEL of 2.0 ppm that was established in a 3-generational rat reproduction study. While a short-term exposure to the peak concentration possibly could cause chronic effects, exposure over a longer duration would have a greater certainty of causing these effects. Therefore, chronic risk to mammals was also assessed based on average EEC's for a 30-day period, beginning with the day of the first application, as well as on peak EEC's.

Table 16. Mammalian Chronic Risk Quotients for Use of EC Products of Dicrotophos on Cotton, Based on a Rat NOAEL of 2 ppm

Use rate (lbs ai/A)	# of Applications	Food Items	EEC (ppm)		Chronic RQ (EEC/NOAEL)	
			Maximum	30-Day Mean[1]	Maximum	30-Day Mean[1]
0.5	1	Short grass	120	18	60	9.0
		Tall grass	55	8.1	28	4.1

Table 16. Mammalian Chronic Risk Quotients for Use of EC Products of Dicrotophos on Cotton, Based on a Rat NOAEL of 2 ppm

Use rate (lbs ai/A)	# of Applications	Food Items	EEC (ppm)		Chronic RQ (EEC/NOAEL)	
			Maximum	30-Day Mean[1]	Maximum	30-Day Mean[1]
		Broadleaf plants/Insects	68	10	34	5.0
		Seeds	7.5	1.1	3.8	0.55
0.5	3	Short grass	160	53	80	27
		Tall Grass	74	24	37	12
		Broadleaf plants/Insects	92	30	46	15
		Seeds	11	3.3	5.5	1.7

Both the maximum and the 30-day risk quotients indicate that use of dicrotophos on cotton at a rate of 0.5 lb ai/A will result in chronic risk to mammals. The risk quotient values were high even when 30-day mean EECs were used, suggesting that the occurrence of chronic effects in mammals is highly certain.

iii) Risk to Insects

Currently, the Agency does not conduct quantitative risk assessments for nontarget insects . However, acute toxicity testing show that dicrotophos is highly toxic to honeybees (LD_{50}=0.076 µg/bee, MRID 05001991). Dicrotophos residues on foliage have been found to remain toxic to bees and other beneficial insects for 2 to 16 days. Therefore, use of dicrotophos on cotton is expected to pose a high risk to honeybees and other nontarget insects, especially when it is applied to flowering cotton plants.

c. Exposure and Risk to Nontarget Aquatic Animals

i) Risk to Fish

As a conservative screen, risk quotients were calculated based on three aerial applications at the maximum use rate (0.5 lb ai/A) with a 5-day interval between applications resulting in RQ's <0.01. These RQ's are much lower than all levels of concern and therefore, the Agency concludes that this use poses minimal risk to all fish, including endangered species. Chronic risk has not been assessed because data on the chronic toxicity of dicrotophos to fish is not available.

ii) Risk to Aquatic Invertebrates

Acute risk quotients are given in Table 17.

Table 17. Risk Quotients for Acute Effects on Aquatic Invertebrates from Use of Dicrotophos on Cotton

Habitat Type	Test Species	LC50 (ppb)	Peak EEC[1] (ppb)	Acute RQ (EEC/LC50)
Freshwater	Waterflea	12.7	21.3	1.68
Marine and estuarine	Mysid	77	21.3	0.28

[1]Based on three applications at the maximum application rate of 0.5 lb ai/A.

For freshwater species, the risk quotient for use of dicrotophos on cotton at the maximum application rate exceeds the levels of concern for acute high risk, restricted use, and endangered species. Therefore, the Agency concludes that this use poses an acute risk to freshwater invertebrates. For marine and estuarine invertebrates, the risk quotient is less than the level of concern for acute risk (0.5), but exceeds the level of concern for restricted use and endangered species. Therefore, the Agency concludes that this use does not pose acute risk to marine and estuarine species, but does pose enough risk that effects on threatened and endangered species is a concern.

The chronic risk quotients are given in Table 18.

Table 18. Risk Quotients for Chronic Effects on Aquatic Invertebrates from Use of Dicrotophos on Cotton

Habitat type	Test Species	MATC (ppb)	21-Day Average EEC[1] (ppb)	Chronic RQ (EEC/MATC)
Freshwater	Daphnia magma	1.3	8.51	6.55
Marine and estuarine	Mysid	4.36	8.51	1.95

[1]Based on three applications at the maximum application rate of 0.5 lb ai/A.

For freshwater and marine and estuarine species, the risk quotients for use of dicrotophos on cotton at the maximum application rate exceed the level of concern for chronic risk. Therefore, the Agency concludes that this use poses a chronic risk to marine and freshwater invertebrates. No chronic data are available for freshwater invertebrates. However, the Agency concludes that chronic risk to freshwater species exists because acute toxicity indicates that freshwater invertebrates are more sensitive to dicrotophos than are marine and estuarine invertebrates.

d. Exposure and Risk to Nontarget Plants

A risk assessment was not conducted for nontarget plants because dicrotophos is an insecticide and there is no indication that it is phytotoxic. Risk to nontarget plants is assumed to be minimal.

5. Ecological Incidents

From 1982 to present several ecological incidents involving dicrotophos poisoning were entered into the OPP Incident Data System. Some of these incidents are linked to apparent mis-use or intentional poisoning, in other incidents, dicrotophos was recovered from carcasses, but the source was unknown.

The absence of additional documented incidents involving non-targeted terrestrial organisms does not necessarily mean that such incidents do not exist. Mortality incidents must be seen, reported, investigated, and submitted to the Agency in order to be recorded in the database. Incidents may not be noted because the carcasses decayed in the field, were removed by scavengers, or were in out-of-the-way or hard-to-see locations. Poisoned birds may fly off-site to less conspicuous areas before dying. An incident also may not be reported to appropriate authorities capable of investigating it.

6. Endangered Species

Endangered species LOCs are exceeded for acute and chronic risks to birds, mammals and freshwater and estuarine invertebrates. At this time there are no federally listed estuarine invertebrates.

Dicrotophos was included in the formal Section 7 consultation with the US Fish and Wildlife Service (USFWS) for the cotton cluster review in 1983. The Biological Opinion stated that this use of dicrotophos would jeopardize the continued existence of the Attwater's greater prairie chicken, the Aleutian Canada goose, the Kern primrose sphinx moth, the valley elderberry longhorn beetle and the delta green ground beetle.

Dicrotophos was also included in the reinitiated Biological Opinion of 1989 from the USFWS. In this opinion, the USFWS found jeopardy to 14 species of freshwater fish, one freshwater crustacean and four bird species for its uses on cotton. Reasonable and Prudent Alternatives were given for each jeopardized species. Reasonable and Prudent Measures were also given for twelve non-jeopardized species to minimize incidental take of these species. These consultations and the findings expressed in the Opinions, however, are based on old labels and application methods, less refined risk assessment procedures and an older approach to consultation which is currently being revised through interagency collaboration.

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

The Agency is currently engaged in a Proactive Conservation Review with FWS and the National Marine Fisheries Service under section 7(a)(1) of the Endangered Species Act. The objective of this review is to clarify and develop consistent processes for endangered species risk assessments and consultations. Subsequent to the completion of this process, the Agency will reassess the potential effects of dicrotophos use to federally listed threatened and endangered species. At that time the Agency will also consider any regulatory changes recommended in the IRED that are being implemented. Until such time as this analysis is completed, the overall environmental effects mitigation strategy articulated in this document and any County Specific Pamphlets described in Section IV which

address dicrotophos, will serve as interim protection measures to reduce the likelihood that endangered and threatened species may be exposed to dicrotophos at levels of concern.

7. Risk Characterization

Like other OP pesticides, dicrotophos exhibits acute toxicity due to irreversible inhibition of cholinesterase enzymes. Significant inhibition of brain and blood cholinesterases have been observed in rats administered dicrotophos at doses as small as 0.5 mg ai/kg (MRID 43759801). As with humans, exposure of wildlife to cholinesterase inhibiting pesticides disrupts normal neuromuscular control. Death can occur rapidly, due primarily to respiratory failure. Organophosphate exposure can also result in chronic effects in animals such as reproduction impairment and delayed neuropathy. Dicrotophos, however, has relatively low toxicity to aquatic organisms compared to most insecticides. The primary risk from the use of dicrotophos is acute and chronic effects in terrestrial vertebrates.

Monocrotophos is a highly toxic metabolite that can be formed by demethylation of dicrotophos and is included in the tolerance expression for dicrotophos. Laboratory studies on the degradation of dicrotophos do not indicate that monocrotophos forms in soil or water in any significant quantities. Animal metabolism studies indicate that monocrotophos is not formed in significant amounts in the metabolism of dicrotophos by animals. However, monocrotophos is a metabolite in plants since a metabolism in cotton study found monocrotophos at harvest. These data are deemed to be unreliable and the amount of monocrotophos that forms in or on foliage soon after application is currently not known (Memorandum, April 2, 1997).

Terrestrial Organisms

An extensive amount of data are available which show that dicrotophos is very highly toxic to a wide variety of birds and mammals. Reproductive impairment has been observed in both birds and mammals at dietary concentrations between 1.5 and 5 ppm.

These avian and mammalian risk assessments are not believed to be conservative. There are several reasons why the risk assessment may underestimate risk. Compared to animals in the laboratory, animals in the wild might be more susceptible because they are exposed to multiple stressors in addition to the chemical (e.g. extreme environmental conditions, predation pressure, and disease). Furthermore, animals in the wild are likely to be exposed to pesticides through routes other than in the diet (e.g., via drinking water, dermal absorption, and inhalation). And even though dicrotophos degrades fairly rapidly, with a calculated half life of 2.7 days, residues may persist at toxic levels for more than two weeks. Therefore, there appears to be a risk of mortality to all birds that feed in cotton fields treated with dicrotophos, although the risk is most certain for songbirds.

Birds are known to make use of cotton fields for food and cover. Field studies conducted in cotton fields in Alabama (MRID 40917001) and Arizona (MRID 40873701) both concluded that birds were "diverse and had high species richness and abundance" in the test fields. Passarines (songbirds) were the most common type of bird using cotton fields in both studies. Quail and doves were also fairly common in cotton fields in Arizona. Bird use of cotton fields was higher in Arizona than in Alabama. More birds are likely attracted to cotton fields in the Southwest because the irrigated fields provide dense vegetative cover that is scarce elsewhere in the desert environment. In addition, cotton fields in

the Southwest frequently occur along rivers, and the associated riparian habitats that are favored by birds. Additional information on the use of cotton field by birds is provided by Gusey and Maturgo (1973). Data for Georgia indicate that there is medium to high use of cotton by songbirds for feeding during the summer months. In addition, data for Georgia, South Carolina, and Texas indicate medium to high use of cotton by quail for feeding, nesting, and brood rearing.

Overall, songbirds and quail are likely to be the most frequently exposed birds in cotton treated with dicrotophos. The risk assessment indicate that many songbirds are highly vulnerable to acute poisoning by dicrotophos due to their small size and insectivorous feeding habit. The risk assessment indicate that adult quail are somewhat less vulnerable but still at risk of acute poisoning. The vulnerability of young quail, which are mostly insectivorous, is likely to be similar to that of songbirds. The field studies confirm that use of dicrotophos on cotton can cause mortality of both quail and songbirds.

In addition to the acute risk, dicrotophos poses a risk of causing impairment of avian reproduction. Risk quotients for chronic effects on birds, based on 30-day time-averaged residues, were 2.2 to 36 for a single application, and 6.6 to 110 for three applications. Laboratory data show that the egg production of the Northern bobwhite is reduced at dietary concentrations as low as 1.5 ppm. Peak environmental concentrations on wildlife food items are predicted to be as high as 120 ppm. and residues of dicrotophos are expected to remain at chronically adverse concentrations for several weeks. With this level and duration of exposure, the probability of impairment of reproduction of birds feeding in and around treated cotton fields is very high. Impaired reproduction and increased mortality of young and old birds will work together to adversely affect population of birds around treated cotton fields.

Although studies have shown that dicrotophos is slightly less toxic to mammals than it is to birds, dicrotophos is still very highly toxic to small mammals. Mammalian reproduction is affected at dietary concentrations of 5 ppm and higher.

Acute toxicity testing show that dicrotophos is highly toxic to honey bees. Dicrotophos residues on foliage have been found to remain toxic to bees and other beneficial insects for 2 to 16 days. Therefore, use of dicrotophos on cotton is expected to pose a high risk to honeybees and other nontarget insects, especially when it is applied to flowering cotton plants.

Aquatic organisms

Surface water models (PRZM-EXAMS) indicate that dicrotophos may reach surface waters at a peak concentration of 37-21 ppb, but levels do not appear to accumulate. Ground water modeling using the SCI-GROW II model show that dicrotophos is not expected to pose a significant ground water problem (0.0048 ppb). NAWQA data indicate that in the cotton growing region of the Mississippi Embayment, dicrotophos was the most frequently detected insecticide analyzed in 1996 and 1997. While the detections were at low concentrations, these monitoring data clearly support the modeling estimates indicating that dicrotophos may be found in water sources.

Dicrotophos applied to cotton is likely to reach freshwater habitats and estuarine habitats along the southern Atlantic Coast and the Gulf Coast. This exposure is not predicted to harm fish. Risk quotients indicate a risk of acute effects to freshwater invertebrates, but not to marine or estuarine invertebrates.

Risk quotients indicate risk of chronic effects to marine and estuarine invertebrates. Although the Agency has no data on the chronic effects of dicrotophos to freshwater invertebrates, chronic risk is assumed since acute risk is predicted. Although some of the risk quotients for aquatic invertebrates indicate risk, the risk to aquatic environments does not appear to be particularly great relative to other insecticides.

IV. Interim Risk Management and Reregistration Decision

A. Determination of Interim Reregistration Eligibility

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

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient dicrotophos, as well as a dicrotophos-specific dietary risk assessment that has not considered the cumulative effects of organophosphates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient dicrotophos, EPA has sufficient information on the human health and ecological effects of dicrotophos to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that dicrotophos is eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) cumulative risks considered for the organophosphates support a final reregistration eligibility decision. Additionally, if any party produces data to show, conclusively, that any of these risk mitigation measures are unnecessary, the Agency will consider these data and will revise the risk mitigation requirements accordingly. In particular, several stakeholders expressed interest in developing exposure data to refine risk estimates for aerial mixer/loader/applicators. However, at this time, the Agency has no data to further refine/revise the worker assessment for dicrotophos; therefore, the mitigation measures are required. Label changes are described in Section IV. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of dicrotophos, and lists the submitted studies that the Agency found acceptable.

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

At the time that a cumulative assessment is completed, the Agency will address any outstanding risk concerns. For dicrotophos, if all changes outlined in this document are incorporated into the labels, then

all current risks will be mitigated, though not eliminated. But, because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for dicrotophos after assessing the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

Because the Agency has not yet completed the cumulative risk assessment for the organophosphates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing dicrotophos food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has completed the cumulative assessment, dicrotophos tolerances will be reassessed in that light. At that time, the Agency will reassess dicrotophos along with the other organophosphate pesticides to complete the FQPA requirements and make a final reregistration eligibility determination. By publishing this interim decision on reregistration eligibility and requesting mitigation measures now for the individual chemical dicrotophos, 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 further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

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

B. Summary of Phase 5 Comments and Responses

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. These comments in their entirety are available in the docket. A brief summary of the comments and the Agency response is noted here.

Comments were received from four sources: the American Bird Conservancy, the National Agricultural Aviator Association, a crop consultant from Wisner, LA and Amvac Chemical Corporation. The American Bird Conservancy stated that since dicrotophos is very likely to cause avian effects, use should be cancelled. The National Ag Aviators and the private crop consultant asked that the Agency consider the importance of dicrotophos to cotton production. Amvac Chemical asked that various points in the risk assessment be reconsidered. All comments have been considered in depth before reaching this regulatory decision.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this

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

EPA has determined that risk from exposure to dicrotophos is within its own "risk cup." In other words, if dicrotophos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for dicrotophos 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. 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 dicrotophos "fit" within the individual risk cup. Therefore, the dicrotophos tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is considered.

b. Tolerance Summary

In the individual assessment, tolerances for residues of dicrotophos in/on plant commodities [40 CFR §180.241] are presently expressed in terms of dicrotophos and its plant metabolite, monocrotophos. The field trial data submitted to support the cottonseed and cotton gin byproducts tolerances are adequate.

The Agency is recommending that the tolerance for residues in/on cottonseed be increased to 0.2 ppm and that tolerance for residues of dicrotophos in/on cotton gin byproducts be established at 2 ppm. The Agency will commence proceedings to revoke the pecan tolerance; however, the establishment of the cotton gin byproduct tolerance and raising the cottonseed tolerance will be deferred, pending the outcome of the cumulative assessment.

Table 19. Tolerance Summary for Dicrotophos

Commodity	Current Tolerance, ppm	Tolerance Reassessment*, ppm	Comment
Tolerances Listed Under 40 CFR §180.241			
cotton seed	0.05	0.2	Increase because field trial data indicate current tolerance is too low
cotton gin by-products	--	2.0	Tolerance to be established
pecans	0.05		propose revocation

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

required, that is supported by all of the submitted residue data.

2. Endocrine Disruptor Effects

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

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

3. Labels

Provided the following risk mitigation measures are incorporated in their entirety into labels for dicrotophos-containing products, the Agency finds that all currently registered uses of dicrotophos are eligible for reregistration, pending consideration of cumulative risks of the organophosphates. The regulatory rationale for each of the mitigation measures outlined below is discussed immediately after this list of mitigation measures. These mitigation measures will reduce, but not eliminate risk; however, the Agency believes the benefits of use outweigh the risks.

4. Mitigation for Agricultural Uses

The following mitigation is necessary to reduce risks to agricultural workers and wildlife:.

- prohibit aerial application with a phase-out so that no aerial applications after January 1, 2005,
- require engineering controls such as closed cabs and closed mixing/loading systems,
- reduce total seasonal applications to 0.83 lbs ai/A and restrict use to 0.5 lb ai/A prior to August 1; maximum single application rate is to remain at 0.5 lb ai/A,
- require a 6 day re-entry interval, and
- impose a production cap limiting the amount of dicrotophos produced annually to the average of the amount produced in the last three years (1999-2001).

D. Benefits Assessment Summary

A benefits assessment was required for dicrotophos based on worker risk and ecological risk to birds. The entire document: "Biological Assessment of Dicrotophos Use on Cotton" dated February 7, 2002 can be found in the dicrotophos docket. This assessment is summarized here.

Dicrotophos is mainly used to contol aphids, fleahoppers, plant bugs, thrips, and stinkbugs on cotton. Of these pests, aphids and thrips can be controlled with a number of other pesticides. Fleahoppers and stinkbugs are not effectively controlled by other pesticides or the alternatives are significantly more expensive. And there are no effective alternative methods to control plant bugs. Current average total seasonal use of dicrotophos is 0.31 to 0.39 lb. ai/acre for these key pests. According to USDA statistics, approximately 13% of the total acres of cotton were treated with dicrotophos between 1994 and 1999. The US Cotton Council estimated that up to 24% of the total acres of cotton are treated with dicrotophos based on their 2001 Survey data.

Based on current use patterns, the Agency believes that a rate of 0.3 lb. ai/acre of dicrotophos will provide acceptable control of the key cotton pests with minor impacts on grower yields. In some cases a late season application of an additional 0.5 lb. ai/acre may be necessary for difficult to control pests to avoid yield losses. The Agency believes that cotton growers will reserve dicrotophos for difficult to control insects such as plant bugs, stink bugs, and flea hoppers and that restricting total maximum seasonal applications to 0.83 lb ai/A is reasonable and will not significantly impact cotton production.

E. Regulatory Rationale

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

1. Human Health Risk Mitigation

a. Dietary Mitigation

i) Dietary (Food)

Acute and chronic dietary risk from food alone is well below the Agency's level of concern. No mitigation is required.

ii) Drinking Water

Drinking water risk estimates based on screening level models for ground and surface waters are also below the Agency's level of concern. No mitigation is required for dietary risk from drinking water. Limited monitoring data collected by the USGS are comparable to the screening level estimates generated by the screening level modeling assessments indicating that the screening level estimates are not conservative. Based on the limited monitoring data which showed the dicrotophos was detected frequently at low levels in the one NAWQA study which included it as an analyte, the Agency believes that dicrotophos may contaminate water sources. The Agency believes that elimination of aerial applications, limiting the amount which can be applied early season, and the production cap will ensure that dicrotophos residues in surface water do not increase significantly.

b. Occupational Risk Mitigation

i) Agricultural Uses

The highest risks for mixer/loaders/applicators of dicrotophos are associated with aerial applications; therefore eliminating aerial applications removes the handler scenarios of greatest concern. Risks to mixers, loaders and applicators for aerial applications are of concern with short term MOEs of 26-220 even when engineering controls are factored into the assessment. According to USDA statistics, most dicrotophos is currently applied by ground equipment so the aerial prohibition does not pose an undue burden on users; for more details, see the Benefits Assessment in Section IV D.

Aerial applications are being prohibited with a phase-out. The registrant has agreed to immediately amend their labels to inform the user that aerial applications are not to be allowed after January 1, 2005. This amendment may be in the form of a sticker which is placed on all labels to be printed after the amendment approval until new labels requiring rate changes and other amendments are approved.

The prohibition of aerial applications should also reduce the amount of dicrotophos that will be handled and may reduce the likelihood of intermediate exposures. Intermediate-term MOEs range from 18-140 when engineering controls are included..

For handlers involved in ground applications, the use of engineering controls such as closed mixing/loading systems and closed cabs is necessary to reduce risks from dermal and inhalation exposures. Mixers and loaders must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)], for 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.

Use at the 0.5 lb ai/A application rate results in risks that are of concern with short term MOEs of 160 for mixer/loader and 270 for applicators and intermediate term MOEs of 110 for mixer loaders and 200 for applicators. MOEs of 300 and greater are considered to be not of concern. However, allowing the 0.5 lb rate is necessary for controlling certain late season pests for which there are no alternative controls. For more details, see the benefits summary in Section IV D.

ii) Post-Application Risk

Re-entry intervals for irrigating and hand-weeding should be set at 6 days postapplication. Current REIs are set at 2 days, however MOEs are not at the target MOE of 300 until 6 days posttreatment. This assessment assumes the 0.5 lb ai application rate and that workers will be exposed for 8 hours/day which is an upper bound for some activities.

2. Environmental Risk Mitigation

The currently registered use of dicrotophos on cotton poses acute and chronic risks to birds, mammals and aquatic invertebrates. The mitigation measures that are expected to lower expected risks to wildlife from use of dicrotophos on cotton are: (1) prohibit aerial applications, (2) reduce total seasonal applications to 0.83 lbs ai/A and restrict the amount that can be used before August 1 to 0.5 lbs ai/A, and (3) a production cap to ensure that dicrotophos use does not increase due to restrictions placed on other cotton insecticides. These measures will reduce, but will not eliminate risks to wildlife from dicrotophos use.

Eliminating aerial applications will reduce drift to wildlife areas adjacent to the field and will also lower the amount of area which may be treated at one time. Lowering the seasonal maximum application rate from 1.5 to 0.83 lb ai/A and restricting the amount that can be applied prior to August 1 to 0.5 lb ai/A is also expected to lower exposure to avian species. Restricting the amount allowed prior to August 1 reduces the amount of dicrotophos avian species are exposed to at a time they are most vulnerable, i.e., during the breeding season. This mitigation allows the cotton grower to retain the 0.5 lb ai/A rate of dicrotophos for a single application which may be necessary for some populations of late season plant bugs for which there are no alternative controls. For more details, see the benefits assessment in Section IV D.

Allowing the 0.5 lb rate results in risks that are of concern for terrestrial avian and mammalian species as well as freshwater aquatic invertebrates. A single application of 0.5 lb ai/A results in acute avian RQs ranging up to 3.8 and chronic avian RQ's of up to 240. But, the reduction from three applications at 0.5 lb ai/A to a maximum of one application at 0.5 lb ai/A will result in lower overall risk to wildlife.

Capping annual production at the average of the production of the last three years ensures that dicrotophos use will not increase dramatically when restrictions are placed on other cotton insecticides.

F. Other Labeling

In order to remain eligible for reregistration, other use and safety information need to be placed on the labeling of all end-use products containing dicrotophos. For the specific labeling statements, refer to Section V of this document.

1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, EPA puts basic toxicity and exposure data developed for REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations, and biological requirements and

behavioral aspects of the particular species. This analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at this time. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

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

2. Spray Drift Management

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

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

For purposes of complying with the deadlines for label submission outlined in this document, registrants (and applicants) may elect to adopt the appropriate sections of the proposed language below, or a version that is equally protective, for their end-use product labeling.

For products applied outdoors as liquids (except mosquito adulticides):

"Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals."

"For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy, and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use _____ (registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles."

On all product labels:
"The applicator also must use all other measures necessary to control drift."

Otherwise, registrants should use the following standard language:

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

"Do not allow this product to drift."

The Agency recognizes that the above option does not address other application types. Registrants may therefore wish to adapt some variation of the old, and proposed new language for their particular products, depending on their application methods.

V. What Registrants Need to Do

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

A. For dicrotophos technical grade active ingredient products, registrants need to submit the following items.

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

(1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

(2) submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

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

Please contact Amaris Johnson at 703-305-9542 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:
Document Processing Desk (DCI/SRRD)
Amaris Johnson
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Amaris Johnson
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

B. For products containing the active ingredient dicrotophos, registrants need to submit the following items for each product.

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

(1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

(2) submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

(1) two copies of the confidential statement of formula (EPA Form 8570-4);

(2) a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

(3) five copies of the draft label incorporating all label amendments outlined in Table [insert table number] of this document;

(4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

(5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

(6) the product-specific data responding to the PDCI.

Please contact Karen Jones at 703-308-8047 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:
Document Processing Desk (PDCI/PRB)
Karen Jones
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:
Document Processing Desk (PDCI/PRB)
Karen Jones
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

GL-830-7050 UV/Visible Absorption
GL-870-1300 Acute Inhalation
GL-870-3465 90 day Inhalation – rat

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 November, 2003. Registrant responses are under review.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in Table 20 at the end of this section.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

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

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 20 at the end of this section.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Interim Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this interim RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrant may distribute and sell dicrotophos products bearing old labels/labeling for 26 months from the date of issuance of this interim RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this interim RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

D. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 20: Summary of Required Labeling Changes for Dicrotophos		
Description	**Required Labeling**	**Placement on Label**
Manufacturing Use Products		
Formulation Instructions required on all MUP's	"Only for formulation into an insecticide for use on (*registrant inserts correct use site(s)*)."	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 MUP 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 MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).	Directions for Use

Description	Required Labeling	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies	**"Environmental Hazards"** "This chemical is toxic to aquatic organisms (fish and invertebrates) and wildlife. 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"	Directions for Use
End Use Products (Except for the Tree injection product).		
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE" "Due to Acute Oral and Dermal Toxicity and Risks to Wildlife." "For retail sale to, and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's certification."	Top of front panel
Handler PPE considerations	Note the following information when preparing labeling for all end use products: For **sole-active-ingredient** end-use products that contain dicrotophos the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed. PPE that is established on the basis of Acute Toxicity testing with the end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.	Precautionary Statements Under PPE Requirements

Description	Required Labeling	Placement on Label
Handler PPE requirements (all formulations)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "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-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: Long-sleeved shirt and long pants Shoes plus socks, In addition, mixers and loaders must wear: Chemical-resistant gloves Chemical resistant apron See engineering controls for additional requirements."	Immediately following/below 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 and 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 for the Water Miscible Formulation marketed in a closed loading system that meets the specifications of the WPS	**"Engineering Controls"** **Mixer and Loader Engineering Control for Liquid Formulations (except for tree injection product):** "Engineering Controls "Mixers and loaders must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)], for 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. Mixers and loaders must: -- wear the personal protective equipment required above for mixers/loaders, -- wear protective eyewear if the system operates under pressure, and -- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown the following: coveralls and chemical-resistant footwear)." "Applicators must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators and flaggers must: -- wear the personal protective equipment required above, -- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant headgear, if overhead exposure, -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the User Safety Requirements

Description	Required Labeling	Placement on Label
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."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	**"Environmental Hazards"** "This pesticide is highly toxic to birds and mammals. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Keep out of lakes, ponds, and streams. Do not contaminate water when disposing of equipment wastewater or rinsate". See Directions for Use for required buffer zones or setbacks." "This product is toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees are visiting the treatment area."	Precautionary Statements immediately following the User Safety Recommendations

Description	Required Labeling	Placement on Label
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 6 days."	Directions for Use, Agricultural Use Requirements Box
Early Re-entry Personal Protective Equipment established by the RED.	"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 worn over long-sleeve shirt and long pants, - chemical-resistant gloves made of any waterproof material, - chemical-resistant footwear plus socks, and - protective eyewear"	Directions for Use, Agricultural Use Requirements Box
Notification Statement	"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."	Directions for Use, Agricultural Use Requirements Box
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."	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions	"Aerial applications are prohibited." Labels must be revised to reflect the maximum seasonal application rate of 0.83 lb ai/A and that only 0.5 lb ai/A may be applied prior to August 1 of any year. In addition: the following statements must be included on the label: "Do not apply more than 0.83 lb ai/A/year." "Do not apply more than 0.5 lb ai/A prior to August 1."	Place in the Direction for Use where appropriate

Description	Required Labeling	Placement on Label
Spray Drift Requirements	"Do not allow spray to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals." "For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy, and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use _____ "(registrant to fill in blank with spray quality, e.g. fine or medium) "or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles." Or: "Do not allow this product to drift." On all product labels: "The applicator also must use all other measures necessary to control drift."	Place in the Direction for Use where appropriate

Description	Required Labeling	Placement on Label
End Use Products for Tree Injection		
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE" "Due to Acute Oral and Dermal Toxicity." "For retail sale to, and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's certification."	Top of front panel
Handler PPE	Applicators and other handlers must wear: - long-sleeve shirt and long pants, - chemical-resistant gloves made of any waterproof material, - shoes plus socks, and - protective eyewear"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
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."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Must be placed in a box.)

Description	Required Labeling	Placement on Label
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."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application.	
WPS exclusionary statement	"Not for use on trees grown for sale or other commercial use, or for commercial seed production, or for the production of timber or wood products, or for research purposes."	Place in the Direction for Use

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.
Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

VI. Related Documents and How to Access Them

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

The docket initially contained preliminary risk assessments and related documents as of January 10, 2000. 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 14, 2000.

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

APPENDICES

APPENDIX A. FOOD/FEED USE PATTERNS SUBJECT TO REREGISTRATION FOR DICROTOPHOS

TABLE A. FOOD/FEED USE PATTERNS SUBJECT TO REREGISTRATION FOR DICROTOPHOS (CASE 0145).		
Site Application Type Application Timing Application Equipment	Max. Single Application Rate, (ai)	Use Limitations
Food/Feed Crop Use		
Cotton		
Broadcast foliar application Ground equipment	0.5 lb/A	Do not apply more than 0.83 lb ai/A/season. Do not apply more than 0.5 lb ai/A prior to August 1 of any year.
Non Food/Non Feed Use		
Ornamental and/or shade trees		
Tree injection equipment	0.5 capsules per 1 inch of tree diameter	Do not use on trees which will be used to produce food within the year. Do not apply to stressed trees. Do not apply within two weeks of spraying or soil treatment.

APPENDIX B. DATA SUPPORTING GUIDELINE REQUIREMENTS FOR THE REREGISTRATION OF DICROTOPHOS

REQUIREMENT			CITATION(S)
PRODUCT CHEMISTRY			
New Guideline Number	**Old Guideline Number**		
830.1550	**61-1**	**Product Identity and Composition**	**00126056, 43772301**
830.1600	**61-2A**	**Start. Mat. & Mnfg. Process**	**00013513, 00013814, 00126056, 43772301, 00013513, 00013814, 00126056, 43772301**
830.1670	**61-2B**	**Formation of Impurities**	**00115285, 43772301**
830.1700	**62-1**	**Preliminary Analysis**	**43772302**
830.1750	**62-2**	**Certification of limits**	**43772301**
830.1800	**62-3**	**Analytical Method**	**00014001, 43772302**
830.6302	**63-2**	**Color**	**00013435, 00115285, 43772303**
830.6303	**63-3**	**Physical State**	**00013435, 43772304**
830.6304	**63-4**	**Odor**	**00013435, 00115285, 43772305**
830.7200	**63-5**	**Melting Point**	**43772306**
830.7220	**63-6**	**Boiling Point**	**43772307**
830.7300	**63-7**	**Density**	**43772309**
830.7840	**63-8**	**Solubility**	**43602301**
830.7860			**43603202**
830.7950	**63-9**	**Vapor Pressure**	**43603203**
830.7370	**63-10**	**Dissociation Constant**	**43772309**
830.7550	**63-11**	**Octanol/Water Partition Coefficient**	**43603204**
830.7000	**63-12**	**pH**	**00126056, 43772310**
830.6313	**63-13**	**Stability**	**00013435, 43603205**

REQUIREMENT			CITATION(S)
830.6314	**63-14**	**Oxidizing/Reducing Action**	**00115285**
830.6315	**63-15**	**Flammability**	**00115285**
830.6316	**63-16**	**Explodability**	**NA**
830.6317	**63-17**	**Storage Stability**	**00115285**
830.6319	**63-19**	**Miscibility**	**00115285**
830.6320	**63-20**	**Corrosion characteristics**	**00115285**
	ECOLOGICAL EFFECTS		
850.2100	**71-1**	**Avian Acute Oral Toxicity**	**00160000**
850.2200	**71-2A**	**Avian Dietary Toxicity - Quail**	**00022923**
850.2200	**71-2B**	**Avian Dietary Toxicity - Duck**	**00022923**
850.2300	**71-4A**	**Avian Reproduction - Quail**	**44005502**
850.2300	**71-4B**	**Avian Reproduction - Duck**	**44005501**
850.1075	**72-1A**	**Fish Toxicity Bluegill**	**40098001**
850.1075	**72-1C**	**Fish Toxicity Rainbow Trout**	**40098001**
850.1010	**72-2A**	**Invertebrate Toxicity**	**43787901, 40098001**
None	**72-3A**	**Estuarine/Marine Toxicity - Fish**	**43603306**
None	**72-3B**	**Estuarine/Marine Toxicity - Mollusk**	**43739801**
None	**72-3C**	**Estuarine/Marine Toxicity - Shrimp**	**43603305**
None	**72-4A**	**Fish- Early Life Stage**	**NA**
None	**72-4B**	**Estuarine/Marine Invertebrate Life Cycle**	**43893901**
	TOXICOLOGY		
870.1100	**81-1**	**Acute Oral Toxicity-Rat**	**00261098, 43893901**
870.1200	**81-2**	**Acute Dermal Toxicity-Rabbit/Rat**	**00261098**
870.1300	**81-3**	**Acute Inhalation Toxicity-Rat**	**data gap**
870.2400	**81-4**	**Primary Eye Irritation-Rabbit**	**00261098**
870.2500	**81-5**	**Primary Skin Irritation**	**00261098**
870.2600	**81-6**	**Dermal Sensitization**	**00261098**
870.6100	**81-7**	**Acute Delayed Neurotoxicity - Hen**	**44943901, 45170201**
870.6200	**81-8**	**Acute Neurotoxicity Screen**	**43759801**

REQUIREMENT			CITATION(S)
870.3100	**82-1A**	**90-Day Feeding - Rodent**	**43980201**
870.3150	**82-1B**	**90-Day Feeding - Non-rodent**	**00013441**
870.3200	**82-2**	**21-Day Dermal - Rabbit/Rat**	**45378201**
870.3465	**82-4**	**90-Day Inhalation-Rat**	**data gap**
870.4100	**83-1A**	**Chronic Feeding Toxicity - Rodent**	**44528802**
870.4100	**83-1B**	**Chronic Feeding Toxicity - Non-Rodent**	**44328401**
870.4200	**83-2A**	**Oncogenicity - Rat**	**44527802**
870.4200	**83-2B**	**Oncogenicity - Mouse**	**44527801**
870.3700	**83-3A**	**Developmental Toxicity - Rat**	**00263684**
870.3700	**83-3B**	**Developmental Toxicity - Rabbit**	**45390701**
870.3800	**83-4**	**2-Generation Reproduction - Rat**	**44296101**
870.4300	**83-5**	**Combined Chronic Toxicity/ Carcinogenicity**	**44527802**
870.5140	**84-2A**	**Gene Mutation (Ames Test)**	**43603301**
870.5375	**84-2B**	**Structural Chromosomal Aberration**	**43603302**
None	**84-4**	**Other Genotoxic Effects (Mammalian gene mutation)**	**43591401**
870.7485	**85-1**	**General Metabolism**	**43942001**
	OCCUPATIONAL/RESIDENTIAL EXPOSURE		
875.2100	**132-1A**	**Foliar Residue Dissipation**	**44731001**
	ENVIRONMENTAL FATE		
None	**160-5**	**Chemical Identity**	**43772301**
835.2120	**161-1**	**Hydrolysis**	**00160823**
835.2240	**161-2**	**Photodegradation - Water**	**00160824**
835.2410	**161-3**	**Photodegradation - Soil**	**00160825**
835.2370	**161-4**	**Photodegradation - Air**	**NA**
835.4100	**162-1**	**Aerobic Soil Metabolism**	**00115295, 00160826**
835.4200	**162-2**	**Anaerobic Soil Metabolism**	**00160826**
835.4400	**162-3**	**Anaerobic Aquatic Metabolism**	**NA**
835.4300	**162-4**	**Aerobic Aquatic Metabolism**	**NA**

REQUIREMENT			CITATION(S)
835.1240	**163-1**	**Leaching/Adsorption/Desorption**	**00160828, 00160829**
	163-2	**Laboratory volatility**	**44824801**
835.6100	**164-1**	**Terrestrial Field Dissipation**	**00115294, 41114301**
835.1850	**165-1**	**Confined Rotational Crop**	**44101001**
None	**165-4**	**Bioaccumulation in Fish**	**waived**
RESIDUE CHEMISTRY			
860.1300	**171-4A**	**Nature of Residue - Plants**	**44614701**
860.1300	**171-4B**	**Nature of Residue - Livestock**	**44031201, 43962401**
860.1340	**171-4C**	**Residue Analytical Method - Plants**	**44750301**
860.1340	**171-4D**	**Residue Analytical Method - Animals**	**NA**
860.1380	**171-4E**	**Storage Stability**	**44728501**
860.1480	**171-4J**	**Magnitude of Residues - Meat/Milk/Poultry /Egg**	**waived**
OTHER			
850.3020	**141-1**	**Honey Bee Acute Contact**	**05000837, 05009353, 05001991**

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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 REGISTRANTS RECEIVING DATA CALL-INS

APPENDIX G. EPA'S BATCHING OF DICROTOPHOS PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

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

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

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

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

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

Three products were found which contain ***Dicrotophos*** as the active ingredient. These three are technical products (EPA Reg. Nos. 5481-447, 5481-448 and 7946-11) . Therefore, acute toxicity data on one product may support all three.

APPENDIX H. TECHNICAL SUPPORT DOCUMENTS

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

The docket initially contained preliminary risk assessments and related documents as of November 10, 1999. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on June 14, 2000.

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

www.epa.gov/pesticides/op

These documents include:

HED Documents:

1. Dicrotophos (List A, Reregistration Case No. 0145). HED Risk Assessment for Reregistration Eligibility Document (RED) Chemical No 035201. November 7, 2001
2. Dicrotophos (List A, Reregistration Case No. 0145). HED Risk Assessment for Reregistration Eligibility Document (RED) Chemical No 035201. DP Barcode D264754. April 5, 2000

EFED Documents:

1. EFED RED Chapter for Dicrotophos. (Chemical # 035201). October 28, 1998.
2. Revised Surface Water EECs (Incorporating the Index Reservoir and Percent Crop Area) October 24, 2001.

Biological and Economic Analysis Division Documents

1. Biological Assessment of Dicrotophos Use on Cotton. February 7, 2002.
2. Dicrotophos Use on Cotton - Information Matrix of 2000 versus 2002 Responses. Appendix to the Biological Assessment of Dicrotophos Use on Cotton from February 2002.

APPENDIX I. LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

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

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

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

Instructions

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

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

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

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

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@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 (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (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' website.

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.

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 website.

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 website: 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:

   1. Date of receipt;
   2. EPA identifying number; and
   3. 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 chemical abstract system (CAS) number if one has been assigned.