US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Phorate

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)

- Phorate 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

Interim Reregistration Eligibility Decision
for
Phorate

Case # 0103

List B

TABLE OF CONTENTS

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

Phorate TEAM

Office of Pesticide Programs:

Health Effects Risk Assessment

Christine Olinger
Jeffery Dawson
Christina Swartz
Michael Metzger
Whang Phang
Yung Yang

Environmental Fate (Drinking Water and Ecological) Risk Assessment

James Breithaupt
David Farrar

Use and Usage Analysis

Virginia Dietrich
Jihad Alsadek

Registration Support

Marilyn Mautz

Risk Management

Ben Chambliss
Stephanie Willett
Mark Hartman
John Leahy

Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for phorate. The decisions outlined in this document do not include the final tolerance reassessment decision for phorate; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. EPA has proposed to revoke tolerances in or on meat, milk, poultry and eggs for residues of phorate because the Agency has determined that there are no reasonable expectations of finite residues and the tolerances are not necessary. Some tolerance reassessment actions such as revocations on alfalfa and barley have already been finalized while other tolerance reassessment decisions for this chemical will be issued once the cumulative assessment for all of the organophosphates is complete. The Agency may need to pursue further risk management measures for phorate once the cumulative assessment is finalized.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. In a continuing effort to make meaningful and practical reduction in risk, the Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on phorate. After considering the revised risks assessments, mitigation proposed by BASF and Aceto Agricultural Chemicals Corporation the technical registrants of phorate, comments and mitigation suggestions from other interested parties including the Natural Resources Defense Council, and several agricultural user groups, EPA developed its risk management decision for uses of phorate that pose risks of concern. This decision is discussed fully in this document.

First registered in 1959, phorate is an organophosphate insecticide and nematicide primarily used on a variety of field agricultural crops. Phorate is a restricted use pesticide based on its high dermal, oral, and inhalation toxicity. It is applied using ground equipment only since the technical registrants, BASF and Aceto Agricultural Chemicals Corporation, have agreed to cancel the aerial use. About three million pounds are used annually, of which 80 % is applied to corn, potatoes, and cotton.

Overall Risk Summary

EPA's human health risk assessment for phorate indicates some risk concerns. Dietary risk from food treated with phorate is not of concern. The aggregate dietary risk from combined food and drinking water exposure may pose concerns, based on modeling results. There are no residential uses of phorate, and therefore no residential risks were considered in the aggregate risk from such uses. The risks of applying phorate using ground equipment are below our level of concern for loaders, handlers, and applicators when closed loading and application systems are used. Risks to aerial applicators are of concern but this application method will be prohibited because registrants have agreed to restrict this method. Phorate ranks high in the number of occupational incidents resulting in adverse health effects.

Dietary Risk

Acute and chronic dietary risks from food alone do not exceed the Agency's level of concern, however for dietary risk from drinking water, based on modeling (SCI-GROW), the maximum estimated concentrations of phorate and metabolites (sulfoxide and sulfone) in groundwater are slightly greater than the Agency's Drinking Water Level of Comparison (DWLOC) for chronic drinking water exposure. Also, the estimated concentrations of phorate and its metabolites in surface water slightly exceed EPA's DWLOC for acute exposure. However, the conservative nature of the food assessment together with extensive risk mitigation proposed in this document lead the Agency to believe that the dietary risk from food and drinking water exposure for phorate and its degradates will be below the Agency's level of concern following implementation of mitigation measures.

Residential Risk

There are no concerns because phorate does not have any residential uses.

Aggregate Risk

Since there are no residential uses for phorate, aggregate risk will only consider exposure from food and water. Acute and chronic dietary risks from food alone do not exceed the Agency's level of concern, however, for dietary risk from drinking water, the maximum estimated concentrations of phorate and metabolites (sulfoxide and sulfone) in groundwater and surface water slightly exceed EPA's level of concern. As noted above, the conservative nature of the food assessment together with extensive risk mitigation proposed in this document lead the Agency to believe that the aggregate risk from food and drinking water exposure for phorate and its degradates will be below the Agency's level of concern following implementation of mitigation measures.

Occupational Risk

Worker risks are of concern for the mixer/loader/applicator when using open bags, open cab ground equipment and minimum Personal Protective Equipment. EPA believes these risks can be mitigated to an acceptable level with the following requirements: use of closed systems/lock-n-load (LNL), use of closed cabs, additional precautionary label language limiting use to only one application per season and requiring soil incorporation. Current label use rates should be reduced by 25 % unless efficacy data shows that lowering use rates reduces the pesticidal effectiveness. This would also reduce worker risks when implemented. Aerial applicators and flaggers (without engineering controls) also have risks above the level of concern but prohibition of aerial application will eliminate this concern.

Since phorate use on wheat is applied by aerial application, the technical registrants have also volunteered to cancel use on wheat. The Agency is also requesting submission of agricultural practice information to further evaluate post application exposure, if any. Based on the current use pattern, when phorate is applied (generally at plant), and the way it is applied (granulars that are soil incorporated) does not indicate a need for new post application studies. Until the Agency has completed the cumulative risk

assessment for all organophosphates, all currently registered uses of phorate, except wheat, may continue with the incorporation of the risk mitigation measures identified in this document.

Ecological Risk

Ecological risks are also of concern to the Agency. Risks to birds, fish, and mammals are high. Study results indicate that ingestion of phorate poses acute and chronic risks to birds. Additionally several bird kills, some involving large numbers of birds, have been reported and linked to the use of phorate on winter wheat. Fall application seems to pose a particular risk because during winter, degradation and downward movement is expected to be slow and in the following spring concentrations of phorate and its metabolites can occur at hazardous levels in pools on the soil surface. Acute and chronic risks to aquatic organisms resulting from surface run-off to rivers, streams and coastal areas is high based on study results. Additionally, a few fish kill incidents have been reportedly and indirectly linked to phorate. Risks to mammals may result from agricultural use, based on study results. Phorate is moderately to highly toxic to honey bees on an acute basis. Cancellation of use on winter wheat, prohibiting aerial application, requiring soil incorporation, requiring additional environmental hazard labeling language and limiting use to once per season will reduce ecological exposure to phorate.

The Agency is issuing this interim Reregistration Eligibility Document (IRED) for phorate, 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 phorate. Note that there is no comment period for this document, and that the time frames for compliance with the required 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 phorate have already been subject to numerous public comment periods, and a further comment period for phorate was deemed unnecessary. The Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period, depending on the content of the risk management decision. With regard to complying with the 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 phorate can be considered final, however, until the cumulative risk assessment for all organophosphate pesticides is complete. The cumulative assessment may result in further required risk mitigation measures for phorate.

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 amended FIFRA to require tolerance reassessment during reregistration. It 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 amended 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. Phorate 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 phorate. It is intended to be only the first phase in the reregistration process for phorate. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision for phorate.

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 published in the *Federal Register* on August 12, 1999 a draft Pesticide Registration Notice that presents EPA's proposed approach for managing risks from organophosphate pesticides to occupational users. This notice describes the Agency's baseline approach to managing risks to handlers and workers of organophosphate pesticides. Generally, basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased restricted entry intervals will be necessary for most uses where current risk assessments indicate a risk and such protective measures are feasible. The draft guidance policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this interim RED are consistent with that draft Pesticide Registration Notice.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental 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 lists 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/phorate.htm, and in the Public Docket.

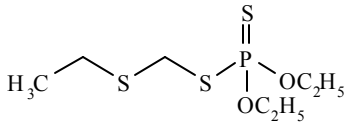
II. Chemical Overview

A. Regulatory History

Phorate was first registered in the United States in 1959. In August 1979, all emulsifiable concentrate formulations containing 65% or more a.i., as well as all granular products used on rice, were classified as restricted use pesticides. In August 1984, the Registration Standard was issued. The Registration Standard expanded the restricted use classification to include all granular products containing 5 % or more active ingredient. Registrants of products containing less than 5 % a.i. were required to submit additional data. In December 1988, the Registration Standard was amended and restricted use classification was imposed on all phorate products based on acute dermal and oral toxicity as well as avian hazards. The Agency sent a preliminary notification (letter dated 12/88) to BASF based on risk concerns to nontarget organisms including birds, wild animals and endangered species. A second notification letter was sent to the registrant in August 1990 indicating continued concern about nontarget organisms and adding risks to aquatic organisms as further basis for a Special Review. In addition to the data requirements imposed in the 1984 Phorate Registration Standard and its 1988 Amendment, additional data requirements including human incident data, neurotoxicity, foliar residue dissipation, dermal and inhalation passive dosimetry data were imposed in Data Call-In Notices in October 1992, August 1993, October 1995, and neurotoxicity studies (acute, subchronic and developmental) in 1999 .

B. Chemical Identification

Phorate:



- **Common Name:** Phorate
- **Chemical Name:** O,O-diethyl S[(ethylthio)methyl] phosphorothioate
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 298-02-2
- **OPP Chemical Code:** 057201
- **Empirical Formula:** $C_7H_{17}O_2PS_3$

- **Molecular Weight:** 260.4
- **Trade and Other Names:** Thimet
- **Basic Manufacturers:** BASF and Aceto Agricultural Chemical Corp.

Technical phorate is a colorless to light yellow clear liquid with a boiling point of 118-120 C. Phorate is slightly soluble in water at 20-50 ppm and soluble in most organic solvents, such as acetone and xylene. It is miscible in alcohols, ethers, ketones, esters, carbon tetrachloride, and vegetable oils. Phorate is subject to hydrolysis under alkaline conditions, but is stable under neutral and acidic conditions.

C. Use Profile

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

Type of Pesticide: Insecticide/nematicide

Summary of Use:

Food: Potatoes, Corn (fresh, sweet, field)), Peanuts, Cotton, Sugarcane, Wheat (spring/winter), Soybeans, Beans, Sorghum, and Sugar Beets.

Residential: No residential uses.

Other Nonfood: Lilies (field grown), Daffodils, Radishes grown for seed.

Target Pests: Phorate is used to control Mexican bean beetle, corn rootworm, mites, European corn borers, wireworms, white grubs, cornleaf aphids, seedcorn beetles, leafminers, thrips, black cutworms, leafhoppers, white flies, nematodes, southern corn rootworm, flea beetle larvae, psyllids, wireworms, Colorado potato beetle, lygus, chinchbug nymphs, Banks grass mites, seedcorn maggots, sugar beet root maggot, sugar beet leafhopper, grasshoppers, and Hessian Fly.

Formulation Types:

Registered: Formulated as 10%, 15% and 20% granular end-use formulations and 92-95 % emulsifiable concentrate manufacturing use product.

Method and Rates of Application:

Equipment - Ground and aerial equipment

Method and Rate - Aerial application; soil and foliar applications (band, broadcast, in-furrow, and drilling). Use rates vary from a minimum of 0.66 lbs ai/acre to a maximum of 3.9 lbs ai/acre per single application with a maximum of 2 applications per year for some uses.

Timing - Generally at planting with soil incorporation, but can be applied at cultivation (corn), late in the season to irrigated cotton (cotton), late in the season with a side dress-application (lillies/daffodils), at pegging with soil incorporation (peanuts), post-emergence at hilling with soil incorporation (potatoes), at bolting (radishes), post emergence at cultivation with soil incorporation (sorghum), and over the plant later in season (wheat).

Use Classification: Phorate is a "restricted use" chemical based on acute dermal and oral toxicity as well as avian hazards.

D. Estimated Usage of Pesticide

An estimated 3 million pounds are produced annually. Crops with the highest usage with reference to pounds produced are corn (46%), potatoes (21%) and cotton (13%). Almost 2.5 million acres are treated annually. Crops with the highest percentage of acres treated include potatoes (20%), fresh sweet corn (10%) and peanuts (9%). Most of the usage is in FL, WI, CA, GA, MS, AL, TX, ID, MT, and MI. Crops with a high percentage of the total U.S. planted acres treated include potatoes (20%), fresh sweet corn (10%), peanuts (9%), and vegetables, cotton, and sugarcane (4%).

Table 1: Usage Analysis

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)
Alfalfa	23,949	1	3	0.00	0.01	1	3	0.9	1.0	0.9	AZ WI 83%
Almonds	429	0	1	0.04	0.21	0	1	1.0	1.0	1.0	CA 100%
Apples	572	0	0	0.00	0.01	0	0	1.0	1.0	1.0	WI 100%
Barley	7,505	3	10	0.04	0.13	2	4	0.6	1.0	0.6	WY ID NE 91%
Beans/Peas, Dry	2,181	29	57	1.32	2.63	32	51	1.1	1.0	1.1	MI WA CO ID NE PA 88%
Beans/Peas, Green	723	12	29	1.62	3.98	14	32	1.2	1.0	1.2	MD NY MI WI VA FL 86%
Cole Crops	313	0	0	0.01	0.02	0	0	1.0	1.0	1.0	AL 100%
Corn	72,284	1,249	2,392	1.73	3.31	1,410	2,690	1.1	1.2	1.0	NE IL IA WI MN IN 67%
Cotton	12,689	536	877	4.23	6.91	410	744	0.8	1.0	0.8	TX CA GA MS AR NC 75%
Cucurbits	285	0	0	0.01	0.02	0	0	1.0	1.0	1.0	TX 100%
Hay, Other	33,427	0	2	0.00	0.01	1	3	1.1	1.0	1.1	TX ID 95%
Hops	40	1	2	1.00	2.00	2	4	3.0	-	-	WA OR 100%
Lilies	-	0	0	0	0	3	4	-	-	-	CA 100%
Lots/Farmsteads/etc	24,815	0	0	0.00	0.00	0	0	1.0	1.0	1.0	MT TX 100%
Melons	368	0	2	0.12	0.48	0	1	0.9	1.0	0.9	CA GA FL 89%
Oats/Rye	6,133	0	1	0.00	0.01	0	1	1.8	1.0	1.8	MN NC 89%
Oranges	867	0	0	0.01	0.03	0	0	0.6	1.4	0.4	FL 100%
Other Crops	2,515	62	127	2.45	5.06	140	324	2.3	1.1	2.2	FL ID WY 81%

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)
Peanuts	1,610	145	180	8.99	11.18	160	210	1.1	1.0	1.1	GA NC TX AL VA 86%
Pecans	488	0	1	0.05	0.19	0	1	1.5	1.0	1.5	GA MS 100%
Potatoes	1,421	284	336	20.01	23.68	630	1,215	2.2	1.0	2.2	ID WA ND OR MN CA 69%
Radishes	46	0	5	0.29	10.98	0	5	1.0	1.0	1.0	ID MT 100%
Safflower	113	ERR	ERR	??	•0	0	-	-	-	-	
Sorghum	11,280	25	78	0.22	0.69	27	80	1.1	1.0	1.1	KS TX NE NM SD 84%
Soybeans	62,879	17	34	0.03	0.05	15	31	0.9	1.0	0.9	MN IN IL WI NC 84%
Sugar Beets	1,415	34	71	2.38	5.00	45	89	1.3	1.0	1.3	ID CA WY 83%
Sugarcane	852	33	82	3.91	9.62	110	286	3.3	1.0	3.3	FL 90%
Sweet Corn, Fresh	233	23	45	9.73	19.08	21	41	0.9	1.3	0.7	FL 100%
Sweet Corn, Proc.	544	9	31	1.61	5.65	7	26	0.9	1.0	0.9	WI 100%
Tobacco	695	0	1	0.05	0.18	1	3	2.2	1.0	2.2	VA 87%
Vegetables, Other	286	12	27	4.05	9.58	14	31	1.2	1.0	1.2	MD NY MI WI VA FL 82%
Wheat, Spring	20,799	2	3	0.01	0.02	1	2	0.8	1.0	0.7	ID MT 95%
Wheat, Winter	45,854	22	46	0.05	0.10	13	30	0.6	1.2	0.5	WA ID NC GA CA SC 82%
Woodland	62,825	0	0	0.00	0.00	0	1	1.8	1.0	1.8	MI 100%
Total		2,499	3,471			3060.19	4486.2573				

III. Summary of Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide phorate, which are fully presented in the documents, "Phorate Revised HED Chapter for the Reregistration Eligibility Decision Document," dated September 2, 1999, and "Revised EFED Chapter for Phorate," dated August 30, 1999 (and addendums thereto). The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to enhance understanding of the conclusions reached in the assessments.

These risk assessments for phorate were presented at a September 2, 1999, Technical Briefing, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's interim risk management decision for phorate only; the Agency must complete a cumulative assessment of the risks of all the organophosphate pesticides before other final decisions can be made.

Using relevant data submitted under section 4(g)(2)(A) of FIFRA, published scientific literature, and available surrogate data, the Agency assessed the human health and ecological risks associated with using phorate. The primary endpoint of concern is cholinesterase inhibition as measured in red blood cell and brain cholinesterase inhibition following exposure to phorate. The Agency calculated human health risks from food, water, and occupational exposures. Acute and chronic dietary risk from residues in or on food were below the Agency level of concern for all subpopulations. For dietary risk from drinking water, based on modeling (SCI-GROW), the maximum estimated concentrations of phorate and metabolites (sulfoxide and sulfone) in groundwater are slightly greater than the Agency's Drinking Water Level of Comparison (DWLOC) for chronic drinking water exposure and the estimated concentrations of phorate and its metabolites in surface water slightly exceed EPA's DWLOC for acute exposure. However, the conservative nature of the food assessment together with extensive risk mitigation proposed in this document lead the Agency to believe that the dietary risk from food and drinking water exposure for phorate and its degradates will be below the Agency's level of concern with implementation of the following mitigation measures prohibiting use on peanuts at pegging, restricting cotton sidedress use to California and Arizona only, allowing only one application per year, requiring soil incorporation, requiring use of vegetated buffer strips and reducing application rates where efficacy tests show rate reductions are feasible.

Since there are no residential or non-occupational uses for phorate, a non-occupational/residential exposure and risk assessment is not applicable. In quantifying aggregate risks, the Agency will only consider exposure from food and water. Acute and chronic dietary risks from food alone do not exceed the Agency's level of concern. However, for dietary risk from drinking water, the maximum estimated concentrations of phorate and metabolites (sulfoxide and sulfone) in groundwater and surface water slightly exceed EPA's level of concern. Again the conservative nature of the food assessment together with extensive risk mitigation proposed in this document lead the Agency to believe that the aggregate risk from food and drinking water exposure for phorate and its degradates will be below the Agency's level of concern following implementation of mitigation measures.

In regard to the ecological risk assessment, risks to birds, mammals, fish and aquatic invertebrates are high. Fall applications in the northern wheat growing states appear to pose a particular risk to birds. During the winter in these regions, degradation and downward movement in soil is expected to be slow. The incident information indicates that in spring the concentrations of phorate and/or phorate degradates sometimes occur at hazardous levels in pools on the soil surface. In terms of the environmental fate assessment for phorate, surface water contamination may occur from the sulfoxide and sulfone degradates of phorate as well as from parent phorate. The risk of ground water contamination is primarily associated with phorate sulfone and phorate sulfoxide rather than parent phorate.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for phorate in February 1999 (Phase 3 of the TRAC process). In response to studies received during Phase 3, the risks assessments were updated and refined. The revisions are listed below:

-The revised risk assessment incorporates the results of a new rat acute neurotoxicity study which leads to the establishment of a new acute dietary endpoint.

-New dietary risk analyses utilizing a Monte Carlo (probabilistic) approach have been conducted by BASF and EPA to further characterize the acute risk and to identify commodities that contribute most significantly to the risk.

-The revised occupational exposure and risk assessment considers a new subchronic dermal toxicity study on rats using a granular formulation, and an occupational exposure study was conducted using a similar chemical, terbufos, that reflects loading with a closed system and varying levels of PPE.

1. Dietary Risk from Food

a. Toxicity

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

b. FQPA Safety Factor

Both acute neurotoxicity and subchronic neurotoxicity data in rats have been evaluated and found acceptable, however, the FQPA Safety Factor was reduced to 3X, based on the outstanding developmental neurotoxicity data requirement. The acute screening study findings of nerve degeneration in young rats after only a single dose trigger the requirement for developmental neurotoxicity data. The registrant provided a short summary of some historical data but the submitted historical control data were judged to be insufficient to support a determination of non-compound related histological changes in the isolated peripheral nerve fibers. The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post-natal studies. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and residential exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risks for infants and children.

c. Population Adjusted Dose (PAD)

The PAD is a relatively new 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). A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

d. Exposure Assumptions

The dietary risk analysis used food consumption data from the 1989-1992 USDA CSFII Survey, Agency validated percent crop treated information, and data from field trial studies. FDA and USDA monitoring data showed non-detectable residues in all commodities with the exception of potatoes.

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

Exposure	Dose (mg/kg/day)	Endpoint	Study
Acute RfD	NOAEL = 0.25	Miosis and brain cholinesterase inhibition	Acute Neurotoxicity - Rat
	UF =100 Acute RfD = 0.0025 mg/kg **FQPA Population Adjusted Dose = 0.00083 mg/kg**		
Chronic RfD	NOAEL = 0.05	Red blood cell and brain cholinesterase inhibition	Chronic - Dog
	UF =100 Chronic RfD = 0.0005 mg/kg/day **FQPA Population Adjusted Dose = 0.00017 mg/kg/day**		

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. The Agency conducted a probabilistic (Monte Carlo) acute dietary risk assessment using Tier 3 (highly refined) exposure estimates. The assessment considers the distribution of food consumption values and the distribution of residue values found in food. Using this approach, the acute dietary risk from residues of phorate in food alone is below the Agency's level of concern at the 99.9th percentile. The most highly exposed subgroup is children 1 to 6 years old with 68 % of the acute Population Adjusted Dose (aPAD) consumed.

The chronic dietary risk from phorate residues in food alone is also below the Agency's level of concern. The most highly exposed subgroup is children 1 to 6 years old with 9% of the chronic Population Adjusted Dose (cPAD) consumed.

The dietary exposure and risk estimates for food are not based on residue monitoring data and thus are considered to be relatively conservative. Exposure estimates for each of the major contributors to dietary exposure (sweet corn, potatoes and peanuts) are based upon either tolerance level residues (sweet corn) or field trial data. It is expected that if suitable monitoring data were available the exposure and risk estimates concerning residues on/in food would be significantly lower allowing for addition space in the "risk cup" for exposures to phorate.

In summary, both acute and chronic dietary exposure and risk associated with phorate-treated foods are considered to be well below the Agency's level of concern. Refinements to the dietary analyses could be made by acquiring monitoring data and/or market basket survey data, rather than relying on assumptions that are likely to overestimate dietary exposure from food. However, the Agency determined that further refinements are not warranted at this time since dietary risk is not of concern based on our current estimates. Refinements will be considered when the cumulative assessment for all of the organophosphates is conducted.

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. In the case of phorate, monitoring data for ground or surface water were insufficient as there were very limited data and the available data did not measure the degradates. Therefore modeling was used to estimate drinking water risks from these sources.

The GENEEC and PRZM-EXAMS models were used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. All of these are considered to be screening models, with the PRZM-EXAMS model being somewhat more refined than the other two. The recently implemented Index Reservoir and Percent Crop Area modifications to the PRZM-EXAMS model were also utilized in developing estimated surface water concentrations.

Based on environmental fate data, hydrolysis and microbial degradation appear to be the most important means of phorate dissipation in the environment. Phorate is very unstable to photolysis in water, but photolysis in the field may not be important since phorate degrades rapidly by hydrolysis and aerobic soil metabolism. Phorate rapidly photolyses in water to form formaldehyde and phorate sulfoxide.

Parent phorate degrades in water with half-lives of 3 days at pH's 5, 7, and 9. Parent phorate is very mobile to essentially immobile in soil depending on the soil organic carbon content, but is not persistent in aerobic soil. In soil, parent phorate degrades into the oxidized metabolites phorate sulfoxide and sulfone. These degradates are more persistent than parent phorate, more mobile, and are more likely to be present in water resources than parent phorate because they are slightly more persistent and mobile.

a. Surface Water

The Agency has estimated the concentration of phorate alone, and phorate plus degradates in surface water using the PRZM/EXAMS model. Model estimates for both the parent and the parent plus metabolites exceed the level of concern for acute and chronic exposure for some use scenarios (see tables 3a and 3b). The estimated maximum peak concentration of phorate and degradates prior to mitigation is 53.2 ppb, and the maximum annual mean is 1.85 ppb based on use rates and patterns for field and sweet corn, peanuts, cotton, potatoes, and grain sorghum.

Monitoring studies have been conducted for phorate only in the Mississippi Basin, Illinois, Colorado, and Florida. Analyses from an Illinois study were reported as total phorate + sulfoxide + sulfone. Only two detects were noted for the Colorado agricultural watershed (out of 25) at concentrations ranging from 0.08 ppb to 0.6 ppb. Phorate was not detected in any of the other samples from any of the other studies. The monitoring data are likely to be of little utility for dietary risk assessment, since the oxidized metabolites are more likely to be present than the parent, but in almost all of the studies, analyses for the degradates were not conducted.

b. Ground Water

The SCI-GROW model provides a screening concentration, an estimate of likely groundwater concentrations if the pesticide is used at the maximum allowed label rate in areas with groundwater exceptionally vulnerable to contamination. In most cases, a majority of the use area will have groundwater that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimate. The SCI-GROW model is based on scaled groundwater concentrations from groundwater monitoring studies, environmental fate properties (aerobic soil half-lives and organic carbon partitioning coefficients (Koc's)) and application rates. The model is based on permeable soils that are vulnerable to leaching and on shallow groundwater (10-30 feet). Results from the SCI-GROW screening model predict that the maximum acute and chronic concentrations of total toxic residues (parent + sulfoxide+ sulfone) in shallow groundwater is not expected to exceed 13.5 ppb for peanuts prior to mitigation.

EPA's "Pesticides in Groundwater Database" reports no detections in 3,341 samples that have been submitted to date for parent phorate.

c. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of water-containing pesticide residues permitted in the diet, EPA first looks at how much of the overall allowable risk is contributed by food (and if appropriate, residential uses) then determines a "drinking water level of comparison"(DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern.

The estimated acute and chronic concentrations of phorate and degradates of concern in groundwater is 13.5 ppb; for the purposes of the screening-level assessment, the maximum and average concentrations in groundwater are not believed to vary significantly. Prior to mitigation, the estimated peak (acute) concentration of phorate and metabolites of concern in surface water is 53.2 ppb, and the annual mean (chronic) is 1.85 ppb. When these estimated concentrations are compared to the DWLOC, the comparison indicates that phorate in drinking water may contribute to aggregate risk. The table below presents the comparison of model estimated drinking water residue levels both prior to and after mitigation and DWLOCs.

Additional estimates of drinking water exposure were developed taking into account several mitigation measures (reduced number of applications per season, soil incorporation and reduced application rates) that have been agreed to by the registrants and are contained in this document. This was done to characterize the potential for exposure to phorate in drinking water after these mitigation measures have been implemented. As the tables below show, these mitigation measures significantly reduce the estimated concentrations of phorate and its degradates in drinking water however, there is still concern for some use patterns.

Table 3a. Acute Drinking Water Risk

Crop Scenario	SCI-GROW (All residues, ppb)	PRZM/ EXAMS (Parent Only, ppb)	PRZM/ EXAMS (All residues, ppb)	SCI-GROW (Including mitigation[2]) (All residues, ppb)	PRZM/ EXAMS (Including mitigation2) (Parent Only, ppb)	PRZM/ EXAMS (Including mitigation[2]) (All residues, ppb)	DWLOC (Acute) (ppb) (Children 1-6)
Peanuts at plant	13.5	39.5[1]	53.21[1]	3.4	NE	NE	2.7
Peanuts at pegging	13.5			6.0	26.8	36.1	
Corn at plant	7.8	5.09	9.41	2.9	4.0	6.0	
Corn at cultivation	7.8	5.09	9.41	2.9	3.6	5.5	
Cotton at plant	11.4	9.08[1]	12.23[1]	3.7	8.1	7.8	
Cotton sidedress	11.4			4.8	10.4	22.6	

Table 3b. Chronic Drinking Water Risk

Crop Scenario	SCI-GROW (All residues, ppb)	PRZM/ EXAMS (Parent Only, ppb)	PRZM/ EXAMS (All residues, ppb)	SCI-GROW (Including mitigation[2]) (All residues, ppb)	PRZM/ EXAMS (Including mitigation2) (Parent Only, ppb)	PRZM/ EXAMS (Including mitigation[2]) (All residues, ppb)	DWLOC (Acute) (ppb) (Children 1-6)
Peanuts at plant	13.5	0.25[1]	1.85[1]	3.4	NE	NE	1.6
Peanuts at pegging	13.5			6.0	0.17	1.3	
Corn at plant	7.8	0.04	0.6	2.9	0.03	0.41	
Corn at cultivation	7.8	0.04	0.6	2.9	0.02	0.25	
Cotton at plant	11.4	0.06[1]	0.35[1]	3.7	0.08	0.6	
Cotton sidedress	11.4			4.8	0.62	1.8	

[1] Modeling assumes currently labels multiple applications per season

[2] Mitigation includes limiting application frequency to once per season, requiring soil incorporation and reducing rates by 25%.

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. There are no residential or other non-occupational uses of phorate.

Additionally, since phorate is not used in a manner that would lead to exposure in the general population, the Agency did not consider residential exposure in the assessment.

a. Toxicity

The toxicity of phorate is integral to assessing the occupational risk. Technical phorate is highly toxic on an acute oral, dermal and inhalation basis (Toxicity Category I). All risk calculations are based on the most current toxicity information available for phorate, including a 28-day dermal toxicity study that was completed using the granular end-use product. The toxicological endpoints, and other factors used in the occupational risk assessments for phorate are listed below.

Table 4. Acute Toxicity Values for Technical Phorate

Study	Results	Category	MRID #
Oral LD_{50} - Rat	3.7 mg/kg (M) 1.4 mg/kg (F)	I	00126343
Dermal LD_{50} - Rat	9.3 mg/kg (M) 3.9 mg/kg (F)	I	00139479
Inhalation LC_{50} - Rat	0.06 mg/L (M) 0.011 mg/L	I	00126343
Eye Irritation	Waived	N/A	N/A
Dermal Irritation	Waived	N/A	N/A
Dermal Sensitization	Waived	N/A	N/A

Table 5. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational and Residential Risk Assessments for Phorate

Assessment	Dose (mg/kg/day)	Endpoint	Study Type	Absorption factor
Short-term dermal	NOAEL = 0.406	RBC, brain ChE inhibition	28-day dermal rat	N/A
Intermediate- term dermal	NOAEL = 0.406	RBC, brain ChE inhibition	28-day dermal rat	N/A
Long-term dermal	Oral NOAEL = 0.05	RBC, brain ChE inhibition	Chronic Dog	100%
Short-term inhalation	Oral NOAEL= 0.25	Miosis and brain ChE inhibition	Acute Neurotoxicity - Rat	100%
Intermediate -term inhalation	Oral NOAEL= 0.05	RBC, brain ChE inhibition	Chronic Dog	100%
Long term inhalation	Oral NOAEL = 0.05	RBC, brain ChE	Chronic Dog	100%

b. Exposure

Chemical-specific exposure data were not available for phorate, however, short- and intermediate-term from dermal exposures to phorate were estimated using the recently submitted terbufos exposure monitoring study completed by BASF. This terbufos exposure monitoring study used a clay-based granular formulation similar to phorate formulations. EPA has used the exposure data from this study as a surrogate for phorate-specific exposure data in the phorate risk assessment as is common Agency practice with occupational exposure monitoring data when exposure scenarios are similar.

Agency policy requires combining chemical-specific data with generic estimates from the *Pesticide Handlers Exposure Database (PHED),* the database the Agency routinely uses for handler risk assessments when there is no study data available. The database calculates exposures and uses standard assumptions such as average body weight, work day hours, and acres treated daily, combined with label application use rates to calculate exposure estimates. The quality of the PHED data and exposure factors varies, but it represents the best exposure data for pesticide handlers currently available to the Agency. The quality of the data used for each scenario assessed is discussed in the Human Health Assessment document for phorate, which is available in the public docket.

Anticipated use patterns and application methods, range of application rates, and daily amount treated were derived from current labeling. Application rates specified on phorate labels range from 0.66 to 3.9 pounds of active ingredient per acre in agricultural settings with typical use rates ranging from 1 to 3.3 pounds per acre. The Agency typically uses acres treated per day values that are thought to represent 8 solid hours of application work for specific types of application 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 minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario, followed by, if required (i.e., MOEs are less than 100), increasing levels of risk mitigation (personal protective equipment (PPE) and engineering controls (EC)). Typically, the current labels for phorate require maximum PPE. The levels of protection that formed the basis for calculations of exposure from phorate activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Label: baseline + chemical resistant gloves.
- Minimum PPE: Baseline + chemical resistant gloves and a respirator.
- Maximum PPE: Baseline + coveralls, chemical resistant gloves, and a respirator.
- Engineering controls: Engineering controls such as a closed cab tractor or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods; there are no known devices that can be used to routinely lower the exposures for these methods.
- Different combinations of items listed above.

For handlers, short-term, intermediate-term, and long term assessments were conducted for phorate, to reflect exposures of 1-7 days, one week to 28 days, and greater than 28 day durations, respectively. Although phorate is applied mostly once per season, some applicators may apply phorate over a period of up to 12 weeks because they need to cover large acreage, or they may be custom or professional applicators. Additionally, the potential for exposure to workers through entry into agricultural fields treated with phorate was also considered.

c. Occupational Handler Risk Summary

Risks for handlers were assessed using separate toxicological endpoints for both dermal and inhalation exposures. The resulting risks (MOE values) were then added in order to obtain an overall risk for each handler that accounted for both dermal and inhalation exposures because the effects are the same. Additionally, where it was logical, the risks associated with certain job functions were combined (e.g., a grower loading and then applying phorate granular to their own crops). Dermal and inhalation risks are mitigated using different types of protective equipment, so it may be acceptable to add a pair of gloves and not a respirator, and vice versa. All of the risk calculations for handlers completed in this assessment are included in the HED chapter, dated September 2, 1999.

For agricultural uses of phorate, six different exposure scenarios were assessed at different levels of personal protection. Within each of the scenarios, further analyses were conducted to determine the MOE at minimum and maximum application rates, and at maximum and typical acreage, where applicable. Each of these analyses is included in the HED chapter. The reader is referred to this chapter for more information on this comprehensive assessment.

Table 6 summarizes the risk concerns after all assessments were revised using the most current data and assumptions for occupational handlers, based on combined dermal and inhalation exposures. The shaded areas represent the scenarios where risk is not of concern. The unshaded represent the scenarios where the Agency assessments indicate risk mitigation is necessary (i.e., MOEs < 100).

(1) Agricultural Handler Risk

For phorate, the Agency has determined that there are potential exposures to workers as a result of mixing, loading, and applying phorate, as well as flagger activities. Risk estimates have been derived for the following scenarios:

(1a) loading granular formulations (completed using PHED data at varying levels of personal protection);
(1b) loading 20G formulation in "Lock-N-Load" packaging (completed using chemical-specific data);
(2a) applying granular formulations using ground-based equipment (completed using PHED data at varying levels of personal protection);

(2b) applying 20G formulation using in-the-row planters and closed tractor cabs (completed using chemical-specific data);
(3) applying granular formulations with aerial equipment (completed using PHED data only with closed cabs);
(4) flagging for the application of granular formulations with aerial equipment (completed using PHED data at varying levels of personal protection)

Based on these estimates, occupational risks do not exceed the Agency's level of concern when closed loading systems and enclosed application equipment (cabs) are used. If minimal PPE is used, open cabs are used, and products are loaded using bags that must be ripped open prior to loading, then risks exceed the Agency's level of concern.

Table 6: Occupational Risk Estimates for Phorate

Exposure Scenario	Data Source	Range of Combined Dermal and Inhalation MOEs							
		Baseline PPE[1] Short and Intermediate term		Minimum PPE[2] Short and Intermediate term		Maximum PPE[3] Short and Intermediate term		Engineering Controls[4] Short and Intermediate term	
Loading open bag granules for ground application	PHED	7 - 28[5]	4 -14	11- 43	8 - 33	22- 86	17- 66	N/A	N/A
Loading granules with a closed system for aerial application	PHED	N/A	N/A	N/A	N/A	N/A	N/A	354 -1419	178 - 714
Loading granules with a closed system for ground application	chemical specific study	N/A	N/A	N/A	N/A	N/A	N/A	1220 - 4895	682 - 2739
Applying granules with ground equipment application	chemical specific study or *PHED	*11- 43	*8 -33	*10 - 42	*9 - 35	*18 - 72	*15 -61	2022 - 8114	1440 - 5778
Mixing/loading/ applying granules for ground application	chemical specific study	N/A	N/A	N/A	N/A	889 - 3569	827 - 3320	761 - 3053	463 - 1858
Flagger for aerial granular application	PHED	26 -104	20 - 79	29 - 115	27 - 108	49 - 195	46 - 184	1297 - 5205	382 - 3943

[1] Baseline PPE assumes typical work clothing (long sleeved shirt , long pants, shoes and socks).
[2] Minimum PPE: Baseline + chemical resistant gloves and a respirator
[3] Maximum PPE: Baseline + coveralls, chemical resistant gloves and respirator.
[4] Engineering controls: closed cab tractor or closed loading system
[5] Ranges of MOEs reflect 69 to 213 acres treated, 90 to 360 lb. ai. Handled daily, and application rates of 1 to 4 lbs. ai/A
* PHED source

(2) Post-Application Occupational Risk

Restricted-entry intervals (REIs) are calculated to determine the minimum length of time required following an application before workers are allowed to reenter a treated area. Entry restrictions are calculated to determine the minimum length of time required following an application before crop workers are allowed to reenter a treated area with, or without the use of personal protective equipment to mitigate risks. REIs and entry restrictions are estimated in hours or days.

The Agency did not complete a quantitative assessment of post-application worker risk for phorate because the use pattern (early season, soil incorporated) suggests that significant exposure to reentry workers is not likely. However, the Agency reviewed two soil residue dissipation studies conducted in peanuts and potatoes which indicate phorate residues may persist for many weeks after application. The Agency is requesting additional information regarding cultural practices, including efficacy data, to determine the extent of reentry worker exposure.

4. Human Incident Data

In addition to use of margins of exposure to estimate the risk, incident data are considered. The following databases were consulted for poisoning incident data on the active ingredient phorate:

- OPP Incident Data System (IDS);
- Poison Control Centers - (data received in response to 1993 Data-Call-In covering the years 1985 to 1992);
- California of Pesticide Regulation ; and,
- National Pesticide Telecommunication Network (NPTN).

IDS (as of 8/99) received seven separate incident reports involving human exposure. Poison Control Centers Data (1985 to 1992) showed 109 cases of occupational and 82 cases of non-occupational exposure to phorate. Poison Control Centers data for the interval 1993-1996 showed a decrease in the rate of incidences, 33 cases of occupational and 27 cases of non-occupational exposure. California data (1982-1993) showed 22 cases of adverse reactions to phorate. NPTN (1985-1991) handled 116 calls on phorate involving 39 incidents (29 humans, 5 animals, and 5 other, e.g. plants, wildlife).

The risk from phorate exposure tended to be higher than other cholinesterase inhibitors. Of the 28 insecticides with Poison Control Center data (1985-1992), phorate ranked 6 for occupational exposure and 7 for non-occupational exposure, with number 1 being most frequently associated with adverse effects. This suggests that phorate is above average in its ability to cause adverse effects.

When using the California data and calculating ratios for the number of systemic poisonings per 1,000 applications, the calculations for phorate are higher than the median score for the 28 other insecticides. Note, however, that California calculations were based on a relatively small number of cases. Applicators and mixer/loaders are the most frequently affected activity categories.

Phorate is currently only used in granular formulations. Some of the above average ratios or measures of hazard (described above) suggest that handlers may not fully observe precautions because of the perception that poisoning is much less likely with a granular than liquid formulation.

5. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and residential exposure to a particular pesticide. There are no residential uses for phorate, therefore an aggregate assessment would only consider exposure from food and water. Generally, all risks from these exposures must not exceed 100% of the acute and chronic PADs to be below the Agency's level of concern. Results of the aggregate risk assessment are summarized here, and are discussed extensively in the September 2, 1999 HED chapter.

Since there are no residential uses for phorate, aggregate risk will only consider exposure from food and water. Acute and chronic dietary risks from food alone do not exceed the Agency's level of concern, however, for dietary risk from drinking water, the maximum estimated concentrations of phorate and metabolites (sulfoxide and sulfone) in groundwater and surface water slightly exceed EPA's level of concern. The conservative nature of the food assessment together with extensive risk mitigation proposed in this document lead the Agency to believe that the aggregate risk from food and drinking water exposure for phorate and its degradates will be below the Agency's level of concern following implementation of mitigation measures.

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 August 31, 1999, which is available in the public docket.

1. Environmental Fate and Transport

The environmental fate database for phorate is essentially complete. Study data indicate that phorate parent is not persistent in the environment. It has been shown to degrade in soil by chemical and microbial action and to dissipate in the field with a half-life of 2-15 days. It is moderately mobile in soil, and may leach in sandy loam soils. Phorate is likely to hydrolyze rapidly. The probable environmental degradates, phorate sulfoxide, and phorate sulfone, are more persistent and more mobile in the environment then the parent.

2. Risk to Birds, Mammals and Nontarget Terrestrial Organisms

To estimate potential ecological risk, EPA uses a risk quotient method which divides the toxicity of the compound by the estimated exposure. The risk quotient is then compared to levels of concern for general populations or endangered species. Exposure is calculated by integrating application rates,

information about applications, and chemical specific data such as degradation rates. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

Phorate is highly toxic to birds and small mammals when applied at label rates. The R Q values for terrestrial animals exceed the acute risk level of concern for all species, crops, and application rates. Endangered species levels of concern are exceeded for birds and small mammals from the use of a single application rate. The greatest exceedances were calculated for small mammals. Risk quotient values suggest that songbirds are the birds most at risk. The RQ value ranged from two to three orders of magnitude greater than the level of concern for all uses and all application methods.

Adverse effects are considered to be very likely for all small mammals with broadcast applications for corn and hops, banded or in-furrow applications for potatoes, and banded or in-furrow applications for radishes. Risk to avian species is likely for songbirds with broadcast use in corn and hops and is less likely, but still a concern, for upland game birds for soil in-furrow use in wheat. Due to higher assumed food consumption, calculations suggest that songbirds are the most sensitive of the species tested. There are indications that phorate may also pose a chronic risk to birds and mammals especially due to the apparent length of time required for phorate residues and degradates to degrade. The Agency has also identified both acute and chronic concerns for bird and small mammalian endangered species resulting from the use of phorate.

Several bird kills, some involving large numbers of birds, have been reported and linked to phorate use. Fall applications in the northern wheat growing states appear to pose a particular risk. During the winter in these regions, degradation and downward movement in soil is expected to be slow. The incident information indicates that in spring the concentrations of phorate and/or phorate degradates sometimes occurs at hazardous levels in pools on the soil surface.

a. Nontarget Terrestrial Organisms Incidents

Phorate risks exceed the acute risk level of concern for terrestrial animals.
The absence of documented incidents involving nontarget terrestrial organisms does not necessarily mean that such incidents do not exist. Mortality incidents must be seen, reported, investigated, and submitted to EPA 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.

3. Risk to Aquatic Species

Phorate is highly toxic to fish and aquatic invertebrates. All acute risk quotients exceed high risk criteria and most chronic risk quotients exceed levels of concern. Field studies and incidents confirm risk to aquatic organisms. Estimated water concentrations from the PRZM-EXAMS model indicate that regular label use of phorate may result in phorate contamination of water sources except for certain in-furrow uses. However, these in-furrow uses may not be adequately simulated by the PRZM-EXAMS model because it does not account for upward movement of pesticide residues in soil. Adverse effects are expected in some instances and this concern is confirmed by field studies and fish kill incidents which are discussed in the EFED Risk Assessment Chapter. Simulated field studies also suggest that contaminated water may be a route of exposure. The original risk quotients using the PRZM-EXAMS model exceeded levels of concern for fish and aquatic invertebrates. Many studies submitted on the mobility, hydrolysis, adsorption/desorption, and volatility of phorate and its degradates represented only alkaline or neutral soils. Based solely on this information, the Agency could not conclusively determine that phorate was necessarily of high concern. However, the Agency also assessed several fish kill incident reports which indicated phorate was either one of the potential pesticides or the only pesticide implicated in the fish kills. No reports of misuse were associated with any of the fish kill incidents.

The Agency has also identified a concern for aquatic endangered species, on an acute and chronic basis from the use of phorate.

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 phorate active ingredients.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient phorate, as well as a phorate-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 phorate, EPA has sufficient information on the human health and ecological effects of phorate 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 phorate 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) the cumulative risk assessment for the organophosphates support a final reregistration eligibility decision. 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 phorate, and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet completed its 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 phorate. Based on its current evaluation of phorate alone, the Agency has determined that phorate 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 phorate.

At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For phorate, if all changes outlined in this document are incorporated into the labels, then all current risks will be mitigated. But, because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for phorate 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 phorate food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has completed the cumulative assessment, phorate tolerances will be reassessed in that light. At that time, the Agency will reassess phorate along with the other organophosphate pesticides to complete the FQPA requirements and make a final reregistration determination. By publishing this interim reregistration eligibility decision and requiring risk mitigation now for the individual chemical phorate, 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.

1. 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. As stated previously, a mitigation proposal was received from BASF and Aceto Agricultural Chemicals Corporation; details of this proposal are discussed in the next section. Several other comments on mitigation were also received from private citizens, trade groups/associations, colleges/ universities and from nongovernment environmental organizations. Generally speaking these comments were testimonial in nature, expressing the sender's opinion relative to the benefits and safety (low risk) of phorate use. Although these comments require no Agency response, EPA considered the views expressed and has taken the information into account when making this regulatory decision concerning phorate use. These comments in their entirety are available in the public docket.

B. 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 was for this individual organophosphate, and does not attempt to fully reassess 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 dietary (food sources only) exposure to phorate is within its own "risk cup." In other words, if phorate did not share a common mechanism of toxicity with other chemicals and if drinking water is not a significant source of phorate exposure, EPA would be able to conclude today that the tolerances for phorate 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 exposure only since there are no residential uses for phorate. Results of this aggregate assessment indicate that the human health risks from these combined exposures may be slightly greater than the acceptable levels; that is, combined risks from all exposures to phorate "do not fit" within the individual risk cup. However, the conservative nature of the food assessment together with extensive risk mitigation proposed in this document lead the Agency to believe that the aggregate risk from food and drinking water exposure for phorate and its degradates will be below the Agency's level of concern after implementing the following mitigation measures.

The Agency further refined its drinking water estimates by taking into consideration the impacts of several key mitigation measures such as reducing the maximum number of applications per season from 2 to 1, requiring soil incorporation and reductions in the maximum application rates for major use patterns.

When these steps were incorporated into the models the maximum estimated concentrations were significantly reduced. The revised estimated concentrations in ground water, including mitigation, range from 2.9 ppb to 6.0 ppb for both acute and chronic exposures. The estimated concentrations in surface water after mitigation range from 5.5 ppb to 36.1 ppb for acute exposures and range from 0.25 ppb to 1.8 ppb for chronic exposures. Two specific use patterns account for the high-end estimates in these ranges; use on peanuts at pegging (36.1 ppb for surface water and 6.0 for groundwater for the acute scenario), and use as a sidedress for cotton (22.6 ppb for surface water and 4.8 ppb for groundwater for the acute scenario). Based on these results the Agency determined that additional mitigation was needed to address these risks. This additional mitigation includes prohibiting use on peanuts at pegging and restricting the use as a sidedress to cotton in CA and AZ only. The rationale for restricting the cotton sidedress to these states is that, given the arid climate and cultural practices in these areas, contamination of water resources is very unlikely to result from this use.

The restrictions on the cotton and peanut use patterns mentioned earlier in this section would result in maximum estimated water concentrations in ground water ranging from 2.9 ppb to 3.7 ppb for both acute and chronic exposures. The estimated concentrations in surface water range from 5.5 ppb to 7.8 ppb for acute exposures following all mitigation and range from 0.25 ppb to 0.6 ppb for chronic exposures. These concentrations, with the exception of chronic exposure to surface water residues, continue to slightly exceed the DWLOCs. However, it is important to note that the dietary exposure and risk estimates for food are not based on residue monitoring data and thus are considered to be relatively conservative. Exposure estimates for each of the major contributors to dietary exposure (sweet corn, potatoes and peanuts) are based upon either tolerance level residues (sweet corn) or field trial data. It is expected that if suitable monitoring data were available the exposure and risk estimates concerning residues on/in food would be significantly lower allowing for additional space in the "risk cup" for exposures to phorate and its degradates in drinking water.

In addition to the mitigation mentioned above, the Agency believes that additional mitigation proposed for protecting surface water resources (e.g. vegetative buffer strips, 50 foot setbacks from drinking water wells for application and equipment cleaning) will additionally reduce the potential for significant exposure from drinking water. Drinking water treatment processes (coagulation-flocculation, sedimentation and activated carbon filtering) will likely further reduce the potential for exposure to phorate and its degradates in drinking water.

Based on all of these considerations, the Agency believes that the risk from drinking water exposure for phorate and its degradates will be below the Agency's level of concern. It should be noted that, in the event that efficacy tests indicate that the proposed rate reductions would not be feasible, additional mitigation would be necessary to address drinking water risks. Therefore, the phorate tolerances will need amendments now and possibly in the future after the full reassessment of the cumulative risk from all organophosphates is completed.

b. Tolerance Summary

The tolerances listed in 40 CFR §180.206 are expressed in terms of phorate and its cholinesterase-inhibiting metabolites. To harmonize with the expression for Codex MRLs for residues of phorate, the tolerance expression should be revised as follows: the tolerances listed in 40 CFR §180.206 are for the combined residues of the insecticide phorate (*O,O*-diethyl *S*[(ethylthio) methyl]phosphorodithioate), phorate sulfoxide, phorate sulfone, phorate oxygen analog, phorate oxygen analog sulfoxide, and phorate oxygen analog sulfone.

Tolerances Listed Under 40 CFR §180.206:

Sufficient field trial data reflecting the maximum registered use patterns are available to ascertain the adequacy of the established tolerances for: coffee, beans, green; corn, field, forage; corn, sweet, forage; cottonseed; hops, cones, dried; peanuts; sorghum, fodder; sugar beet, roots; sugar beet, tops; wheat, forage; wheat, grain; and wheat, straw. The available data indicate that the tolerance levels can be reduced for the following commodities: beans (succulent and dry); field corn grain; sweet corn (kernel plus cob with husk removed or K+CWHR); potatoes; sorghum grain; soybeans; and sugarcane.

The established tolerances for milk, eggs, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, sheep, and poultry can be revoked. It is not possible to establish with certainty that finite residues of phorate occur in these commodities and there is no reasonable expectation that finite residues will occur. Therefore the Agency has determined that pursuant to §180.6(a)(3) tolerances are not required for these commodities.

The tolerance level for hops must be increased to reflect that fact that the raw agricultural commodity (RAC)is now considered to be dried hops and not fresh hops. Adequate data are available to support a dried hops tolerance.

Because the Agency no longer considers bean vines and peanut vines to be significant livestock feed items, the established tolerances for these commodities should be revoked. The established tolerance for peanut hay should also be revoked since a restriction against the feeding of treated peanut hay exists on current product labels.

No registered uses of phorate currently exist on the following crops for which tolerances have been established: alfalfa, barley, Bermuda grass, lettuce, rice, and tomatoes. The established tolerances for the commodities of these crops should be revoked.

Sufficient data are available to assess the adequacy of the established tolerances for dried sugar beet pulp. These data indicate that phorate residues of concern do not concentrate in dried sugar beet pulp; therefore, the established feed additive tolerance should be revoked.

Tolerances To Be Proposed:

When adequate field trial data have been submitted, the registrant[s] must propose a tolerance for field and sweet corn stover (fodder), cotton gin byproducts, sorghum forage, and wheat hay.

A summary of phorate tolerance reassessments is presented in Table 7.

Table 7. Tolerance Reassessment Summary for Phorate.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.206:			
Alfalfa (fresh)	0.5	Revoke	No registered uses.
Alfalfa hay	1	Revoke	No registered uses.
Barley grain	0.1	Revoke	No registered uses.
Barley straw	0.1	Revoke	No registered uses.
Bean vines	0.5	Revoke	Not considered a significant feed item (Table 1, 860.1000).
Beans	0.1	0.05	Residues from the registered uses do not exceed the 0.05 ppm level *[Beans, succulent and dry]*
Bermuda grass straw	0.5	Revoke	No registered uses.
Cattle, fat	0.05	Revoke	180.6(a)(3)
Cattle, meat	0.05		
Cattle, meat byproducts	0.05		
Coffee beans	0.02	0.02	*[Coffee, beans, green]*
Corn grain	0.1	0.05	Residues from registered uses do not exceed 0.05 ppm for Codex harmonization. *[Corn, field, grain]*
Corn forage	0.5	0.5	*[Corn, field, forage]* *[Corn, sweet, forage]*
Cottonseed	0.05	0.05	*[Cotton, undelinted seed]*
Eggs	0.05	Revoke	180.6(a)(3)
Goats, fat	0.05	Revoke	180.6(a)(3)
Goats, meat	0.05		
Goats, meat byproducts	0.05		
Hogs, fat	0.05	Revoke	180.6(a)(3)
Hogs, meat	0.05		
Hogs, meat byproducts	0.05		

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Hops	0.5	2	*[Hops, cones, dried]*
Horses, fat	0.05	Revoke	180.6(a)(3)
Horses, meat	0.05		
Horses, meat byproducts	0.05		
Lettuce	0.1	Revoke	No registered uses.
Milk	0.02	Revoke	180.6(a)(3)
Peanut vines	0.3	Revoke	Not considered a significant feed item (Table 1, 860.1000).
Peanut hay	0.3	Revoke	Feeding restriction exists.
Peanuts	0.1	0.1	
Potatoes	0.5	0.2	Residues from the registered uses do not exceed 0.2 ppm for Codex harmonization.
Poultry, fat	0.05	Revoke	180.6(a)(3)
Poultry, meat	0.05		
Poultry, meat byproducts	0.05		
Rice	0.1	Revoke	No registered uses.
Sheep, fat	0.05	Revoke	180.6(a)(3)
Sheep, meat	0.05		
Sheep, meat byproducts	0.05		
Sorghum fodder	0.1	0.1	*[Sorghum, fodder]*
Sorghum grain	0.1	0.05	Residues from the registered uses do not exceed 0.05 ppm for Codex harmonization. *[Sorghum, grain]*
Soybeans	0.1	0.05	Residues from registered uses do not exceed 0.05 ppm for Codex harmonization.
Sugar beet roots	0.3	0.3	*[Sugar beets, roots]*
Sugar beet tops	3	3	*[Sugar beets, tops]*
Sugarcane	0.1	0.05	Residues from the registered uses do not exceed 0.05 ppm.
Sweet corn (K+CWHR)	0.1	0.05	Residues from the registered uses do not exceed 0.05 ppm. *[Corn, sweet (K+CWHR)]*
Tomatoes	0.1	Revoke	No registered uses.
Wheat grain	0.05	0.05	*[Wheat, grain]*
Wheat (green fodder)	1.5	1.5	*[Wheat, forage]*
Wheat straw	0.05	0.05	*[Wheat, straw]*
Tolerances Listed Under 40 CFR §186.4750:			
Dried sugarbeet pulp	1	Revoke	Available data indicate that residues do not concentrate.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances to be Proposed:			
Corn, field, stover (fodder)	--	TBD[1]	
Corn, sweet, stover (fodder)	--	TBD	
Cotton, gin byproducts	--	TBD	
Sorghum, forage	--	TBD	
Wheat, hay	--	TBD	

[1] TBD = To be determined. Residue data are outstanding.

Codex Harmonization

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for phorate residues in various commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part 2, FAO CX/PR, 4/91*). The Codex and U.S. tolerance expressions will be in harmony when the U.S. tolerance expression is revised to specify phorate, phorate sulfoxide, phorate sulfone, phorate oxygen analog, phorate oxygen analog sulfoxide, and phorate oxygen analog sulfone. A comparison of the Codex MRLs and the corresponding reassessed U.S. tolerances is presented in Table 7.

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs with respect to MRL/tolerance level: (i) compatibility between the U.S. tolerances and Codex MRLs exists for beans, cottonseed, eggs, field corn grain (maize), potatoes, sorghum, soybeans, and wheat; and (ii) incompatibility of the U.S. tolerances and Codex MRLs remains for field corn forage, peanuts, and sugar beet roots and tops because of differences in agricultural practices; no questions of compatibility exist with respect to commodities where Codex MRLs have been established but U.S. tolerances do not exist or will be revoked.

Table 8. Codex MRLs and Applicable U.S. Tolerances. Recommendations for Compatibility are Based on Conclusions Following Reassessment of U.S. Tolerances (see Table 6).

Codex		Reassessed U.S. Tolerance (ppm)	Recommendation And Comments
Commodity (As Defined)	MRL [1] (mg/kg)		
Barley	0.05	Revoke	No registered uses in U.S.
Carrot	0.2 [2]	--	No registered uses in U.S.
Common bean (pods and/or immature seeds)	0.1	0.05	
Cotton seed	0.05	0.05	Compatibility exists.
Eggs	0.05 *	Revoke	
Beet fodder	0.05	–	No registered uses in U.S.
Maize	0.05	0.05	Compatibility exists.
Maize fodder	0.2	TBD [3]	

Codex		Reassessed U.S. Tolerance (ppm)	Recommendation And Comments
Commodity (As Defined)	MRL [1] (mg/kg)		
Maize forage	0.1	0.5	
Meat	0.05 *	Revoke	
Milk	0.05 *	Revoke	
Peanut	0.05	0.1	
Peanut oil, crude	0.05 *	--	
Peanut oil, edible	0.05 *	--	
Potato	0.2	0.2	Compatibility exists.
Rape seed	0.1	–	No registered uses in U.S.
Sorghum	0.05	0.05	Compatibility exists.
Soya bean (dry)	0.05	0.05	Compatibility exists.
Sugar beet	0.05	0.3	
Sugar beet leaves or tops	1	3	
Tomato	0.1	Revoke	No registered uses in U.S.
Wheat	0.05	0.05	Compatibility exists.

[1] An asterisk (*) signifies that the MRL was established at or about the limit of detection.

[2] Decreased from 0.5 ppm by 1993 JMPR.

[3] TBD = To be determined. Residue data are outstanding.

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

3. Label Modifications

Currently the maximum estimated concentrations of phorate and metabolites (sulfoxide and sulfone) in groundwater are slightly greater than the Agency's Drinking Water Level of Comparison (DWLOC) for chronic drinking water exposure. Also, the estimated concentrations of phorate and its metabolites in surface water slightly exceed EPA's DWLOC for acute exposure. However, the conservative nature of the food assessment together with extensive risk mitigation proposed in this document lead the Agency to believe that the dietary risk from food and drinking water exposure for phorate and its degradates will be below the Agency's level of concern following implementation of mitigation measures. As an interim measure to address the concern for the potential contamination of drinking water resources, the following label language modifications are needed:

- Prohibit aerial application.

- Prohibit use of phorate on peanuts at pegging.

- Require soil incorporation.

- Allow sidedress use on cotton only in Arizona and California.

- Allow only one application per season.

- Reduce application rates by 25 % unless efficacy data demonstrates that desired pesticidal effects are prohibited by the reduction in use rates.

- Environmental Hazard Statement: This pesticide is very highly toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wastewater or rinsate. Birds and mammals may be killed if granules are not properly covered with soil in all areas of the treated field and in loading areas.

- Do not apply in wet soil conditions that may prevent the equipment from covering pesticide granules.

- Under some conditions phorate may have a high potential for runoff into surface water for several days post application. Do not apply in the following situations:
  Frequently flooded areas
  Areas where intense or sustained rainfall is forecasted to occur within 48 hours

- Use Best Management Practices for minimizing surface runoff in the following areas:
  Poorly draining or wet soils with readily visible slopes toward adjacent surface water
  Areas over-laying extremely shallow ground water
  Areas with in-field canals or ditches that drain to surface water

Areas not separated from adjacent surface waters with vegetated filter strips
Areas over-laying tile drainage systems that drain to surface water

- When used on erodible soils, best management practices for minimizing runoff should be employed. Consult your local soil conservation service for recommendations in your use area.

- In particular, where highly erodible land (HEL) is adjacent to aquatic bodies, a 66 foot buffer/ setback area should be left in grass or other natural vegetation.

- Do not apply within 50 feet of any drinking water well to minimize potential contamination.
- Do not wash, load, or empty application equipment near any well, as this practice is a potential source of ground water contamination.

The Agency has determined that there are potential exposures to workers as a result of mixing, loading and applying phorate. In addition to mitigation measures necessary to reduce occupational risk such as enclosed loading and enclosed application equipment, phase out of open bag use, voluntary cancellation of aerial application, and PPE, the Agency wants the following additional precautionary label language since incident data on phorate shows above average ratios or measures of hazard (see Human Incident Data section chapter III)) suggest that handlers may not fully observe precautions because of the perception that poisoning is much less likely to occur with a granular formulation.:

Failure to follow precautions including wearing proper Personal Protective Equipment (PPE) may result in serious or even life threatening poisoning requiring immediate medical attention. The active ingredient of this granular formulation can be absorbed across the skin to cause poisoning.

C. Regulatory Rationale

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

1. Human Health Risk Mitigation

a. Dietary Mitigation

(1) Acute Dietary (Food)

The acute dietary risk (food) of phorate is below the Agency's level of concern for the general U.S. population and all population subgroups, including infants and children at the 99.9 percentile. The most highly exposed subgroup is children 1-6 with 70% of the acute Population Adjusted Dose (aPAD) consumed. No mitigation is necessary for acute dietary exposure.

(2) Chronic Dietary (Food)

The chronic dietary risk for phorate does not exceed the Agency's level of concern (i.e., less than 100% of the chronic PAD is utilized) for all subpopulations. The most exposed subgroup is children (1-6 years), with 9.0% of the population adjusted dose consumed. No mitigation is necessary for chronic dietary exposure.

(3) Drinking Water

The maximum estimated drinking water concentrations for phorate and its degradates prior to consideration of mitigation exceed the DWLOCs for both acute and chronic exposures from both groundwater and surface water sources. The DWLOC for acute exposure is 2.7 ppb for the most exposed sub-population (children 1-6). The chronic DWLOC is 1.6 ppb for that same sub-population. The estimated concentrations in ground water prior to mitigation range from 7.8 ppb to 13.5 ppb for both acute and chronic exposures. The estimated concentrations in surface water prior to mitigation range from 9.41 ppb to 53.21 ppb for acute exposures and range from 0.35 ppb to 1.85 ppb for chronic exposures.

The Agency further refined its drinking water estimates by taking into consideration the impacts of several key mitigation measures that are proposed in this document including reducing the maximum number of applications per season from 2 to 1, requiring soil incorporation and reductions in the maximum application rates for major use patterns. When these steps were incorporated into the models the maximum estimated concentrations were significantly reduced. The revised estimated concentrations in ground water including mitigation range from 2.9 ppb to 6.0 ppb for both acute and chronic exposures. The estimated concentrations in surface water after mitigation range from 5.5 ppb to 36.1 ppb for acute exposures and range from 0.25 ppb to 1.8 ppb for chronic exposures. Two specific use patterns account for the high-end estimates in these ranges; use on peanuts at pegging (36.1 ppb for surface water and 6.0 for groundwater for the acute scenario), and use as a sidedress for cotton (22.6 ppb for surface water and 4.8 ppb for groundwater for the acute scenario). Based on these results the Agency determined that additional mitigation was needed to address these risks. This additional mitigation includes prohibiting use on peanuts at pegging and restricting the use as a sidedress to cotton to CA and AZ only. The rationale for restricting the cotton sidedress to these states is that, given the arid climate and cultural practices in these areas, contamination of water resources is very unlikely to result from this use.

The restrictions on the cotton and peanut use patterns together with the mitigation mentioned earlier in this section would result in maximum estimated water concentrations in ground water including all mitigation ranging from 2.9 ppb to 3.7 ppb for both acute and chronic exposures. The estimated concentrations in surface water range from 5.5 ppb to 7.8 ppb for acute exposures following all mitigation and range from 0.25 ppb to 0.6 ppb for chronic exposures. These concentrations, with the exception of

chronic exposure to surface water residues, continue to slightly exceed the DWLOCs. However, it is important to note that the dietary exposure and risk estimates for food are not based on residue monitoring data and thus are considered to be relatively conservative. Exposure estimates for each of the major contributors to dietary exposure (sweet corn, potatoes and peanuts) are based upon either tolerance level residues (sweet corn) or field trial data. It is expected that if suitable monitoring data were available the exposure and risk estimates concerning residues on/in food would be significantly lower allowing for additional space in the "risk cup" for exposures to phorate and its degradates in drinking water.

In addition to the mitigation mentioned above, the Agency believes that additional mitigation proposed for protecting surface water resources (e.g. vegetative buffer strips, 50 foot setbacks from drinking water wells for application and equipment cleaning) will additionally reduce the potential for significant exposure from drinking water. Drinking water treatment processes (coagulation-flocculation, sedimentation and activated carbon filtering) will likely further reduce the potential for exposure to phorate and its degradates in drinking water.

Based on all of these considerations, the Agency believes that the risk from drinking water exposure for phorate and its degradates will be below the Agency's level of concern. It should be noted that, in the event that efficacy tests indicate that the proposed rate reductions would not be feasible, additional mitigation would be necessary to address drinking water risks.

(4) Residential

The Agency is not considering mitigation options for phorate since there are no residential or other non-occupational sources of exposure.

(5) Aggregate

Since there are no residential uses for phorate, aggregate risk will only consider exposure from food and water. Acute and chronic dietary risks from food alone do not exceed the Agency's level of concern, however, for dietary risk from drinking water, the maximum estimated concentrations of phorate and metabolites (sulfoxide and sulfone) in groundwater and surface water slightly exceed EPA's level of concern. The conservative nature of the food assessment together with extensive risk mitigation proposed in this document lead the Agency to believe that the aggregate risk from food and drinking water exposure for phorate and its degradates will be below the Agency's level of concern following implementation of mitigation measures. These measures are described in the drinking water discussion presented above.

b. Occupational Risk Mitigation

Occupational risks do not exceed the Agency's level of concern when closed loading systems and enclosed application equipment (cabs) are used. If minimal PPE is used, open cabs are used, and products

are loaded using bags that must be ripped open prior to loading, then risks exceed the Agency's level of concern.

Based on the Agency's revised occupational risk assessment, handlers of phorate are exposed by dermal and inhalation routes, with dermal exposure being the most significant route. Handler risks are not of concern when exposure is reduced through the use of closed loading systems and enclosed application equipment.

(1) Loaders

Ground equipment: The MOEs for short term exposure (1 to 7 days), for intermediate term exposure (8 to 28 days) and for mid to long term exposure (>28 days) to loaders do not exceed the Agency's level of concern. Although the data used in the assessment were done using an LNL system, gloves, apron and respirator, the Agency believes that adequate protection will be afforded with a LNL system, long sleeve shirt, long pants and chemical resistant gloves.

The MOEs for short term exposure to loaders using open bags, double layered clothing, gloves and respirator ranged from 22 to 86; from 17 to 66 for intermediate term exposure; and from 3 to 11 for mid- to long term exposure. It should be noted that the Agency fully anticipates that the duration of the majority of exposures will be less than 28 days and that the population exposed to phorate for greater than 28 days will be small. Based on our estimates, use of phorate in open bags presents a potential concern when phorate is used on some crops.

Because of the concern for open bag use, as of January 1, 2002, only products marketed in lock-n-load systems will be reregistered and labels will limit use to only one application per season.

Aerial Equipment: The MOEs for loaders of aerial equipment (closed systems) ranged from 48 to 193 for long term exposures. This application method, however, is being voluntarily canceled by the registrants. The proposed cancellation eliminates this risk to workers.

(2) Applicators and Flaggers

Ground Equipment Applicators: Based on chemical specific study data, MOEs for applicators from short term, intermediate term and long term exposure are not of concern where open cabs and no respirators are used. Based on chemical specific study data, for combined loader and applicators using closed loading systems, aprons, gloves, open cabs and no respirator, again, the risk are not of Agency concern for all terms of exposure.

However, when estimates are derived from PHED and assumes use of clay based formulations in open bags and the maximum protection of engineering controls (enclosed cabs), risk estimates ranged from 32 to 129 for short term exposures; from 20 to 82 for intermediate term exposure; and from 4 to 17 for long term exposure. These risk estimates indicate a concern for applicators exposed in such situations and further warrant the discontinuation of use of open bags. Based on the applicator concerns for short, intermediate, and long term exposure plus the fact that technical phorate is classified as Toxicity Category I for acute oral, dermal and inhalation EPA is believes applicators should be in enclosed cabs.

Aerial: Aerial application use is being voluntarily canceled by the registrants due to ecological concerns. However, the MOEs for aerial applicators are of concern based on risk estimates derived from PHED. Thus the proposed cancellation eliminates this risk to workers.

Flaggers: According to the Agency's estimates which are based on PHED, risk to flaggers is of concern for some crop use scenarios (see table 6). However since the registrants are voluntarily canceling aerial applications, risk to these workers is eliminated.

(3) Other Handlers

No other handling scenarios are expected.

(4) Postapplication Workers

Current phorate labels specify re-entry intervals of 48 to 72 hours, and specify the PPE required by the Worker Protection Standard (WPS), 40 CFR 170. Based on the results of soil dissipation studies on peanuts and potatoes that indicated phorate residues could persist for many weeks after application, the Agency now believes that a more thorough assessment of exposure to re-entry workers is needed. The Agency is requiring efficacy data and additional agricultural practice data to help define if any activities could be associated with post application exposure. Pending review of the efficacy data EPA, believes that application rates should be reduced up to 25 % unless the studies show that the reduced rates are not effective to the levels needed. After reviewing the additional agricultural practice data, EPA also reserves the right to require guideline 132-1 (foliar residue dissipation study) and 133-3 (dermal exposure upon reentry study) data. In the interim, the reentry intervals will remain unchanged since several of the uses are preplant and we expect very little opportunity for exposure .

(5) Other Information Considered

The Agency requested the public to submit any mitigation proposals or comments to address the potential worker risks identified in the risk assessment for phorate at the technical briefing held on September 2, 1999. The Agency did receive proposals or input that affected the risk mitigation for phorate from the registrants BASF and Aceto Agricultural Chemicals Corporation The mitigation proposals mentioned above reflect the Agency's recommendations as well as recommendations of the registrants.

2. Environmental Risk Mitigation

a. Risk Characterization

(1) Aquatic Animals

All acute risk quotients exceed high risk criteria and most chronic risk quotients exceed levels of concern. Field studies and incidents confirm risk to aquatic organisms. Simulated field studies also suggest that contaminated water may be a route of exposure. The original risk quotients using the PRZM-EXAMS model exceeded levels of concern for fish and aquatic invertebrates. Many studies submitted on the mobility, hydrolysis, adsorption/desorption, and volatility of phorate and its degradates represented only alkaline or neutral soils. Based solely on this information, the Agency could not conclusively determine that phorate was necessarily of high concern. However, the Agency also assessed several fish kill incident reports which indicated phorate was either one of the potential pesticides or the only pesticide implicated in the fish kills. No reports of misuse were associated with any of the fish kill incidents.

Phorate is highly toxic to fish and aquatic invertebrates. Estimated water concentrations from the PRZM-EXAMS model indicate that regular label use of phorate may result in phorate contamination of water sources except for certain in-furrow uses. However, these in-furrow uses may not be adequately simulated by the PRZM-EXAMS model because it does not account for upward movement of pesticide residues in soil. Adverse effects are expected in some instances and this concern is confirmed by field studies and fish kill incidents which are discussed in the EFED Risk Assessment Chapter.

(2) Nontarget Terrestrial Organisms

Phorate is highly toxic to bees and birds and small mammals based on test results. The Risk Quotient values for terrestrial animals exceed the acute risk level of concern for all species, crops, and application rates. Endangered species levels of concern are exceeded for birds and small mammals from the use of a single application rate. The greatest exceedances were calculated for small mammals. Risk quotient values suggest that songbirds are the birds most at risk. The RQ value ranged from two to three orders of magnitude greater than the level of concern for all uses and all application methods.

The absence of documented incidents involving nontarget terrestrial organisms does not necessarily mean that such incidents do not exist. Mortality incidents must be seen, reported, investigated, and submitted to EPA 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 may not be reported to appropriate authorities capable of investigating it because the finder may not be aware of the importance of reporting incidents, may not know who to call, or may be hesitant to call because of lack of time or desire or because the kill occurred on their property.

b. Mitigation Measures

(1) Aquatic animals

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

- Use vegetative buffer strips as a means of protecting water bodies from runoff. The label should state that buffer width determination should be made in consultation with the local United States Department of Agriculture/Natural Resource Conservation Service officials, taking into account the fact that phorate sulfoxide and sulfone metabolites have limited adsorption characteristics of phorate.

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

- Reduction in the number of applications, reduction in use rates, restricting cotton sidedress use to Arizona and California as well as prohibiting use on peanuts at pegging will reduce the amount of pesticide used thereby reducing potential exposure by eliminating the 2 greatest contributors to water.

- Limit to only one application per season.

- Application must be incorporated into the soil.

(2) Birds and Mammals

The Agency has concerns about the effects of phorate on birds and small mammals. The Agency believes there are unreasonable adverse effects to the environment when phorate is used as currently labeled and applied using aerial equipment. Currently, aerial equipment is only used for wheat. The registrants have voluntarily agreed to remove use on wheat and aerial equipment from the current labels. The Agency believes sufficient alternatives exist for wheat and expects the proposed mitigation measures discussed above may have some effect on exposure for terrestrial animals. The proposed measures will reduce drift to off-field habitats and, thus, reduce exposure via food sources at and beyond the edge of the field. Also, allowing only a single use per season with soil incorporation should reduce the amount of pesticide applied and would have the effect of reducing the level of exposure. The Agency typically receives fewer incident reports for terrestrial organisms unless the exposure involves immediate mortality to large numbers of birds. Such incidents are not usually observed or reported. Should additional information come to the Agency's attention indicating birds or small animals are being adversely impacted, the Agency will take appropriate action at that time.

Additional Measures

The registrants support two voluntary educational programs that are available to growers and provide valuable information on the use of phorate and potential hazards. The Delta program provides information to growers in Mississippi on a case-by-case basis what best management practices to implement to avoid runoff into surface waters. The other program known as the Stewardship program is a website sponsored by the National Cotton Council that provides information on how to use phorate to prevent impacts on the environment. The information is important because it advises the user on ways to minimize risks to aquatic life and prevent future fish kills. The registrants have agreed to expand the Stewardship program to ensure that all growers are aware of the label/use requirements and the potential impacts of phorate on aquatic animals. The program expansion will require the registrants to take the following steps:

- Provide information at the various grower meetings.
- Link company website to cotton council website on Stewardship program.
- Include information on the label concerning the website (address, information on use practices).
- Maintain the website until the Agency receives information confirming that there are no further unacceptable risks to aquatic animals; and coordinate with State Agencies, Universities and special interest groups to provide outreach programs. Periodically (annually) evaluate the website use to determine the percentage of users that are accessing the information as a gauge of its utility.

c. Other Options Considered

The Agency requested the public to submit any mitigation proposals or comments to address the potential worker risks identified in the risk assessment for phorate at the technical briefing held on September 2, 1999. The Agency did receive proposals or input that affected the risk mitigation for phorate from the registrants BASF and Aceto Agricultural Chemicals Corporation The mitigation proposals mentioned above reflect the Agency's recommendations as well as recommendations of the registrants.

D. Labeling

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 will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As

currently planned, but subject to change as the final program is developed, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

2. Spray Drift Management

Phorate is currently labeled for aerial application but the registrants have agreed to voluntarily cancel all aerial application uses. Additionally, all phorate end use products are applied as granulars rather than liquid sprays, therefore, spray drift management is no longer applicable.

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, by submitting label amendments and meeting the data requirements described in this section.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

Guideline 830.7050 UV/Visible Absorption
Guideline 860.1200 Directions for Use
Guideline 860.1340 Residue Analytical Methods- Livestock commodities
Guideline 860.1500 Crop Field Trials
Guideline 860.1900 Field Rotational Crop

Regarding the "Post Application Occupational Risk," the Agency is requesting that the technical registrant submit efficacy data using lower application rates (rates reduced up to 25 %) and further information on agricultural practices that will allow EPA to reassess reentry scenarios for post application exposure. Based on the review of such data the Agency reserves the right to reduce application rates by up to 25 % and require foliar residue dissipation data (guideline 132-1) and dermal exposure upon reentry data (guideline 133-3) at a later time.

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. The acute and subchronic studies have been submitted, reviewed and classified as acceptable. The registrant has committed to submit developmental neurotoxicity data by 9/2001.

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.

All registrants need to submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all required label amendments outlined in Table 8 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. All amended labels need to be submitted within 90 days of signature of this document. The Product Reregistration Branch contact for phorate is Ms. Barbara Briscoe . Her phone number is (703) 308-8177.

B. End-Use Products

1. Additional Generic 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 10 at the end of this section. Registrants need to submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all label amendments outlined in Table 11 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. All amended labels need to be submitted within 90 days of signature of this document. The Product Reregistration Branch contact is Ms. Barbara Briscoe. Her phone number is (703) 308-8177.

C. Existing Stocks

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

The Agency has determined that registrant may distribute and sell phorate products bearing old labels/labeling for 12 months from the date of issuance of this interim RED. Persons other than the registrant may distribute or sell such products for 24 months from the date of the issuance of this interim RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

D. 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 8: Summary of Labeling Changes for Phorate

Description	Amended Labeling language	Placement on Label
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into an insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This chemical is very highly toxic to fish 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." (Insert any additional chemical specific manufacturing use environmental hazards here)	Directions for Use
End Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide Statement	"RESTRICTED USE PESTICIDE Due to acute oral, dermal, and inhalation toxicity and avian hazards. For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certificate."	Front panel at top of page
PPE Requirements Established by the RED[1]	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (registrant inserts correct material as per supplements 3 of PR Notice 93-7). " If you want more options, follow the instructions for category" [insert A,B,C,D,E,F,G,or H] "on an EPA chemical-resistance category selection chart." "Loaders, applicators and other handlers must wear: * long-sleeved shirt and long pants, * shoes plus socks In addition loaders must wear: * chemical resistant gloves	Precautionary Statements under Hazards to Humans and Domestic Animals

Description	Amended Labeling language	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)
Engineering Controls	This product is formulated into an enclosed system that meets the definition of a closed loading system as defined by the Worker Protection Standard for Agricultural Pesticides. In addition to wearing the required PPE specified above, loaders must be provided and must have immediately available for use in case of an accident or spill: chemical-resistant apron, chemical resistant footwear, and a NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH approved respirator with any N^2 , R, P, or HE filter.	Precautionary Statements: Hazards to Human and Domestic Animals (Immediately following PPE and User Safety Requirements)
Engineering Controls (Continued)	Applicators must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides for dermal protection. In addition the applicator: C must wear PPE specified above, C must either use an enclosed cab that also provides equivalent respiratory protection to a dust/mist filtering respirator or wear a NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH approved respirator with any N^2, R, P, or HE filter. C must be provided and must have immediately available for use in case they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical resistant footwear, and if using an enclosed cab that provides respiratory protection NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH approved respirator with any N^2, R, P, or HE filter.	(Immediately following PPE and User Safety Requirements)

Description	Amended Labeling language	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." "Failure to follow precautions including wearing proper Personal Protective Equipment (PPE) may result in serious or even life threatening poisoning requiring immediate medical attention. The active ingredient of this granular formulation can be absorbed across the skin to cause poisoning."	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 very highly toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wastewater or rinsate. Birds and mammals may be killed if granules are not properly covered with soil in all areas of the treated field and in loading areas.	Precautionary Statements following the User Safety Recommendations under the Heading "Environmental Hazards"
Restricted-Entry Interval	"Do not enter or allow entry into treated areas for 48 hours during the restricted entry interval (REI) of 48 hours. Each 48- hour REI is increased to 72 hours in outdoor areas where the average rainfall is less than 25 inches per year. Exception: If the product is soil-injected or soil incorporated, the Worker Protection Standard, under certain circumstances, will allow workers to enter the treated areas without restriction if there will be no contact with anything that has been treated.	Directions for Use, Agricultural Use Requirements Box

Description	Amended Labeling language	Placement on Label
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: C coveralls worn over long-sleeve shirt and long pants C chemical-resistant gloves C chemical-resistant footwear plus socks C protective eye wear" Notify workers of the application by warning them orally and by posting signs at entrances to treated areas.	Directions for Use, Agricultural Use Requirements Box

Description	Amended Labeling language	Placement on Label
General Application Restrictions	Use on peanuts at pegging is prohibited. Cotton sidedress use is restricted to only Arizona and California. Only one application per season is allowed. Aerial application must be removed from all labels. Application must be incorporated into the soil. Prohibit application of phorate in saturated soils. Do not treat while precipitation is occurring or while conditions favor runoff from the treated area. "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." "Do not apply in wet soil conditions that may prevent the equipment from covering pesticide granules." " Under some conditions phorate may have a high potential for runoff into surface water for several days post application. Do not apply in the following areas: Frequently flooded areas Areas where intense or sustained rainfall is forecasted to occur within 48 hours" Use Best Management Practices for minimizing surface runoff in the following areas: Poorly draining or wet soils with readily visible slopes toward adjacent surface water Areas over-laying extremely shallow ground water Areas with in-field canals or ditches that drain to surface water Areas not separated from adjacent surface waters with vegetated filter strips Areas over-laying tile drainage systems that drain to surface water	Place in the Direction for Use directly above the Agricultural Use Box.
General Application Restrictions (continued)	"When used on erodible soils, best management practices for minimizing runoff should be employed. Consult your local soil conservation service for recommendations in your use area." "In particular, where highly erodible land (HEL) is adjacent to aquatic bodies, a 66 foot buffer/setback area should be left in grass or other natural vegetation." "Do not apply within 50 feet of any drinking water well to minimize potential contamination." "Do not wash, load, or empty application equipment near any well, as this practice is a potential source of ground water contamination."	Place in the Direction for Use directly above the Agricultural Use Box.

Description	Amended Labeling language	Placement on Label
Other	"For additional best management practices to avoid runoff to surface waters, see the following website (insert website address).	Directions for Use

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE 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.

[2] If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.

Instructions in the Labeling Required section appearing in quotations represent the exact language that should appear on the label.
Instructions in the Labeling Required 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 September 10, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on July 7, 1999.

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

VII. APPENDICES

Appendix A. Table of Use Patterns Eligible for Reregistration

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications	Preharvest Interval (Days)	Use Limitations [1]
Beans					
Soil drilled At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.9 oz./1000 ft of row (minimum 30-inch row spacing); or 2.0 lb/A	1	60	The grazing or feeding of treated hay or forage to livestock is prohibited.
Soil drilled or banded At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.4 oz/1000 ft of row (minimum 30-inch row spacing); or 1.5 lb/A	1	60	
Corn, Field					
Soil banded incorporated At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.2 oz/1000 ft of row (minimum 30-inch row spacing); or 1.3 lb/A	1	N/A	In -furrow application is prohibited.
Soil banded At cultivation Ground	10% G [241-53] 15% G [241-145] 20% G [241-257	1.2 oz/1000 ft of row (minimum 30-inch row spacing); or 1.3 lb/A	1	30	Application after cultivation treatment is prohibited. [2]

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications	Preharvest Interval (Days)	Use Limitations [1]
Corn, Sweet					
Soil banded incorporated At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.2 oz/1000 ft of row (minimum 30-inch row spacing); or 1.3 lb/A	1	N/A	In-furrow application is prohibited.
Soil banded At cultivation Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.2 oz/1000 ft of row (minimum 30-inch row spacing); or 1.3 lb/A	1	30	Application after cultivation treatment is prohibited.
Cotton					
In furrow At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.5 oz/1000 ft of row (minimum 30-inch row spacing); 1.8 oz/1000 ft of row (minimum 36-inch row spacing); or 1.6 lb/A	1	N/A	The grazing or feeding of treated hay or forage to livestock is prohibited.
Soil incorporated Side-dressing Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	2.0 oz/1000 ft of row (minimum 30-inch row spacing); 2.4 oz/1000 ft of row (minimum 36-inch row spacing); or 2.2 lb/A	1	60	The grazing or feeding of treated hay or forage to livestock is prohibited. Application is to be made to irrigated cotton only.
Hops					
Soil banded Post-emergence Ground	10% G [OR880002] [WA830021] [WA930010]	3.0 lb/A	1	42	The feeding of crop refuse to livestock is prohibited.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications	Preharvest Interval (Days)	Use Limitations [1]
Peanuts					
In furrow At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.1 oz/1000 ft of row (minimum 24-inch row spacing); or 1.5 lb/A	1	90	The grazing or feeding of treated hay or forage to livestock is prohibited.
Potatoes					
In furrow or soil banded At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257] [MT910004] [OR890005] [WA870010] [WA920005] [WI870003] [WI910004]	Light or sandy soils: 2.3 oz/1000 ft of row (minimum 32-inch row spacing); or 2.3 lb/A Heavy or clay soils: 3.5 oz/1000 ft of row (minimum 32-inch row spacing); or 3.5 lb/A	1	90	Use for Colorado potato beetle control in the Del Marva Peninsula is prohibited. For SLNs MT910004, OR890005, WA870010, WA920005, WI870003, and WI910004, a maximum seasonal rate of 3 lb ai/A has been established.
Soil banded At planting Ground	12% G [ME910001] [NC910006] [OR920025] [WA910007]	3.0 lb/A; or 2.9-3.5 oz/1000 ft of row (32- to 38-inch row spacing)	1	120	

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications	Preharvest Interval (Days)	Use Limitations [1]
Soil banded/side-dress Post-emergence Ground	20% G [241-257] [MT910004] [WA920005] [WI910006]	2.3 oz/1000 ft of row (minimum 32-inch row spacing) MT910004 and WA920005 only: Heavy or clay soils: 3.5 oz/1000 ft of row (any row spacing)	1	90	Use for Colorado potato beetle control in the Del Marva Peninsula is prohibited. Post-emergence application is prohibited if phorate was applied at planting. Apply within 4 to 6 weeks of planting.
Radishes grown for seed					
Soil banded At bolting Ground	10% G [WA900019] 20% G [WA910013]	3.0 lb/A	1	60	
Lilies and Daffodils (field grown)					
Soil incorporated at plant or as side dressing after planting (For State Registrations Only)	10% G [CA87006900]	8.0 lb/A	1	N/A	
Sorghum					
Soil drilled or banded At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.2 oz/1000 ft of row (minimum 30-inch row spacing); or 1.3 lb/A	1	N/A	

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications	Preharvest Interval (Days)	Use Limitations [1]
Soil banded At cultivation Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.2 oz/1000 ft of row (minimum 30-inch row spacing); or 1.3 lb/A	1	30	Use limited to CO, KS, and NE. A 30-day pre-grazing interval has been established. Applications after cultivation treatment are prohibited.
Soybeans					
Soil drilled or banded At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.8 oz/1000 ft of row (minimum 30-inch row spacing); or 2.0 lb/A	1	N/A	The feeding of treated foliage to livestock is prohibited.
Sugar beets					
Soil drilled or banded At planting Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	0.9 oz/1000 ft of row (minimum 20-inch row spacing); or 1.5 lb/A	1	30	
Soil banded At planting Ground	12% G [MT910002]	1.0 oz/1000 ft of row; (minimum 22-inch row spacing) or 1.4 lb/A	1	N/A	
Foliar Post-emergence Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	1.5 lb/A	1	30	The feeding of treated sugar beet tops or silage to dairy cattle is prohibited. Broadcast applications are prohibited.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications	Preharvest Interval (Days)	Use Limitations [1]
Sugarcane					
Soil banded Before covering Ground	10% G [241-53] 15% G [241-145] 20% G [241-257]	3.9 lb/A	1	N/A	Use limited to FL. The grazing or feeding of treated forage or hay to livestock is prohibited.
Soil banded At planting Ground	20% G [LA920011] [LA920014]	3.9 lb/A	1	N/A	Use limited to LA. The grazing or feeding of treated forage or hay to livestock is prohibited.

1. PHI = Preharvest interval. A 48-hour reentry interval has been established for the 10%, 12%, 15%, and 20% G formulations. Applications of the 10%, 15%, and 20% G formulations (EPA Reg. Nos. 241-53, 241-145, and 241-257, respectively) to any crop on Long Island, NY or using aerial equipment is prohibited.

2. Cultivation application may be made to control corn rootworms or chinch bug nymphs. When made to control chinch bug nymphs, application may only be made in AR, CO, KS, LA, MS, NE, OK, TN, and TX and a 30-day PHI/PGI has been established.

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

GUIDE TO APPENDIX B

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

The data table is organized in the following formats:

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

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

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

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

Appendix B: Data Supporting Guideline Requirements for the Reregistration of Phorate

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity		43109401 43381601
61-2(a)	Starting Material & Mnfg. Process		41348501 43381601
61-2(b)	Formation of Impurities		42655501 43381601
62-1	Preliminary Analysis		41391001 43109401 43381601
62-2	Certification of Limits		43109401
62-3	Analytical Method		43109401
63-6	Boiling Point		41348502
63-8	Solubility		41348502
63-9	Vapor Pressure		41348502
63-11	Octanol/Water Partition Coefficient		41348502
63-13	Stability		41348502
63-17	Storage Stability		41348502
63-18	Viscosity		41348502
63-20	Corrosion Characteristics		41348502
ECOLOGICAL EFFECTS			
71-1(a)	Acute Avian Oral, Quail/Duck (TGAI)	A, B	20560 160000
71-1(b)	Acute Avian Oral, Quail/Duck (TEP)	A, B	N/A
71-2(a)	Acute Avian Diet, Quail	A, B	22923
71-2(b)	Acute Avian Diet, Duck	A, B	22923
71-3	Wild Mammal Toxicity	A, B	5014313 43961101
71-4(a)	Avian Reproduction Quail	A, B	158333 41131114
71-4(b)	Avian reproduction Duck	A, B	158334
71-5(a)	Simulated Terrestrial Field Study	A, B	7534 74623 74624
71-5(b)	Actual Terrestrial Field Study	A, B	40165901
72-1(a)	Acute Fish Toxicity Bluegill (TGAI)	A, B	40094602 40098001

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
72-1(b)	Acute Fish Toxicity Bluegill (TEP)	A, B	161823
72-1(c)	Acute Fish Toxicity Rainbow Trout (TGAI)	A, B	40094602
72-1(d)	Acute Fish Toxicity Rainbow Trout (TEP)	A, B	90490 161822
72-2(a)	Acute Aquatic Invertebrate Toxicity (TGAI)	A, B	97842 5017538 42000000
72-2(b)	Acute Aquatic Invertebrate Toxicity (TEP)	A, B	161825 161826 165000
72-3(a)	Acute Estu/Mari Tox Fish (TGAI)	A, B	40001801 40228401 41803804
72-3(b)	Acute Estu/Mari Tox Mollusk (TGAI)	A, B	40228401
72-3(c)	Acute Estu/Mari Tox Shrimp (TGAI)	A, B	40228401
72-3(d)	Acute Estu/Mari Tox Fish (TEP)	A, B	40001801
72-3(e)	Acute Estu/Mari Tox Mollusk (TEP)	A, B	40004201
72-3(f)	Acute Estu/Mari ox Shrimp (TEP)	A, B	40001802 41803804
72-4(a)	Early Life-Stage Fish	A, B	158335 40228401 41131115 41803806 42227102
72-4(b)	Live-Cycle Aquatic Invertebrate	A, B	158335 41131115 42227102 42227129 43730501
72-5	Life-Cycle Fish	A, B	Reserved
72-6	Aquatic Org. Accumulation	A, B	Reserved
72-7(a)	Simulated Aquatic Field Study	A, B	42227101 43957801
72-7(b)	Actual Aquatic Field Study	A, B	Waived 42227101
122-1(a)	Seed Germ./Seedling Emerg .	A, B	
122-1(b)	Vegetative Vigor	A, B	
122-2	Aquatic Plant Growth	A, B	40228401
123-1(a)	Seed Germ./Seedling Emerg.	A, B	
123-1(b)	Vegetative Vigor	A, B	

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
123-2	Aquatic Plant Growth	A, B	
124-1	Terrestrial Field Study	A, B	
124-2	Aquatic Field Study	A, B	
141-1	Honey Bee Acute Contact	A,	(36935 & 5001991); not required for granular formulated products.
141-2	Honey Bee residue on Foliage	A, B	
141-5	Field Test for Pollinators	A, B	
TOXICOLOGY			
81-1	Acute Oral Toxicity		126343
81-2	Acute Dermal Toxicity		126343 139479
81-3	Acute Inhalation Toxicity		126343
81-4	Primary Eye Irritation		Waived
81-5	Dermal Irritation		Waived
81-6	Primary Dermal Sensitization		Waived
81-7	Delayed Neurotoxicity		152640
81-8	Neurotoxicity Screening		44719901
82-1(a)	90-Day Oral Neurotoxicity		92873
82-1(b)	Subchronic Non-Rodent Oral Tox.		92873
82-2	Repeated Dose Derm.Tox.-21/28-Day		Waived 44794201
82-3	Subchronic Dermal Toxicity- 90-Day		Waived
82-5(b)	90-Day Neurotoxicity- Mammal		192475 (protocol)
83-1	Chronic Toxicity		40174527
83-2	Carcinogenicity		124845
83-2(b)	Oncogenicity- Mouse		124845 41616101
83-3	Prenatal Developmental Tox. Study		122775 40174528 44422301
83-4	Reproduction and Fertility Effects		44422302
83-5	Combined Chronic Tox./ Carcinogen.		125233
83-6	Developmental Neurotoxicity Study		Reserved
84-2	Chronic Toxicity Studies		124901 151633 155597
85-1	General Metabolism		41803803

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1(a)	Foliar Residue Dissipation		Reserved
132-1(b)	Soil Residue Dissipation		Reserved 41616102 41616103
133-3	Dermal Passive Dosimetry		Reserved
133-4	Inhalation Passive Dosimetry		146524 41348502 (waiver granted)
ENVIRONMENTAL FATE			
161-1	Hydrolysis		41348507 44863001
161-2	Photodegradation- Water		41348508
161-3	Photodegradation- Soil		Waived
161-4	Photodegradation- Air		Reserved
162-1	Aerobic Soil Metabolism		41131112
162-2	Anaerobic Soil Metabolism		41936002
162-4	Aerobic Aquatic Metabolism		44863002
163-1	Adsorption/Desorption Studies		44671204 44671205
163-2	Volatility- Lab		42930301
163-3	Volatility- Field		Waived
164-1	Terrestrial Field Dissipation		41348506 42547701
164-5	Long Term Soil Dissipation		Reserved
165-1	Confined Rotational Crop		42657001
165-2	Field Rotational Crop		Reserved; exceptions apply to various individual crops.
165-4	Bioaccumulation in Fish		42701101
RESIDUE CHEMISTRY			
171-4(a)	Nature of Residue- Plants		Satisfied per science chapter 153487

DATA REQUIREMENTS		USE PATTERN	BIBLIOGRAPHIC CITATION(S)
171-4(b)	Nature of Residue- Livestock		42093501
171-4(c)	Residue Analytical Method- Plant		42597003
171-4(d)	Residue Analytical Method- Animal		42093501 43861801
171-4(e)	Storage Stability		43763901 43861802
171-4(j)	Mag. of Residue in Meat/Milk/ Poultry/Eggs		43861803
171-4(k)	Crop Field Trials		43281605 43661701 43730502
171-4(l)	Processed Food/Feed		42337901 42597001 42597002 42597003 43730502
OTHER SUBMISSIONS (Special Study)			
80-A-SS	Acute Eye Oral Rat Study		Reserved
81-8-SS	Acute Neurotoxicity- Rat		192475 (protocol)
82-B-SS	Subchronic Eye Rat Study		Reserved
82-C-SS	Short Term Mouse Study		41616101
85-2-SS	Six Month Eye Study		Reserved

Appendix C. 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 August 10, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on June 16, 1999.

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

www.epa.gov/pesticides/op

These documents include:

HED Documents:

1. Dobozy, Virginia (USEPA/OPPTS/HED) Phorate: Review of Pesticide Poisoning Incident Data. No date provided.

2. Miller, David (USEPA/OPPTS/HED) Phorate: Evaluation of Novigen Chronic and Acute Monte-Carlo Analyses. January 29, 1998.

3. Odiott, Olga (USEPA/OPPTS/HED) Occupational and Residential Exposure Assessment and Recommendations for the R.E.D. for Phorate. March 13, 1995.

4. Olinger, Christine (USEPA/OPP/HED) Human Health Risk Assessment: Phorate. September 2, 1999.

5. Olinger, Christine (USEPA/OPPTS/HED) Phorate: Revised HED Chapter of the R.E.D. Document. March 12, 1998.

6. Robertson, Jason (USEPA/OPPTS/SRRD) Phorate: revised HED Science Chapter. March 17, 1998.

7. Rowland, Jess (USEPA/OPPTS/HED) Phorate-FQPA Requirement: Report of the Hazard Identification Assessment review Committee. September 25, 1997.

8. Smith, Jane (USEPA/OPPTS/HED) Phorate: HED Chapter of the R.E.D.

9. Smith, (USEPA/OPPTS/HED) Phorate: HED Chapter of the R.E.D. April 6, 1996.

10. Steinwand, Brian (USEPA/OPPTS/HED) Acute Dietary Exposure Analysis for Phorate in Support of the R.E.D. May 9, 1996.

11. Steinwand, Brian (USEPA/OPPTS/HED) Dietary Exposure Analysis for Phorate in Support of the R.E.D. July, 29, 1998.

12. Tarplee, Brenda (USEPA/OPPTS/HED) FQPA Safety Factor Recommendations for the Organophosphates. August 6, 1998.

13. USEPA/OPP/SRRD. Overview of Phorate Revised Risk Assessment. September 2, 1999.

14. USEPA/OPP/SRRD. Phorate Summary. September 2, 1999.

EFED Documents:

1. American Cyanamid, Ecological Risk Assessment for THIMET Soil and Systemic Insecticide. December 1, 1997.

2. Farrar, David (USEPA/OPP/EFED) Updated EFED RED Chapter/Revisions of Exposure Estimates/Response to comments from American Cyanamid. August 30, 1999.

3. Wagner, Pauline (USEPA/OPPTS/EFED) EFED Science Chapter for Phorate R.E.D. July, 18, 1998.

Other Related Documents:

1. Alsadek, Jihad (USEPA/OPP/BEAD) Quantitative Usage Analysis. January 8, 1998.

2. American Cyanamid, Amercian Cyanamid Rebuttal to EPA's Health Effects Division Draft Chapter of the Red for Phorate. July, 29, 1998.

3. Angulo, Karen (USEPA/OPPTS/SRRD) Increasing Transparency for the Tolerance Reassessment Process: Phorate. August 12, 1998.

4. Chambliss, Ben (USEPA/OPP/SRRD) Response to Comments on the Preliminary Risk Assessment for the Organophosphate Phorate. September 2, 1999.

5. Hazard Assessments of the Organophosphates. (USEPA/OPPTS/HED). July 22, 1998.

6. Wrubel, (American Cyanamid) Transmittal letter: Phorate Reregistration Case #103 Response to Draft Science Chapter and Submissions of Acute and Chronic... December 1, 1998.

7. Wrubel, (Amercian Cyanamid) Phorate Response to the US EPA's Draft Science Chapter and FQPA Requirements.

8. Wrubel, (Amercian Cyanamid) Phorate Reregistration Request for "Monte Carlo" Acute Dietary Risk Assessment EPA Letter dated August 14, 1997.

9. Wrubel, John (American Cyanamid) Partial Response to the Draft Environmental Fate and Effects Science Chapter. December 17, 1997.

10. Wrubel, John (American Cyanamid) Phorate and Its Potential Environmental Risk in Perspective. December 17, 1997.

11. Various Authors, Public Comments regarding Phorate. July 23, 1998 thru August 21, 1998.

12. Various Authors, Comments regarding Preliminary risk Assessment for Phorate. October 8, 1998 thru November 13, 1998.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Interim Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

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

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

contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID CITATION

7534 Industrial Bio-Test Laboratories, Incorporated (1961) Halane Toxicological Studies. (Unpublished study received May 5, 1969 under 8556-1; submitted by San O Matic Manufacturing Co.

20560 Schafer, E.W. (1972) The acute oral toxicity of 369 pesticidal, pharmaceutical and other chemicals to wild birds. Toxicology and Applied Pharmacology 21(?):315-330. (Also in unpublished submission received Apr 25, 1978 under 476-2180; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:233577-C)

22923 Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific report-Wildlife No. 191. (U.S. Dept. of the Interior, fish and Wildlife Service, Patuxent Wildlife research Center; unpublished report)

74623 Fink, R.; Beskid, J.C. (1981) Final Report: Simulated Field Study--Bobwhite Quail: Project No. 130-131A. (Unpublished study received May 21, 1981 under 241-257; prepared by Wildlife International Ltd., submitted by American Cyanamid Co., Princeton, N.J.; CDL:245263-B)

74624 Fink, R.; Beskid, J.C. (1981) Final Report: Simulated Field Study--Bobwhite Quail: Project No. 130-131B. (Unpublished study received May 21, 1981 under 241-257; prepared by Wildlife Intenational Ltd., submitted by American Cyanamid Co., Princeton, N.J.; CDL:245263-C)

74625 Fink, R.; Beskid, J.C. (1981) Final Report: Simulated Field Study--Bobwhite Quail: Project No. 130-131C. (Unpublished study received May 21, 1981 under 241-257; prepared by Wildlife International Ltd., submitted by American Cyanamid Co., Princeton, N.J.; CDL:245263-D)

74626 Fink, R.; Beskid, J.C. (1981) Final Report: Simulated Field Study--Bobwhite Quail: Project No. 130-131D. (Unpublished study received May 21, 1981 under 241-257; prepared by Wildlife International Ltd., submitted by American Cyanamid Co., Princeton, N.J.; CDL:245263-E)

92873 Tusing, T.W. (1956) Progress Report: Repeated Oral Administration--Dogs. (Unpublished study, including letter dated Jan 25, 1956 from T.W. Tusing to D.O. Hamblin, received Feb 20, 1956 under 241-36; prepared by Hazleton Laboratories, submitted by American Cyanamid Co., Princeton, N.J.; CDL:092661-M)

BIBLIOGRAPHY

MRID	CITATION
97842	(Study is a duplicate of MRID# 108338)
122775	Beliles, R. (1979) Teratology Study in Rats: Thimet Phorate: LBI Project No. 20819. Final rept. (Unpublished study received Dec 30, 1982 under 0E2391; prepared by Litton Bionetics, submitted by American Cyanamid Co., Princeton, NJ; CDL:071332-A)
124845	Manus, A.; Goldsmith, L.; Sekerke, H.; et al. (1981) 18-month Chronic Toxicity and Potential Carcinogenicity Study in Mice: Phorate: LBI Project No. 20820. Final rept. (Unpublished study received Oct 13, 1982 under 241-53; prepared by Litton Bionetics, Inc., submitted by American Cyanamid Co., Princeton, NJ; CDL:248780-A)
124901	Simmon, V.; Mitchell, A.; Jorgenson, T. (1977) Evaluation of Selected Pesticides as Chemical Mutagens: In vitro and in vivo studies: EPA-600/1-77-028: Pre RPAR Review Submission #3. (Unpublished study received Sep 14, 1977 under 1471-35; prepared by Stanford Research Institute, Environmental Toxicology Div., Health Effects Research Laboratory, and U.S. Environmental Protection Agency, Office of Research and Development, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:233222-L)
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Appendix E. 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 F. 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 G. EPA'S Batching of Phorate 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 phorate as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing

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

Twelve products were found which contain Phorate as the active ingredient. These products have been placed into seven batches in accordance with the active and inert ingredients and type of formulation.

C The products in Batch 2 may be supported by citing/submitting the acute data from Batch 1.

C The products in Batch 3 may be supported by citing/submitting the acute data from Batch 1.

C The products in Batch 4 may be supported by citing/submitting the acute data from Batch 1.

C The products in Batch 5 may be supported by citing/submitting the acute data from Batch 1.

C The products in Batch 6 may be supported by citing/submitting the acute data from Batch 1.

C The products in Batch 7 may be supported by citing/submitting the acute data from Batch 1.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	2749-106	95.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	241-212	85.0	Solid
	241-213	85.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	241-257	20.0	Solid
	9779-293	20.0	Solid
	34704-259	20.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
4	241-145	15.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
5	241-53	10.0	Solid
	34704-712	10.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
6	264-521	10.0	Solid
	34704-710	10.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
7	400-412	6.5	Solid

Appendix H. List of Registrants Sent This Data Call-In

Insert List–Page 1 of 1

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@epamail.epa.gov.

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.

8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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

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

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

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

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

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

1. The Office of Pesticide Programs' Web Site

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

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

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

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

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

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

   Date of receipt
   EPA identifying number
   Product Manager assignment

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

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

Documents Associated with this RED

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

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