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

September 28, 2001

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised risk assessments for the organophosphate pesticide terbufos. The public comment period on the revised risk assessment phase of the reregistration process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health and environmental effects risk assessments and made them available to the public on September 14, 1999. Additionally, the Agency held a Technical Briefing on September 2, 1999, where the results of the revised human health and environmental effects risk assessments were presented to the general public. This Technical Briefing concluded Phase 4 of the OP Public Participation Pilot Process developed by the Tolerance Reassessment Advisory Committee (TRAC), and initiated Phase 5 of that process. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate any estimated risks presented in the revised risk assessments. This public participation and comment period commenced on September 14, 1999, and closed on November 12, 1999.

Based on its review, EPA has identified risk management measures that it believes are necessary to address the human health and environmental risks associated with the current use of terbufos. The EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of terbufos and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for terbufos will be finalized once the cumulative risks for all of the organophosphate pesticides are considered. The enclosed "Interim Reregistration Eligibility Decision for Terbufos," which was approved on September 28, 2001, contains the Agency's decision on the individual chemical terbufos.

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

The Interim RED is based on the updated technical information found in the terbufos public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessment for terbufos (revised as of September 14, 1999), and a document summarizing the Agency's Response to Comments dated August 30, 1999. The Response to Comments document describes new studies submitted by the chemical registrant that were used to revise the risk assessments, and responds to comments submitted by the registrant, general public, and other stakeholders. The docket also includes comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For terbufos, a risk mitigation proposal was submitted by the chemical registrant, BASF Corporation (formerly American Cyanamid).

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

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

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

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

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

If you have questions on this document or the label changes necessary for reregistration, please contact the Special Review and Reregistration Division's Chemical Review Manager, Eric R. Olson at (703) 308-8067. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Karen Jones (703) 308-8047.

Sincerely

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Interim Reregistration Eligibility Decision
for
TERBUFOS

Case No. 0109

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir

LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/	

EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its interim risk management decisions for terbufos. The decisions outlined in this document do not include the final tolerance reassessment decision for terbufos. At this time, no tolerance actions are necessary for terbufos. The final tolerance reassessment decision for this chemical will be issued once the cumulative risks for all of the organophosphates are considered. The Agency may need to pursue further risk management measures for terbufos once cumulative risks are considered.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on terbufos. After considering the revised risks, as well as mitigation proposed by BASF the technical registrant of terbufos, and comments and mitigation suggestions from other interested parties, including the states of North Carolina and Indiana, Defenders of Wildlife, several property owners, growers and grower organizations, and agricultural extension agents, EPA developed its risk management decision for uses of terbufos that pose risks of concern. This decision is discussed fully in this document.

Terbufos is an organophosphate insecticide-nematicide used to control a variety of insect pests, first registered in 1974 to control insect pests on corn, sugar beets, and sorghum. Use data from 1987 to 1996 indicate an average domestic use of approximately 7.5 million pounds of active ingredient per year during that period.

Overall Risk Summary

EPA's human health risk assessment for terbufos indicates some risk concerns. Food risk, both acute and chronic, is below the Agency's level of concern. Drinking water risk estimates based on models, from both ground and surface water for acute and chronic exposures, is of concern for most populations, notably infants and children. Even when potential food exposures to terbufos are not considered, modeled concentrations of terbufos in groundwater and surface water alone exceed the Agency's level of acute and chronic dietary risk concern based on Estimated Environmental Concentrations (EEC's). The Agency also has some risk concerns for handlers who handle terbufos in open bag/open cab and closed systems (i.e., Lock-N-Load system and enclosed cabs). Terbufos is not registered for use in residential settings, and so the Agency expects no residential/homeowner exposures.

EPA's environmental risk assessment for terbufos indicates risk concerns to non-target organisms. The Agency is particularly concerned about risks to aquatic species, based on the Agency's aquatic assessment, and supported by fish kill incidents associated with the use of terbufos on corn.

To manage risks of concern posed by the uses of terbufos, EPA considered the risk

management proposal submitted by the technical registrant, as well as comments and ideas from other interested parties, and has decided on a number of label amendments to address the ecological, drinking water, and worker risk concerns. Results of the risk assessments, and required label amendments to manage those risks, are presented in this interim RED.

Dietary Risk

Acute and chronic dietary risk for food alone do not exceed the Agency's level of concern. However, acute and chronic dietary risks are a concern when potential modeled drinking water exposures are added to the acute and chronic dietary risk assessment. Drinking water risks of concern are expected to be managed by the steps outlined in the discussion of ecological risk explained below.

Occupational Risk

Occupational exposures to terbufos are not a risk concern for most handler scenarios. However, the Agency does have risk concerns for handlers loading and applying the Counter 15G Lock-N-Load product and Counter 20CR open bag product. The Agency has determined that risk concerns for Counter 15G can be mitigated to acceptable levels if applications are restricted to closed cab tractors and the maximum application rate on sorghum is reduced. For the Counter 20CR open bag product, risk concerns on sorghum can also be mitigated to an acceptable level if there is a reduction in the maximum application rate. The Agency also has risk concerns for workers using the Counter 20CR product in open bags under a Special Local Need (SLN) registration in North Carolina which allows use on corn at twice the maximum application rate of the Section 3 registration. The Agency has determined that this risk concern can be mitigated to an acceptable level if North Carolina revises the SLN registration to permit use of Counter 20CR in closed loading systems only (i.e., "Lock-N-Load" packaging).

EPA does not believe there is a significant potential for post-application exposures to terbufos based on application methods, timing, and frequency. The Agency concludes that the 48 hour Restricted Entry Interval (REI) established under EPA's Worker Protection Standards (WPS) is sufficient to protect workers who may re-enter treated areas. Therefore, with the addition of the label restrictions and amendments detailed in this document, the Agency has determined that, until the outcome of the cumulative risk assessment for all of the organophosphates has been decided, all currently registered uses of terbufos may continue.

Ecological Risk

Ecological risks to terrestrial and aquatic organisms are of concern to the Agency. The Agency is concerned about potential adverse effects to terrestrial and aquatic organisms, based on the Agency's assessment and fish kills associated with the use of terbufos on corn. Aquatic incidents reported to EPA indicate that terbufos is the leading cause of fish kills among pesticides applied to corn, and is fourth in causing fish kills for any pesticide applied to any crop.

The Agency has determined that these risks can be reduced by implementing limitations on sales of terbufos and adding buffers to the labels. The registrant has agreed to a phased approach that will ultimately reduce sales of terbufos by 55% by 2008 based on 2000 sales figures. By reducing the total amount of terbufos available to be applied, the Agency expects that risks to aquatic and terrestrial organisms will be reduced.

The buffers to be implemented are; 1) a 500 ft. vegetative buffer between treated area and surface water on neighboring land, 2) a 500 ft. vegetative buffer between a standpipe drain outlet and surface water on neighboring land, 3) a 66 ft. setback between the treated area and entry points to surface water bodies on non-highly erodible soils and 300 ft. on highly erodible soils, 4) a 66 ft. setback between treated area and standpipes on terraced fields as well as 66 ft. vegetative buffer between the tile outlet and surface water bodies, and 5) restricting loading, rinsing, and washing equipment within 300 ft. from surface water bodies or within 50 ft. from wells unless conducted on an impervious surface. All setbacks must be planted to a crop or seeded with grass or other suitable cover.

In addition, the registrant has agreed to voluntarily remove from its labels the "over the top" application on corn for European corn borer control. Banded applications on corn will also require placing granules in a 7 inch band over the row, in front of the press wheel, and incorporated into the soil to a depth of 1 inch. To prevent the flow of rainfall down planted rows, the label text will read "To prevent channeling of surface water run-off, adjust the planter row-cleaners appropriately to prevent rows lower in height than adjacent soil".

Benefits

The benefits of terbufos on corn were estimated using a comparative product performance assessment. This assessment aimed at quantifying, to the extent possible, the benefits derived from the use of terbufos on corn primarily for control of corn rootworm. It relied on data from numerous product performance studies available in the open scientific literature. These data were analyzed using statistical methods to determine the relative effects on corn yields of using terbufos and other corn insecticides especially tefluthrin. The benefits assessment concluded that under most conditions the alternative insecticides produced similar or greater yields than fields where terbufos was used. Terbufos did show an advantage over the alternatives in controlling billbugs in North Carolina and controlling corn rootworm in the Northeast. Terbufos also performed more effectively on some secondary corn pests. However, there are uncertainties associated with the assessment that were taken into consideration when developing the risk management measures outlined in the IRED.

For the uses of terbufos the Agency has determined that, with the adoption of all of the label amendments noted in this document, use may continue until the outcome of the cumulative assessment of all of the organophosphates has been decided.

The Agency is issuing this interim Reregistration Eligibility Document (RED) for terbufos, 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 terbufos. There is a 60-day public comment period for this document to allow stakeholders the opportunity to review and provide comments on this document. With regard to complying with the requirements in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for terbufos can be considered final, however, until the cumulative risks for all organophosphate pesticides are considered. The cumulative assessment may result in further required risk mitigation measures for terbufos.

I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment of all existing tolerances. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. 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 amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Terbufos 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 reregistration eligibility for terbufos. It is intended to be only the first phase in the reregistration process for terbufos. The Agency will eventually proceed with its assessment of the cumulative risk of the OP pesticides and issue a final reregistration eligibility decision for terbufos.

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

- Applying the FQPA 10-Fold Safety Factor
- Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments
- How to Interpret "No Detectable Residues" in Dietary Exposure Assessments

- Refining Dietary (Food) Exposure Estimates
- Refining Dietary (Drinking Water) Exposure Estimates
- Assessing Residential Exposure
- Aggregating Exposure from all Non-Occupational Sources
- How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- Whether and How to Use Data Derived from Human Studies

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

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

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk 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 reregistration eligibility and risk management decisions. Section V summarizes required label changes based on the risk mitigation and risk reduction 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, and in the Public Docket.

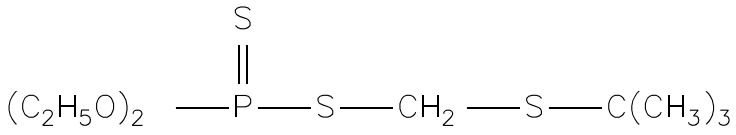
II. Chemical Overview

A. Regulatory History

Terbufos was first registered in the United States in 1974 by EPA for use as a systemic insecticide-nematicide on corn. Registrations for the use of terbufos on sugar beets and sorghum followed in 1976 and 1982, respectively. A Registration Standard was issued in 1983 and, in 1988, a Revised Registration Standard was issued for terbufos requiring numerous studies to support continued registration. The 1983 Registration standard was amended in February 1985 to require Restricted Use classification due to acute oral and dermal toxicity. Two Preliminary Notifications (i.e., Grassley-Allen letters) were sent to the technical registrant, in 1988 and 1990, identifying terbufos as a candidate for Special Review based on risks to nontarget organisms; birds, mammals, aquatic species, and endangered species.

B. Chemical Identification

Chemical Structure of Terbufos:



- **Common Name:** Terbufos
- **Chemical Name:** S-[[1,1-dimethylethyl) thio] O,O-di-ethyl phosphorodithioate
- **Chemical family:** Organophosphate
- **CAS registry number:** 13071-79-9
- **OPP chemical code:** 105001
- **Empirical formula:** $C_9H_{21}O_2PS_3$
- **Molecular weight:** 288.4
- **Trade and other names:** Counter®
- **Basic manufacturer:** BASF Corporation (technical registrant)

Technical terbufos is a colorless to pale yellow clear liquid with a mercaptan-like odor. It has a boiling point of 55 °C at 0.02 mm Hg, and a density of 1.11 g/ml at 20 °C. The solubility of terbufos in water at 25 °C is 5.4 ppm. Its solubility in acetone, acetonitrile, benzene, chloroform, dichloromethane, ethanol, n-heptane, methylene chloride, and toluene is reported as ≥ 100 g/100 ml at 20 °C. Water solubilities of the two major soil/water degradates at 25 °C are 3214 mg/L and 407 mg/L for terbufos sulfoxide and terbufos sulfone, respectively.

C. Use Profile

The following information is based on the currently registered uses of terbufos.

Type of Pesticide: Systemic insecticide-nematicide

Summary of Use Sites:

Food: Terbufos is applied at-plant/at-bedding, post emergent, or at cultivation to control many types of insect pests. Registered use sites are corn (field, sweet, and pop), sugarbeets, and grain sorghum. Approximately 80 percent of terbufos is applied to field corn. Terbufos is also used on imported bananas grown in South America and Mexico.

Residential: None.

Public Health: None.

Other Nonfood: None.

Target Pests: Target pests include corn rootworms, wireworms, white grubs, billbugs, sugarbeet root maggots, cutworms, and nematodes.

Formulation Types Registered: In addition to the technical, there are two end-use formulations registered: a clay-based granular formulation and a polymeric granular formulation.

Method and Rates of Application:

Equipment - Granular row planters; in front of planter's press wheel with light soil incorporation using, for example, drag chains, tines, or cultivators.

Method and Rate - Applied 1) at-plant/at-bedding (banded, in-furrow, knifed-in); 2) post emergent (banded alongside plant); and 3) at cultivation. All applications require soil incorporation.

- The typical application rate for corn is 1.0 lb a.i./A, and the maximum application rate for corn is 1.3 lbs a.i./A, applied one time per year. A Special Local Need (SLN) registration in North Carolina allows use on corn at up to 2.6 lbs a.i./A, one time per year.

- The typical application rate for sugarbeets is 1.3 lbs a.i./A and for sorghum is 0.7 lbs a.i./A, both limited to one application per year. The maximum application rate on these crops is 1.96 lbs a.i./A, applied one time per year.

Timing - At-plant/at-bedding, post-emergent, at-cultivation

Use Classification: The registered terbufos end-use products are restricted use products due to acute oral and dermal toxicity.

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of terbufos, based on available pesticide usage information for 1987 to 1996. A full listing of all uses of terbufos, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 7.5 million pounds of Terbufos a.i. are used annually, according to Agency estimates.

Table 1. Terbufos Estimated Usage

Crop	Lbs. Active Ingredient Applied (Wt. Avg.)[1]	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wt. Avg.)
Corn (field, pop)	6,530,000	10%	8%
Sugar Beets	670,000	43%	35%
Sorghum	190,000	4%	2%
Sweet Corn	55,000	6%	5%

[1] Weighted Average is based on data for 1987-1996; the most recent years and more reliable data are weighted more heavily.

The registrant has provided the Agency with proprietary domestic sales figures for 2000. It should be noted that while these figures are significantly lower than the Agency estimates presented in the table above, the proportions among the crops are comparable.

III. Summary of Terbufos Risk Assessments

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide terbufos, as fully presented in the documents, "Terbufos, Human Health Risk Assessment" dated September 2, 1999, and "Terbufos, Revised EFED Reregistration Eligibility Decision (RED) Chapter," dated August 26, 1999. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to better understand the conclusions reached in the assessments.

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

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for terbufos in August 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were refined and updated. Major revisions to the human health risk assessment are listed below:

- Use of new acute and subchronic oral rat neurotoxicity studies in the acute and chronic dietary risk assessments.

- Reduction of the FQPA Safety Factor from 3X to 1X, based on reevaluation of the hazard and exposure database, including the new acute and subchronic oral rat neurotoxicity studies.

- Use of new corn and banana residue field trial studies in the acute and chronic dietary risk assessments, in combination with previously submitted field trial data.

- Use of new chemical specific worker exposure studies and formulation-specific 28-day rat dermal toxicity studies in the occupational risk assessment.

- Use of separate toxicological endpoints for dermal and inhalation exposures for the occupational assessment.

- Use of the SCI-GROW and PRZM-EXAMS models and new aquatic metabolism data to estimate potential environmental concentrations (EECs) of terbufos in drinking water through groundwater and surface water.

1. Dietary Risk from Food

a. Toxicity

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

b. FQPA Safety Factor

The FQPA Safety Factor was reduced to a 1X. Based on a weight-of-the-evidence evaluation of the hazard and exposure database for terbufos, there is no indication of increased susceptibility of young rats or rabbits to terbufos. Therefore, the additional 10X factor as required by FQPA was reduced to 1X. Terbufos did not cause acute delayed neurotoxicity in hens given a single oral dose of terbufos, and there was no evidence of neuropathology in the acute, subchronic, and chronic studies in dogs or a long-term mouse study. The toxicity database includes acceptable acute and subchronic neurotoxicity studies in rats, which were data gaps previously. In the rat acute neurotoxicity study, no effects were observed on motor activity, but several functional observational battery (FOB) parameters (e.g., ataxia, decreased forelimb grip strength, tremors) were affected. No treatment-related effects were observed on motor activity or in the FOB parameters measured in the rat subchronic neurotoxicity study. In the developmental and reproduction studies, effects were observed in fetuses/offspring only at or above treatment levels, which resulted in evidence of parental toxicity. The dietary food exposure assessment does not underestimate potential exposures to infants and children from terbufos residues in food. No exposure is expected to infants and children from residential (non-occupational) sources because terbufos is only registered on three agricultural crops.

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

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study	UF	FQPA Safety Factor	PAD (mg/kg/day)
Acute Dietary	**NOAEL = 0.15**	**Plasma ChE inhibition in both sexes and clinical signs.**	**Acute Oral Neurotoxicity in Rats (MRID 44672003)**	**500**	**1X**	**0.0003 mg/kg/day**
Chronic Dietary	**NOAEL = 0.005**	**Plasma ChE inhibition in both sexes.**	**Chronic 1-year and subchronic oral toxicity in dog (MRIDs 00263678, 40374701)**	**100**	**1X**	**0.00005 mg/kg/day**

c. Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose (RfD), 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. The RfD is calculated by taking the no observed adverse effect level (NOAEL) from an appropriate toxicity study and dividing it by an uncertainty factor (UF) (i.e., NOAEL/UF). In the case of terbufos, the FQPA safety factor is 1X; therefore, the RfD equals the PAD.

The acute PAD for terbufos is 0.0003 mg/kg/day (0.15 mg/kg/day/500) based on plasma ChE and clinical signs observed in the acute rat neurotoxicity study. The UF of 500 is calculated as follows: 10X for interspecies extrapolation x 10X for intraspecies variability x 5X for differences in sensitivity between rats and dogs. The additional UF of 5X is required based on an analysis of plasma ChE in the rat subchronic neurotoxicity study and a 28-day oral toxicity study in dogs. The analysis was performed to determine a species sensitivity factor that would be appropriate to apply to the rat acute neurotoxicity study. Previously, EPA had selected results from the 28-day dog toxicity study for the acute endpoint, which had a plasma ChE measurement at day 7. Using the rat acute neurotoxicity study for the endpoint with a derived species sensitivity factor provides the appropriate time-related endpoint and takes into account the observed sensitivity between the rat and dog.

The chronic PAD for terbufos is 0.00005 mg/kg/day (0.005 mg/kg/day ÷ 100) based on plasma ChE observed in a 28-day oral toxicity study in dogs (NOAEL = 0.005 mg/kg/day) and a 1-year oral toxicity study in dogs.

d. Exposure Assumptions

Revised acute and chronic dietary risk analyses for terbufos were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-91.

The acute dietary analysis uses anticipated residue values from crop residue field trial studies, and percent crop-treated figures. The chronic dietary analysis was refined using anticipated residue values from crop residue field trial studies, and weighted average percent crop treated figures. The dietary exposure analyses for terbufos are based largely on residue values from field trial data below the limit of detection (LOD), between the LOD and limit of quantitation (LOQ), or at the LOQ. The Agency considered using monitoring data from USDA's Pesticide Data Program (PDP) and FDA enforcement monitoring data available for terbufos on bananas and sweet corn, but determined that these data are not appropriate for use in this risk assessment for several reasons, including that the monitoring effort did not measure all the terbufos degradates of concern. It should also be noted that exposure from coffee beans treated with terbufos was included in the dietary assessment because a proposal to extend the time-limited tolerance for that commodity is currently pending.

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 EPA's risk concerns. The terbufos acute dietary risk from food alone is below the Agency's level of concern—that is, less than 100% of the acute PAD is used. For example, for the most exposed subgroups, non-nursing infants and infants (< 1 year), the percent acute PAD values are 86% and 82%, respectively, at the 99.9th percentile of exposure from consumption of food alone.

The chronic dietary risk from food alone is well below the Agency's level of concern. For the most exposed subgroups, infants, the percent chronic PAD values are no more than 9%.

Both the acute and chronic dietary exposure and risks associated with terbufos are below the Agency's level of concern. To further characterize acute dietary risk, additional analysis were conducted indicating that bananas are the most significant contributor to the estimated acute dietary risk from food alone. Both the acute and chronic dietary risk assessments are considered to be refined using the data available. However, the acute and chronic analyses do not take into consideration the potential for reduction or concentration of terbufos residues in cooked/canned/processed bananas and sweet corn, since there are no chemical-specific cooking studies available. EPA could refine the terbufos dietary exposure analysis if these data were generated and could be further refined if appropriate monitoring data were available. It should be noted that the available PDP monitoring data, while not appropriate for the purposes of quantitative risk assessment, found no detections of terbufos or terbufos sulfone residues in over 100 samples of sweet corn. Any and all available 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.

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.

In the case of terbufos, EPA is concerned about the potential for parent terbufos and its two major degradates in water, terbufos sulfoxide and terbufos sulfone, to runoff to surface water sources, and the potential for these degradates to leach to groundwater sources. The PRZM-EXAMS model was used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. Although some monitoring data for terbufos were

available, these data were deemed of limited value for several reasons, including that the degradates of concern were typically not included as part of the analyses. Further discussion follows below regarding the monitoring data the Agency considered for terbufos. EPA also reviewed and considered new environmental fate data submitted on the abiotic hydrolysis and aerobic aquatic metabolism of parent terbufos and its degradates.

a. Surface Water

The Tier II PRZM-EXAMS screening model is used to estimate upper-bound environmental concentrations (EECs) in drinking water derived from surface water. This model, in general, is based on more refined, less conservative assumptions than the Tier I GENEEC screening model. Acute modeled EECs for terbufos parent and its degradates, terbufos sulfoxide and terbufos sulfone, in surface water range from 5.4 ppb to 13.3 ppb, depending on the crop site. Chronic modeled EECs for terbufos parent and its degradates range from 1.3 ppb to 5.5 ppb, depending on the crop site.

The Agency also used the recently implemented Index Reservoir (IR) and Percent Crop Area (PCA) modifications to the Tier II PRZM-EXAMS model to calculate upper-bound EECs for terbufos and its degradates in drinking water derived from surface water. Applying the IR and PCA modifications, acute modeled EECs for terbufos parent and its degradates, terbufos sulfoxide and sulfone, in surface water range from 8.4 ppb to 25.5 ppb depending on the crop site. Chronic modeled EECs for terbufos parent and its degradates, terbufos sulfoxide and sulfone, range from 1.8 ppb to 5.9 ppb, depending on the crop site.

The surface water model assumes terbufos applications are made at the maximum rate for each crop on the current label, using the labeled methods of application (i.e., T-banded, in-furrow, or knifed-in). In addition, the Agency applied the standard assumption that 85 percent of the applied end-use product granules would be found in the top two cm of the soil. Finally, half-life inputs in the model were derived using direct measurements of terbufos parent and its degradates from aerobic aquatic metabolism data (MRID 44862502), rather than default or "worst-case" assumptions, which provides additional refinement to the terbufos modeling.

Monitoring for terbufos in surface water is limited and has been undertaken by U.S. Geological Survey (USGS) in its National Water Quality Assessment (NAWQA) program and by some states. Terbufos parent was not found above 2.25 ppb in monitoring data. The Agency believes that the terbufos monitoring data available are limited and often not associated with periods of terbufos use. For instance, samples were often taken throughout the year rather than concentrating sampling during the time period when terbufos application is expected. Furthermore, the degradates of concern, terbufos sulfoxide and sulfone, were not included in any of the analyses. Given these limitations, the existing surface water monitoring database cannot be used to estimate concentrations of terbufos in surface water. However, the Agency notes that the available NAWQA data found 17 detections of parent terbufos in 5,198 samples. The detections ranged from 0.013 ug/L to 0.56 ug/L.

b. Ground Water

The Tier I screening model, SCI-GROW, was used to estimate drinking water concentrations derived from groundwater. Acute and chronic EECs for terbufos parent and its degradates, terbufos sulfoxide and sulfone, in groundwater range from 4.8 ppb to 7.4 ppb. The groundwater modeling assumes applications are made at the maximum rate for each crop on the current label, using the labeled methods of application (i.e., T-banded, in-furrow, or knifed-in). The half-life inputs in the model are derived from direct measurements of terbufos parent and its degradates from an aerobic soil metabolism study (MRID 00156853).

Monitoring of groundwater supplies for terbufos has been limited. Information on terbufos in groundwater has been gathered by the registrant, USGS NAWQA, EPA's Pesticides in Groundwater Database, and some states within the major use areas. These data represent 4,563 samples from 13 states, including 20 detections of parent terbufos with an additional 7 apparent detections in Iowa that are questionable or unconfirmed. Thirteen wells were also sampled in Iowa for terbufos sulfone, but no residues were detected. Detections of Terbufos parent in groundwater studies has ranged from 0.011 ppb up to 20.0 ppb. However, only two detections were about 0.06 ppb. EPA has determined that the groundwater monitoring data available to the Agency are inadequate for use in assessing groundwater exposures for several reasons, including that the monitoring studies did not analyze for the degradates of concern.

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 results of the Agency's drinking water analysis are summarized here. Details of this analysis, which used screening models, are found in the HED Human Health Risk Assessment dated September 2, 1999 and the EFED Environmental Risk Assessment dated August 26, 1999.

For acute risk, groundwater and surface water EECs exceed the acute DWLOCs for infants and children (Table 3). Even if it is assumed that there are no food exposures to terbufos, drinking water alone, based on model estimates, would result in exceedences of the risk cup, particularly for infants and children. The table below presents the calculations for the acute drinking water assessment.

Table 3. Summary of DWLOC Calculations for Acute Risk

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Maximum Groundwater EECs (SCI-GROW, total toxic residue, ppb)	Maximum Surface Water EECs (PRZM/ EXAMS, total toxic residue, ppb)	Maximum Surface Water EECs (PRZM/ EXAMS, IR & PCA modifications, total toxic residue, ppb)	DWLOC (ppb)
U.S. Population	3.0e-4	7.0e-5	2.3e-4	7.4	13.3	25.5	8.10
Non-nursing Infants (<1 yr)	3.0e-4	2.6e-4	4.1e-5	7.4	13.3	25.5	0.41
All Infants (<1 yr)	3.0e-4	2.5e-4	5.0e-5	7.4	13.3	25.5	0.50
Children (1-6 years)	3.0e-4	1.4e-4	1.6e-4	7.4	13.3	25.5	1.60
Children (7-12 years)	3.0e-4	6.9e-5	2.3e-4	7.4	13.3	25.5	2.30

For chronic risk, groundwater and surface water EEC's exceed the chronic DWLOC's for all population subgroups, regardless of the treated crop (Table 4). Even if it is assumed that there are no food exposures to terbufos, drinking water alone, based on model estimates, would result in exceedences of the risk cup, particularly for infants and children. The table below presents the calculations for the chronic drinking water assessment.

Table 4. Summary of DWLOC Calculations for Chronic Risk

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Maximum Groundwater EECs (SCI-GROW, total toxic residue, ppb)	Maximum Surface Water EECs (PRZM/ EXAMS, total toxic residue, ppb)	Maximum Surface Water EECs (PRZM/ EXAMS, IR & PCA modifications, total toxic residue, ppb)	DWLOC (ppb)
U.S. Population	5.0e-5	1.0e-6	4.9e-5	7.4	5.5	5.9	1.70
Non-nursing infants (<1 yr)	5.0e-5	5.0e-6	4.5e-5	7.4	5.5	5.9	0.45
All Infants (<1 yr)	5.0e-5	4.0e-6	4.6e-5	7.4	5.5	5.9	0.46
Children (1-6 years)	5.0e-5	2.0e-6	4.8e-5	7.4	5.5	5.9	0.48
Children (7-12 years)	5.0e-5	1.0e-6	4.9e-5	7.4	5.5	5.9	0.49

The acute and chronic dietary risks from drinking water exposure are above the Agency's level of concern for most subpopulations. However, there are uncertainties which lead the Agency to expect that exposure from drinking water may not be as high as the levels used in the development of the risk assessment. These uncertainties are described in Section IV.

3. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes). Acute and chronic aggregate risk assessments were conducted for terbufos. Since terbufos is not registered for use in residential settings, residential exposures are not expected, and aggregate short- and intermediate-term exposures were not estimated. Results of the aggregate risk assessment are summarized here, and are discussed in the terbufos human health risk assessment.

The Agency was only able to quantify food sources of dietary exposure to terbufos because dietary exposures through drinking water have only been estimated using models. Neither adequate groundwater or surface water monitoring data were available to estimate potential drinking water exposures to terbufos and its degradates.

Acute Aggregate Risk Assessment: Potential acute dietary risks from food sources alone do not exceed the Agency's level of concern. The most exposed subpopulation, non-nursing infants, consume 86% of the acute PAD at the 99.9th percentile of exposure, based on highly refined exposure estimates. However, when drinking water exposure concentrations, derived

from groundwater and surface water models, are added to the acute dietary risk assessment, the potential exists for acute dietary exposures through drinking water that exceed the acute DWLOCs, resulting in acute aggregate risks of concern.

Chronic Aggregate Risk Assessment: In the case of the food component of the chronic aggregate risk assessment, risks are well below the Agency's level of concern. No more than 9% of chronic PAD is consumed for infants. However, based on modeled estimates of terbufos concentrations in groundwater and surface water, the potential exists for chronic dietary exposures through drinking water that exceed the chronic DWLOCs, resulting in chronic aggregate risks of concern.

4. 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. Terbufos is not registered for use in residential settings so homeowner or non-occupational exposures are not expected. Occupational handlers of terbufos include individual farmers or growers who load and/or apply pesticides, and professional or custom agricultural applicators. Risk for all of the potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 are considered to not exceed EPA's risk concern.

a. Toxicity

The toxicity of terbufos is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for terbufos including a 28 day dermal toxicity study. The toxicological endpoints, and other factors used in the occupational risk assessment for terbufos are listed below in Table 5a. The endpoints selected for the dermal and inhalation risk assessments have been applied to both short-term and intermediate-term exposure scenarios.

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

Assessment	Dose	Endpoint	Study	Absorption factor
Short-term and Intermediate-Term dermal	Counter 15G: NOAEL = 0.32 mg/kg/day	plasma and brain ChE inhibition	28-day dermal toxicity study in rats using Counter 15G (MRID 44520501)	NA[1]
	Counter CR: NOAEL = 2.0 mg/kg/day	plasma and RBC ChE inhibition	28-day dermal toxicity study in rats using Counter CR (MRID 44690501)	
Short-term and Intermediate-term inhalation	NOAEL = 0.0035 mg/kg/day[2]	Red blood cell, plasma, and brain ChE inhibition	90-day subchronic inhalation study in rats (MRID 00258710)	100%

[1]A dermal absorption factor is not required for terbufos since product-specific data were available from two dermal toxicity studies.
[2]Calculated as follows: 0.00001 mg/L x 100% absorption x 43.5 L/hr/kg for rat strain x 8 hour duration x 1 activity factor = 0.0035 mg/kg/day.

In acute toxicity studies, terbufos exhibits severe acute toxicity via the oral, dermal, and inhalation routes of exposure (Table 5b). Terbufos is also considered to be a severe eye and dermal irritant, although dermal and eye irritant assessments were not possible due to death of all test animals within 24 hours of exposure in the eye and dermal irritation studies. The dermal sensitization study was waived due to lethality.

Table 5b. Acute Toxicity Profile for Occupational Exposure for terbufos

Route of Exposure	Toxicity Category	Category Basis	Study Type and Results	MRID No.
Oral	I	$LD_{50} \leq 50$ mg/kg	Acute oral toxicity study in rats, $LD_{50} \approx 1.5$ mg/kg	00029863
Dermal	I	$LD_{50} \leq 200$ mg/kg	Acute dermal toxicity study in rabbits, $LD_{50} = 0.87$ mg/L males and females	00258710
Inhalation	I	$LC_{50} \leq 0.05$ mg/L	Acute inhalation study in rats, $LC_{50} = 1.7$ μg/L	41538101
Eye Irritation	I	Corrosive	Primary eye irritation study in rabbits, all animals died within 24 hrs of exposure	00044957
Dermal Irritation	I	Corrosive	Primary skin irritation study in rabbits, all animals died within 24 hrs of exposure	00044957
Dermal Sensitizer	NA	NA	Waived due to lethality	NA

b. Exposure

Two chemical- and scenario-specific occupational exposure studies were submitted to support the terbufos reregistration:

1) Exposure of farm workers to terbufos while loading Counter 15G with a Lock-N-Load closed handling system and applying Counter 15G to corn at planting time (closed cab applications) (MRID 44793301, Exhibit 1).

2) Exposure of farm workers to terbufos while loading Counter CR from open bags and applying to corn at planting time (open cab applications) (MRID 44793301, Exhibit 2).

In addition, a method validation study (MRID 44793301) was submitted to establish the parameters for the analytical methods used in the occupational exposure studies. These studies were reviewed and accepted by the Agency, and are being used in the terbufos occupational risk assessment. The Agency also used the *Pesticide Handlers Exposure Database (PHED)* for risk characterization purposes to evaluate occupational risks at reduced levels of personal protection and engineering controls.

Generally, results from the occupational exposure studies indicate low exposures to loaders and applicators when using high levels of PPE and closed loading. Terbufos was not detected in many of the exposure scenarios for which it was monitored in the studies. A large percentage of the exposure values were either below the limit of detection (LOD) or limit of quantification (LOQ). Figures used to calculate unit exposure values in these cases were ½ the LOD or LOQ. Refer to the occupational risk assessment dated August 26, 1999, for additional information on results from these two studies.

When conducting occupational risk assessments, EPA usually combines chemical-specific data with PHED data to obtain a more robust data set. The terbufos worker exposure studies, however, have not been integrated with PHED because the Agency believes physical differences in the formulations and packaging preclude combining the data with PHED. The terbufos studies are also unique because they represent a slightly higher level of personal protection than is typically considered using PHED. In the study, an enclosed cab was used for application with the windows open in an attempt to simulate open cab conditions. In PHED, applicators in an enclosed cab only wear baseline PPE, however, in this study, applicators wore maximum personal protective equipment.

The Agency uses a concept known as *unit exposure* as the basis for job scenarios used to assess occupational exposures to pesticides. Unit exposures represent the estimated exposures a pesticide handler would receive when making a particular application. EPA has developed a series of unit exposures unique to each type of job scenario in PHED. For terbufos, unit exposures were calculated by the registrant from the occupational exposure studies representing the minimum, maximum, and geometric mean values. These values have been verified by the Agency, and are being used in the risk assessment to represent typical to maximum exposures. The geometric mean values (a measure of the central tendency of the data) are the closest

approximation of the unit exposure values, and are the values used to determine whether the exposures exceed the Agency's level of concern.

Anticipated use patterns, application methods, and range of application rates were derived from the current terbufos labeling. Application rates for crops specified on the terbufos labeling range from 1.3 to 2.0 lbs. a.i./A. A Special Local Need (SLN) registration in North Carolina allows use on corn up to 2.6 lbs a.i./A.

Because chemical- and scenario-specific occupational exposure studies are available for terbufos, the combinations of engineering controls and personal protective equipment (PPE) evaluated in the risk assessment are slightly different than combinations typically considered by the Agency. First, all Counter 15G is loaded using a Lock-N-Load, closed handling system, whereas Counter CR formulation is available in both Lock-N-Load packaging and open bags. Secondly, current terbufos labels require applicators and other handlers to wear coveralls over long-sleeved shirt and pants, waterproof gloves, chemical-resistant footwear plus socks, protective eye-wear, chemical-resistent headgear, a chemical-resistent apron, and a PF 10 APR respirator. The levels of protection that form the basis for the terbufos exposure calculations are:

- Baseline: Long-sleeved shirt and long pants, shoes and socks. [Note: This scenario was used only for exposure data developed using the Pesticide Handlers Exposure Database]
- Minimum PPE: Baseline + chemical resistant gloves and a dust/mist respirator with a protection factor of 5. [Note: This scenario was used only for exposure data developed using the Pesticide Handlers Exposure Database]
- Maximum PPE: Baseline + coveralls, chemical resistant gloves, and an air purifying respirator with a protection factor of 10. [Note: This scenario was used for exposure data developed using the Pesticide Handlers Exposure Database and Counter 20 CR chemical- and scenario specific exposure monitoring studies]
- Engineering controls: Engineering controls such as an enclosed cab tractor or closed loading system for granulars. [Note: This scenario was used only for exposure data developed using the Pesticide Handlers Exposure Database]
- Engineering controls + PPE: Engineering controls such as an enclosed cab tractor or closed loading system for granulars with associated PPE required by the WPS when engineering controls are used (e.g., apron and chemical resistant gloves). [Note: This scenario was used only for exposure data developed from

the Counter 15 G chemical- and scenario specific exposure monitoring studies]

A chemical can produce different effects depending on how long a person is exposed to it, how frequently any exposures occur, and the level of exposure. For terbufos, EPA completed occupational risk assessments for short- and intermediate-term duration, to reflect potential exposures from 1-30 days up to several months. Some applicators may apply terbufos over a period of weeks because they may need to cover large acreage, or they may be professional applicators completing numerous applications within a region. A chronic risk assessment was not conducted for terbufos because exposures of a chronic duration are not expected.

c. Occupational Handler Risk Summary

In the revised risk assessment, risks to handlers has been assessed using separate toxicological endpoints for both dermal and inhalation exposures because the dose levels at which effects occur differ depending on whether terbufos was deposited on the skin or inhaled. In addition, the Agency selected two sets of dermal endpoints to assess dermal exposures because the physical nature of each formulated product has different impacts on dermal toxicity. A single endpoint has been selected to assess inhalation exposures for both granular formulations because only a single study was available. The resulting risks (MOE values) were then added to obtain an overall risk for handlers that accounted for both dermal and inhalation exposures. These endpoints are believed to be appropriate for both short- and intermediate-term risk assessment. All the risk calculations for handlers completed in this assessment are included in Appendix A of the Occupational and Residential Exposure (ORE) Chapter dated August 26, 1999.

Analyses were conducted to determine the MOEs at typical and maximum application rates, and at typical and maximum acreage-treated for the different exposure scenarios. Each of these analyses is included in Appendix A, Tables 1-14 of the ORE Chapter. The following tables in this document, summarize the exposure scenarios at maximum application rates and acreage-treated.

1) Agricultural Handler Risk

For terbufos, combinations of target crops, application rates, acreage treated, and worker scenarios were assessed for short- and intermediate-term exposures for each of the end-use products. The Agency has some remaining risk concerns for exposure scenarios assessed for the Counter 15G and Counter 20CR formulations when used in a manner consistent with the parameters in the occupational exposure studies.

Counter 15G is only available in closed system packaging (i.e., Lock-N-Load) according to the registrant, and therefore the Agency did not assess other types of packaging for the product. The registrant used the occupational exposure study for Counter 15G, which was conducted using tractors with enclosed cabs and open windows, to extrapolate to an open cab application exposure scenario. The Agency does not believe this is a valid approach for

assessing open cab exposures for Counter 15G given the study's reliance on unrefined protection factors and since empirical data exist in PHED for this scenario. Instead, the Agency used this data to assess exposures for closed cabs scenarios even though the registrant believes the study represents open cab conditions. Current labels do not require the use of an enclosed cab during application. The occupational exposure study for Counter 20CR was conducted with open bag packaging and open cabs.

Based on the PHED data (maximum PPE), the Agency has risk concerns for loading and applying Counter 15G (Table 6). However, based on the chemical specific study, the Agency has risk concerns only for loading Counter 15G (Table 6). This study determined that applying 15G with a closed cab is not of concern.

The Counter 20CR formulation is available in open bag packaging and closed (Lock-N-Load) packaging. For Counter 20CR in open bag and open cab, the Agency also has risk concerns for some exposure scenarios (Table 7). There are no risk concerns when the Counter 20CR formulation is used in closed systems (Lock-N-Load) and open or closed cabs.

All the MOEs in the tables below are based on combined dermal and inhalation MOEs. The scenario numbers correspond to the scenario numbers detailed and discussed in Appendix A of the ORE Chapter. The current labels do not require an enclosed cab for application of terbufos. Thus the remaining risk concerns for Counter 15G are based on the chemical specific study for loading and PHED data (maximum PPE). For Counter 20CR, the remaining risk concerns are based on the chemical specific study. The scenarios with remaining risk concerns are:

(1b) Loading Counter 15G in closed system using the North Carolina SLN 2x rate on corn, the maximum rate/acreage on sugar beets, and the maximum rate/acreage on sorghum.;

(2b) Applying Counter 15G in open cabs (maximum PPE) using the maximum rate/acreage on corn, the North Carolina SLN 2x rate on corn, the maximum rate/acreage on sugar beets, and the maximum rate/acreage on sorghum.;

(1c) Loading Counter 20CR in open bags using the North Carolina SLN 2x rate on corn, the maximum rate and acreage on sugar beets, the maximum rate and acreage on sorghum.;

Table 6 describes the short- and intermediate-term MOEs derived from PHED and chemical specific data for Counter 15G exposure scenarios. Table 7 describes the short- and intermediate-term MOEs derived from the Agency's use of the chemical specific worker exposure studies for Counter 20CR.

It is notable that inhalation exposures are driving the Agency's risk concern for the occupational scenarios in question rather than dermal exposures. In addition, the risk concern for handlers using Counter on corn is associated with a North Carolina Special Local Need (SLN) registration. This use on corn is twice the labeled maximum rate (2.6 lbs a.i./A).

Table 6. Counter 15G, Agricultural Uses: Completed using PHED and chemical specific data, combined dermal & inhalation MOEs.

				Short-Term and Intermediate-Term MOEs	
Scenario	Crop Type	Rate	Acres	Maximum PPE (PHED data)	Eng. Controls (chemical specific data[1])
(1b) Loading Counter 15G formulation in lock-n-load containers	Corn	1.3	213	4.3	105.2
		2.6	213	2.1	52.6
		2.6	150	n.c.[2]	75
	Sugar Beets	1.96	213	2.8	69.8
		1.96	130	4.6	114
	Sorghum	1.96	213	2.8	69.8
		1.7	213	n.c.	81
(2b) Applying Counter 15G	Corn	1.3	213	5.3	314.4
		2.6	213	2.7	157.2
	Sugar Beets	1.96	213	3.5	208.6
	Sorghum	1.96	213	3.5	208.6

[1] For loading- Chemical-resistant apron over long pants, long sleeve shirt, shoes, socks, chemical-resistant gloves. For applying- Enclosed cabs
[2] Not calculated

Table 7. Counter CR, Agricultural Uses: Completed using chemical specific data, combined dermal & inhalation MOEs

				Short-Term and Intermediate-Term MOEs	
Scenario	Crop Type	Rate	Acres	Max. PPE[1] without respirator	Max. PPE[1] with respirator[2]
(1c) Loading Counter CR Formulation in Open Bags	Corn	1.3	213	13.0	128.7
		2.6	213	6.5	64.4
	Sugar Beets	1.96	213	8.6	85.4
		1.96	130	n.c.[3]	140
	Sorghum	1.96	213	8.6	85.4
		1.7	213	n.c.	98
(2c) Applying Counter 20 CR	Corn	1.3	213	687.0	5752.0
		2.6	213	343.5	2876.0
	Sugar Beets	1.96	213	455.7	3815.1

				Short-Term and Intermediate-Term MOEs	
Scenario	Crop Type	Rate	Acres	Max. PPE[1] without respirator	Max. PPE[1] with respirator[2]
	Sorghum	1.96	213	455.1	3815.1

[1] For loading- Apron over long pants, long sleeve shirt, shoes, socks, and chemical-resistant gloves.
For applying- Coveralls over long pants, long sleeve shirt, shoes, socks, and chemical-resistant gloves.
[2] Respirator = PF 10
[3] Not calculated

2) Post-Application Occupational Risk

EPA does not believe there is a significant potential for post-application exposures to terbufos based on application methods, timing, and frequency. In addition, the Agency does not believe there is significant potential for drift into adjoining areas such as residential areas since the product is soil incorporated in granular form using ground equipment only. Terbufos use in residential areas is not permitted. Given these factors, the Agency concludes that the Restricted Entry Intervals (REIs) established under EPA's Worker Protection Standards (WPS) are sufficient to protect workers who may re-enter treated areas. The REI for areas treated with terbufos is 48 hours and 72 hours in areas where average annual rainfall is less than 25 inches per years.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For a detailed discussion on all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated August 26, 1999, available in the public docket, and supporting documents dated August 20 and August 5, responding to comments from the registrant and other stakeholders.

Several revisions have been made since the preliminary risk assessment was completed, and include:

- modifications to the ecological risk assessment and characterization, including an update of the Agency's aquatic and terrestrial incident database, based on information supplied by states, the registrant, and other stakeholders.

- consideration of new environmental fate data submitted on the abiotic hydrolysis and aerobic aquatic metabolism of parent terbufos and its degradates.

- revisions to the estimated concentrations of terbufos and its degradates in surface water and groundwater using the PRZM-EXAMS and SCI-GROW models;

- use of index reservoir and percent crop area modifications to the PRZM-EXAMS modeling, and the available environmental fate data for terbufos, to estimate terbufos and its degradates in surface water used for drinking water.

EPA has used the quotient method to evaluate potential risks to nontarget organisms from use of terbufos. Applying this method, risk quotients (RQs) have been calculated by comparing estimated concentrations of terbufos in the environment (or EECs) to results from ecological toxicity studies in a variety of organisms. A finding of concern results when an RQ exceeds a level of concern (LOC), which is a value calculated based on the category of nontarget organism and category of concern. EPA has further characterized the ecological risk to nontarget organisms for terbufos based on terrestrial field studies and adverse aquatic and terrestrial incidents reported to the Agency associated with the use of terbufos on corn.

1. Environmental Fate and Transport

The environmental fate database for terbufos is mostly complete, and provides a comprehensive understanding of terbufos fate and transport in the environment.

a. Degradation and Mobility

Based on a review of the environmental fate database for terbufos, total toxic residues of terbufos (parent + degradates) are considered to be highly mobile and persistent. Hydrolysis and microbial degradation are the primary dissipation processes for terbufos in the environment when it is incorporated into the soil as required by the current label. The linear metabolic half-life of parent terbufos in aerobic soil is approximately 27 days (5.6 days for non-linear). Under abiotic (i.e., not biological) conditions, the hydrolysis half-life for parent terbufos is 12.3 to 13.7 days in the typical range of environmental pH values (pHs 5,7, and 9). Volatilization may be a major dissipation route for the portion of parent terbufos that remains on the soil surface after incorporation. The relatively high vapor pressure (3.16×10^{-4} mm Hg) and the observed Henry's Law Constant (6.58×10^{-3}) suggest that some parent material will dissipate by diffusion into the atmosphere, but that the expected amount varies depending on site conditions and application methods.

The metabolites of toxicological concern, terbufos sulfoxide and terbufos sulfone, are more mobile and substantially more persistent than parent terbufos. Terbufos sulfoxide and sulfone have non-linear half-lives in aerobic soil of 116 and 96 days, respectively. These metabolites are also mobile in all tested soils with Freundlich K_{ads} values ranging from 0.40 to 2.93, and may reach groundwater when terbufos is used in locations where irrigation or rain water moves through the soil profile to groundwater. In addition, terbufos parent and its metabolites may reach surface water sources as a result of runoff events.

In the case of terbufos, EPA is concerned about the potential for parent terbufos and its two major degradates, terbufos sulfoxide and sulfone, to runoff to surface water sources, and the potential for the degradates to leach to groundwater sources. The PRZM-EXAMS model was used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. Although some monitoring data for terbufos were available, these data were deemed of limited value for several reasons, including that the degradates of concern were typically not included as part of the analyses.

The data inputs used in the PRZM-EXAMS model were based on results from an aerobic aquatic metabolism study in pond water for parent terbufos and the terbufos sulfoxide and sulfone degradates (MRID 44862502). EPA used these data to determine the expected persistence of parent terbufos and terbufos sulfoxide and sulfone in water, and the formation rate of terbufos sulfone from applied sulfoxide. Terbufos parent degraded with a half-life of 1.5 days using non-linear analysis in nonsterile pond water, and reached nondetectable levels by 7 days. Applied terbufos sulfoxide degraded with a half life of 68 days and declined to 50-62 percent by 30 days (end of study). Applied terbufos sulfone degraded with a calculated half-life of 32 days and declined to 39-43 percent by 30 days.

EPA did not use the results from the abiotic hydrolysis study (MRID 44862501) for estimating concentrations of terbufos in surface water since the aerobic metabolism data were deemed to be more relevant. However, for groundwater, the hydrolysis data provided useful information on the persistence and degradation products in the event terbufos were to reach groundwater sources.

b. Field Dissipation

The database for field dissipation is complete. The terrestrial field data submitted indicate that terbufos dissipated in the field with half-lives of 24 days in sandy loam in California, and 14-40 days in loamy and sandy loam soils in Illinois and Colorado. These half-lives are comparable to findings from the aerobic soil metabolism study discussed above (half-life 27 days). Data from the open scientific literature (Felsot, et al., 1987) reported half-lives of 11-16 days for parent terbufos and total toxic residue half-lives of 25-28 days in silt loam and silty clay loam soils in the field when terbufos was applied at a rate of 1.0 lb a.i./Acre.

2. Risk to Birds and Mammals

Terbufos presents high acute and chronic risks to non-target terrestrial wildlife species. This is based on a weight of evidence evaluation from laboratory and field studies and adverse incidents in the field, some of which were associated with misuse/misapplication. Granular pesticides, such as the terbufos formulations, present a unique hazard to wildlife in that the granules may be ingested directly by birds foraging for seed and grit at or below the soil surface. Birds and mammals may also ingest granules adhered to the surface of invertebrate prey, such as earthworms and grubs, or through ingestion of water or food sources contaminated with terbufos.

All currently registered uses of terbufos pose acute risks of concern based on the Agency's standard LOC criteria. Acute RQs for avian species ranges from 1.3 to 32.0 and for mammalian species from 2.2 to 327. The ranges provided reflect differences in the application method and rate, and size of the bird or mammal. Both acute avian and mammalian risks exceed the Agency's LOC of 0.5, indicating potential risks of concern to terrestrial organisms. Acute RQs associated with banded applications tend to be greater than RQs calculated for other application methods (e.g., in-furrow) due to less efficient soil incorporation. The database to assess risk to birds and mammals is complete.

3. Risk to Aquatic Species

The Agency is concerned about potential adverse effects to nontarget aquatic species, based on the Agency's aquatic LOC assessment, which is strongly supported by fish kill incidents associated with the use of terbufos on corn. No aquatic field studies are available. The basis for the Agency's aquatic risk concern is summarized below. The database to assess risk to aquatic species is complete.

a. Aquatic LOC Assessment

Acute and chronic RQs calculated for terbufos and its degradates exceed the Agency's level of concern. Acute and chronic RQs that exceed the Agency's acute LOC of 0.5 and chronic LOC of 1.0, respectively, are considered to be a risk concern. The acute RQs calculated for terbufos and its degradates using banded applications range from 3-17 for fish, and 14-60 for invertebrates. The chronic RQs calculated for terbufos and its degradates using banded applications range from 2-8 for fish and 113-403 for invertebrates. The ranges in RQs are due to the different application rates and EEC values for the crops.

The Agency's consideration of the total toxic residue of terbufos (parent + degradates) raises the acute EECs and RQs by a factor of 2.5-3X, and raises the chronic EECs and RQs by a factor of 15 - 50X. The greater increase for the chronic results may be due to the persistence of the degradates. As indicated above, the surface water EECs calculated by the Agency are based on measurements obtained from an aerobic aquatic metabolism study on terbufos parent and the terbufos sulfoxide and sulfone degradates.

Note that for application methods other than banded, the Agency's estimated exposures equal zero. However, fish kills associated with other methods of application (i.e., in-furrow) on corn suggest that runoff can be associated with in-furrow applications to all three labeled uses, corn, sugarbeets, and sorghum. The PRZM-EXAMS model used by EPA to estimate concentrations of terbufos and its degradates in surface water may not adequately represent the availability of the pesticide for runoff under all conditions.

b. Aquatic Incidents

Terbufos is the leading cause of fish kill incidents reported to EPA for any pesticide applied to corn, and ranks fourth in fish kill incidents reported to EPA for any pesticide applied to any crop. From 1976 to present, 96 fish kill incidents involving terbufos have been reported to the Agency, mostly by the registrant under FIFRA 6(a)(2), adverse effects reporting requirements. A causal relationship between terbufos and fish kills has not been fully established in all of the incidents.

The average rate of incidents is about 4 per year, although in any given year the number of incidents reported can fluctuate broadly. For example, 3 incidents occurred in 2000; zero incidents were reported for 1999, 4 in 1997, and 18 incidents were reported for 1990. The Agency does not consider the aquatic incidents involving terbufos to be an exhaustive

accounting of all the incidents. The following summarizes some other key points concerning the incidents. Refer to the environmental assessment and addenda for additional details.

- All the incidents reported to the Agency are associated with the corn use, involve all methods of application, and both granular formulations (Counter 15G and Counter CR).

- About 85 percent of the incidents to date have occurred in the midwest, corn belt region (Iowa, Indiana, Illinois, Nebraska, Ohio). Some incidents have occurred in North Carolina.

- Most of the incidents occurred in static water bodies ("farm ponds") ranging in size from 2 to 20 acres; some occurred in canals feeding into rivers.

- Incidents generally occurred from 2 days to 3 weeks after application.

- Incidents were reported on property not owned by the applicator/farmer, in recent cases, and involve reports of substantial economic loss, impacts to quality of life, pet mortality, and concerns about health of people swimming in impacted lakes and ponds.

- Individual incidents indicate a broad range of mortality; from 30 up to 90,000 fish mortalities. On average 3,600 mortalities were reported per incident based on data from 1976 to 1998. Nineteen incidents reported greater than 1,000 mortalities.

- 51% of the incidents were defined as highly probable or probable where terbufos and/or its degradates were identified from water analysis of impacted surface water bodies or there was adequate information on the application of the chemical. 46% of the incidents were defined as possible where either no water analysis was conducted or the water was analyzed only for the parent. In many of these instances terbufos was the only pesticide reported as being used near/adjacent to the incident site. 3% of the incidents were due to misapplication.

- In a limited number of cases, in the early 1990's, it appears that pasture/grass buffer strips or setbacks did not prevent incidents.

- Most of the incidents appear to be associated with normal use.

- In some of the incidents, rainfall was reported as occurring over a period of days to weeks prior to the incident. Based on the limited weather information provided, the Agency believes the incidents could be associated with normal spring rain events, as opposed to unusually severe rainfall events over a short period of time.

4. Endangered Species

The Agency has initiated three consultations with the Fish and Wildlife Service (FWS) on the potential effects of terbufos corn use on endangered and threatened species. To date, the FWS has issued two Biological Opinions. In these Opinions, the FWS found jeopardy for 13 fish species, 25 aquatic invertebrate species, and 4 insect species. An additional 15 fish species and 2 aquatic invertebrate species were expected to be affected, but not jeopardized. The FWS also found jeopardy for one avian species due to the potential effects of reducing its aquatic food source. These consultations and the findings expressed in the Opinions, however, are based on old labels and application methods, less refined risk assessment procedures, and an older approach to consultation which is currently being revised through interagency collaboration.

EPA's current assessment of ecological risks uses both more refined methods to define ecological risks of pesticides and new data, such as that for spray drift. Therefore, the Reasonable and Prudent Measures (RPMs) in the Biological Opinion(s) may need to be reassessed and modified based on these new approaches.

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

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 terbufos active ingredients.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient terbufos , as well as a terbufos-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 terbufos, EPA has sufficient information on the human health and ecological effects of terbufos to make an interim decisions as part of the

tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that terbufos products are eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) cumulative risks considered for the organophosphates support a final reregistration eligibility decision. 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 terbufos, and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet considered cumulative risks 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 terbufos. Based on its current evaluation of terbufos alone, the Agency has determined that terbufos 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 terbufos.

At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For terbufos, if all changes outlined in this document are incorporated into the labels, then all current risks will be adequately managed. But, because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for terbufos 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 mitigation measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

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

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

B. Summary of Phase 5 Comments and Responses

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. These comments in their entirety are available in the docket. The Agency received comments and a risk mitigation proposal from the registrant, BASF Corporation. The International Banana Association also sent comments on the risk assessment and USDA commented on ecological risks of terbufos. The Agency also received 113 comments from various agri-business companies and associations, commodity companies, farm bureaus, universities, extension, and state agencies, as well as private citizens, supporting the use of terbufos. Comments opposing the use of terbufos were received from the Defenders of Wildlife and a private citizen. The Agency also received six comments on fish kill incidents attributed to terbufos.

BASF Corporation submitted various comments pertaining to the Occupational and Residential Revised Risk Assessment. Some of the comments are included below and a complete response to the comments can be found in the public docket.

Comment

BASF found acceptable MOE's in their worker exposure studies with Counter 20C. This differs from the Agency's assessment.

Response

The Agency does not concur with BASF's findings and states that if is not clear from the registrants letter what input values were used to calculate the risk values.

Comment

BASF objected to the Agency's use of surrogate Pesticide Handlers Exposure Database (PHED) data instead of available high quality product specific exposure data.

Response

The Agency does not concur with this comment. The Agency did use chemical specific data from studies completed by American Cyanamid where appropriate and used PHED data in cases where there was a lack of chemical-specific data to calculate risks.

Comment

BASF objects to the Agency's failure to use the enclosed cab tractors with open windows scenario as an appropriate surrogate for open cab tractors.

Response

Review of the data shows that dermal exposure in the closed cab with open windows scenario is two orders of magnitude less than PHED exposures with open cabs. Therefore, the Agency feels closed cab tractors with open windows is more analogous to closed cabs than open cab tractors. This data was used to assess worker risk for enclosed cab scenarios.

Comment

BASF states that the EPA used 180 acres per day for corn in the chlorethoxyfos assessment, a chemical with the same use pattern as terbufos. In addition, 180 acres is an appropriate maximum estimate given that it is likely that the exposure is shared by two people an average of 20% of the time.

Response

The Agency has used the acreage estimates from the corn cluster analysis for several years and cannot substantiate why a different value was used for chlorethoxyfos. However, 180 acres was included in the Occupational and Residential Exposure chapter to allow for a more informed risk management decision.

The International Banana Association (IBA) also sent a comment pertaining to the Agency's use assumptions for terbufos in bananas. Some of the comments are included below and a complete response to the comments can be found in the public docket.

Comment

The IBA calculated that 10.9% of a banana crop is treated with terbufos whereas the Agency calculated the figure to be 26%.

Response

The Agency has reviewed the IBA proposal and concluded that this is not a valid approach for assessing percent crop treated. The dietary risk from food was not a concern for terbufos even with the 26% figure.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

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

EPA has determined that risk from exposure to terbufos is within its own "risk cup." In other words, if terbufos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for terbufos 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, residential uses, and drinking

water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to terbufos "fit" within the individual risk cup. Therefore, with the exception of corn, pop fodder, the terbufos tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is considered. The tolerance for corn, pop, fodder, has been revoked because it is no longer a significant food item.

b. Tolerance Summary

In the individual assessment, tolerances for residues of terbufos in/on plant commodities [40 CFR §180.352] are presently expressed in terms of the combined residues of terbufos [(S-((1, 1-dimethyl)thio)methyl) O, O-diethyl phosphorodithioate] and its cholinesterase-inhibiting metabolites [40 CFR §180.352(a)]. The Agency concludes that the tolerance expression should be stated in terms of " ...terbufos...and its phosphorylated (cholinesterase-inhibiting) metabolites:

- phosphorothioic acid, S-(t-butylthio)methyl O,.O-diethyl ester;
- phosphorothioic acid, S-(t-butylsulfinyl)methyl O,.O-diethyl ester;
- phosphorothioic acid, S-(t-butylsulfonyl)methyl O,.O-diethyl ester;
- phosphorodithioic acid, S-(t-butylsulfinyl)methyl O,.O-diethyl ester;
- phosphorodithioic acid, S-(t-butylsulfonyl)methyl O,.O-diethyl ester;

The chemical name for terbufos specified in 40 CFR §180.352(a) is incorrect, and should be revised to read as "phosphorodithioic acid, S-(t-butylthio)methyl O, O-diethyl ester."

Tolerances Listed Under 40 CFR §180.352(a):

The tolerances listed in 40 CFR §180.352(a) are for residues of terbufos and its cholinesterase-inhibiting metabolites. Please note that several of the commodity definitions will need to corrected to conform with current definitions.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.352(a) for: bananas, beets, sugar, roots; beets, sugar, tops; corn, field, fodder; corn, field, forage; corn, pop, fodder; corn, pop, forage; corn, grain; corn, sweet, (K+CWHR); corn, sweet, forage; corn, sweet, fodder; sorghum, fodder, sorghum, forage, and sorghum, grain. Certain commodity definitions of the above tolerances are not in accordance with the current definitions and therefore need to be updated.

An adequate method is available for data collection and enforcement of terbufos tolerances in or on plant commodities. The GLC/flame ionization-detection method for determining terbufos and its phosphorylated metabolites is described in PAM, Vol. II, as Method I. The hazardous reagent benzene is specified in this method.

Method M-1754, a modification of Method I in PAM that substitutes acetone for benzene and methylene chloride for chloroform, underwent a successful Residue Analytical Laboratory method validation trial and was forwarded to FDA for revision of PAM, Vol II.

Table 8a. Tolerance Summary for Terbufos.

Commodity	Current Tolerance, ppm	Tolerance Reassessment*, ppm	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §352			
Bananas	0.025	0.025	Banana
Beets, sugar, roots	0.05(N)	0.05	The negligible residue residue (N) should be deleted. beet, sugar, roots
Beets, sugar tops	0.1	0.1	beet, sugar, tops
Corn, field, fodder	0.5	0.5	corn, field, stover
Corn, field, forage	0.5	0.5	NA
Corn, pop, fodder	0.5	0.5	corn, pop, stover
Corn, pop forage	0.5	revoke	NA
Corn, grain	0.05(N)	0.05	The tolerance for "Corn, grain" should be replaced with separate tolerances for *corn, field, grain* and *Corn, pop, grain*. The negligible residue residue (N) should be deleted
Corn, sweet (K=CWHR)	0.05(N)	0.05	corn, sweet, kernel plus cob with husks removed The negligible residue residue (N) should be deleted
Corn, sweet, forage	0.5	0.5	NA
Corn, sweet, fodder	0.5	0.5	corn, sweet, stover
Sorghum, fodder	0.5	0.5	sorghum, grain, stover
Sorghum, forage	0.5	0.5	sorghum, grain, forage
Sorghum, grain	0.05	0.05	sorghum, grain, grain

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

Codex Maximum Residue Limits (MRLs) for the sum of terbufos, its oxygen analog and their sulfoxides and sulfones, expressed as terbufos, have been established for a number of plant and animal commodities. The Codex definition is compatible with the recommended revision to the U.S. Tolerance definition, which specifically names terbufos, its oxygen analog, and their sulfoxides and sulfones.

No questions of compatibility exist with respect to commodities where: (i) no Codex MRLs have been established but U.S. Tolerances exist; and (ii) Codex MRLs have been established but U.S. Tolerances do not exist. Tolerances in such commodities as maize (corn), popcorn, and sweet corn cannot currently be harmonized with CODEX tolerances; although both U.S. and Codex tolerances in these commodities are based on the limit of detection (LOD), the LOD under the CODEX system is 0.01 ppm, while the LOD under the U.S. system is 0.05 ppm.

Table 8b. Codex MRLs and Applicable U.S. Tolerances.

Commodity		MRL (Step) (mg/kg)	Reassessed U.S. Tolerance (ppm)
Codex definition	Reassessed U.S. definition		
Fodder beet leaves or tops	beet, sugar, tops	1 (5/8)	0.1
Maize	corn, field, grain	0.01 (5/8)	0.05
Maize forage	corn, field, forage	1 (5/8)	0.5
Popcorn	corn, pop, grain	0.01 (5/8)	0.05
Straw and fodder (dry) of cereal grains	corn, field, stover corn, pop, stover corn, sweet, stover sorghum, grain, stover	1 (5)	0.5 0.5 0.5 1
Sugar beet	beet, sugar, roots	0.1 (5)	0.05
Sweet corn (corn-on-the-cob)	corn, sweet, kernel plus cob with husks removed	0.01 (5)	0.05

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

3. Labels

A number of label amendments, in addition to the existing label requirements, are necessary in order for terbufos products to be eligible for reregistration. The Agency has determined that these measures, in addition to the existing label requirements, will adequately reduce risks to handlers.

Provided the following risk management measures are incorporated in their entirety into labels for terbufos-containing products, the Agency finds that all currently registered uses of terbufos are eligible for interim reregistration, pending consideration of cumulative risks of the organophosphates. The regulatory rationale for each of the risk management measures outlined below is discussed immediately after this list of required risk management measures.

a. Agricultural Use Exposure Reduction Measures

For agricultural use, the following measures are required, in addition to the existing labeling requirements to address drinking water, occupational handler and ecological risks of concern. The registrant has agreed to these measures.

- Amend the North Carolina SLN registration of Counter 20CR to require the use of a closed loading system.
- Require that the Counter 15G label be amended to indicate that applications must be made using enclosed cab tractors.
- Reduce the application rate on sorghum from 1.96 lbs. a.i. per acre to 1.70 lbs. a.i. per acre.
- Require a 500 ft. vegetative buffer between treated area and surface water on neighboring land
- Require a 500 ft. vegetative buffer between a standpipe drain outlet and surface water on neighboring land.
- Require a 66 ft. setback between the treated area and entry points to surface water bodies on non-highly erodible soils
- Require a 300 foot setback between the treated area and entry points to surface water bodies on highly erodible soils.
- Require a 66 ft. setback between treated area and standpipes on terraced fields as well as 66 ft. vegetative buffer between the tile outlet and surface water bodies
- Restrict loading, rinsing, and washing equipment within 300 ft. from surface water bodies or within 50 ft. from wells unless conducted on an impervious surface.
- Remove the "over the top" application for European corn borer control on corn.
- Require placing granules for banded applications on corn in a 7 inch band over the row, in front of the press wheel, and incorporated into the top 1 inch of soil.

- To prevent the flow of rainfall down planted rows, the label text will be required to read "To prevent channeling of surface water run-off, adjust the planter row-cleaners appropriately to prevent rows lower in height than adjacent soil".

b. Homeowner Use Exposure Reduction Measures

There are no residential uses for terbufos.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of terbufos. Where labeling revisions are imposed, 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)

Acute dietary risk from food is below the Agency's level of concern – less than 100% of the acute PAD is used. For the most exposed subgroups, non-nursing infants and infants (< 1 year), the percent acute PAD values are 86% and 82%, respectively, at the 99.9th percentile of exposure from consumption of food alone. No mitigation measures are necessary at this time to address acute dietary risk from food. Dietary risk from food consumption is estimated using anticipated residues from field trial data rather than residues from monitoring data. Anticipated residues are generally considered to be more conservative than monitoring data in terms of residue levels that consumers are exposed to in their diet. They represent maximum allowed treatment parameters and do not account for any reduction in pesticide residue levels that may occur from the time the crop is harvested until it is consumed. Additionally, the exposures are based largely on residue values from field trial data below the limit of detection (LOD), between the LOD and limit of quantitation (LOQ), or at the LOQ for which the Agency assumed residues to be one half of the LOD. It should be noted that the available PDP monitoring data, while not appropriate for the purposes of quantitative risk assessment, showed no detections of terbufos or terbufos sulfone residues in over 100 samples of sweet corn. This suggests that the acute dietary assessment is based on conservative exposure values that likely overstate risk.

2) Chronic Dietary (Food)

Chronic dietary risk from food alone is well below the Agency's level of concern. For the most exposed subgroups, infants, the percent chronic PAD values are 9% or less. No mitigation measures are necessary at this time to address chronic dietary risk from food.

3) Drinking Water

The acute and chronic dietary risks from drinking water exposure are above the Agency's level of concern for most subpopulations. However, there are uncertainties which lead the Agency to expect that exposure from drinking water is unlikely to be as high as the levels used in the development of the risk assessment. Based on these uncertainties and the anticipated impacts on water resources from implementing the risk reduction measures contained in this document, the Agency believes that the risks from drinking water are not of concern.

The drinking water risk assessments are based on screening level models that are conservative in their estimates of drinking water exposure. Actual exposure is expected to be lower than the EEC's reported in the IRED. An example of the type of assumptions used in the model that can contribute to conservative estimates involves rainfall levels. To determine what rainfall level to use in the model, the Agency identifies a peak rainfall level for each of 36 years of daily rainfall data. The model then assumes that rainfall will equal the 90th percentile of these 36 annual peak values when estimating concentrations, a conservative assumption. Also, the percent cropped area (PCA) assumption for sugar beets and sorghum used in the model is 0.87, the default assumption. This means the model assumes that 87% of a watershed is planted with one of these crops and that 100% of this crop is treated with terbufos, which appears unlikely to occur especially considering that the PCA calculated for a major crop like corn using data submitted to the Agency is 0.46.

Further, although the available NAWQA monitoring data were deemed insufficient for the purpose of quantitative risk assessment primarily due to the failure to include metabolites of terbufos, these data yielded surface water concentrations that were lower than the results of the model. These levels ranged from 0.013 ppb to 0.56 ppb as compared to the model estimate for parent terbufos of 9.39 ppm.

To provide additional perspective, it should also be noted that the maximum ground water and surface water EEC's result from modeling terbufos use on sorghum. According to sales figures for 2000 provided by the registrant, sorghum accounts for approximately 1% of total terbufos use. The acute EEC's for corn which accounts for 90% of terbufos use are significantly lower at 4.8 ppb (ground water) and 8.44 (surface water).

In addition, as explained earlier, the DWLOC is calculated based on dietary risk from food consumption that is estimated using conservative exposure estimates (i.e. anticipated residues from field trials, etc.). Therefore, the Agency expects that the actual exposure from food is lower, which would result in additional space in the risk cup for residues in drinking water.

The risk reduction measures contained in this IRED, including the limitations on sales of terbufos, reducing the maximum application rate for sorghum, increasing the depth of incorporation of granules into the soil, removal of "over-the-top" applications, and the use of vegetative buffer strips between treated field and water bodies and other areas where water contamination could occur, particularly the use of a 500 foot buffer between a treated area and water resources on nearby lands which would include such things as reservoirs, are expected to provide improved protection of water resources from terbufos contamination. This supports the Agency's belief that drinking water risks will be reduced to a level at which the risk cup is not exceeded.

Finally, the Agency is requiring surface and ground water monitoring data to confirm the Agency's conclusions on dietary risks from drinking water. The Agency notes that drinking water monitoring studies are either planned or underway which will inform the Agency regarding its conclusions on levels of terbufos and its metabolites in drinking water. One of these studies is related to the Unregulated Contaminant Monitoring Rule under which the EPA is considering whether or not to set a drinking water standard for terbufos under the Safe Drinking Water Act. This study is monitoring the levels of chemicals, including terbufos, in over 300 drinking water plants across the United States. The other study is being sponsored by the American Crop Protection Association which will also monitor drinking water for pesticide residues. In order for these studies to be used the Agency will need to confirm that samples were taken from areas of terbufos use and during the time period when terbufos is used. Further, monitoring for the important degradates of terbufos, terbufos sulfoxide and terbufis sulfone, will need to be addressed.

b. Occupational Risk Mitigation

1) Agricultural Uses

EPA has risk concerns for occupational exposure scenarios assessed for the Counter 15G product, even when used in a manner consistent with the engineering control parameters from the occupational study. This assumes both use of a closed mixing and loading system (currently on labels) and enclosed cabs for application (not a current label requirement) . Specifically, handlers have risks of concern when loading Counter 15G at the 2x North Carolina SLN rate on corn and loading for sugar beets and sorghum at the maximum labeled rate (1.97 lbs ai/acre) and maximum acreage treated per day assumption of 213 acres. In addition, there are risks of concern when applying Counter 15G in open cabs (maximum PPE) using the maximum rate/acreage on corn, the North Carolina SLN 2x rate on corn, the maximum rate/acreage on sugar beets, and the maximum rate/acreage on sorghum. The Agency also has risk concerns for the scenario for 15G where application is made without a enclosed cab.

For application of Counter 15G, applicator risks are of concern at maximum PPE with MOEs ranging from 2.7-5.3. When an enclosed cab is used the MOEs range from 157-208 and are not of concern.

For loading of Counter 15G at the 2x North Carolina SLN rate on corn, the MOE is 53, a value below the target MOE of 100. This value is based on a maximum acreage treated/day of 213 acres. However, based on survey data from North Carolina, the Agency has determined the typical acreage treated per day to be 150 acres. The analysis conducted using this acreage assumption results in a MOE of 75. In addition, the Agency's benefits assessment determined there are currently no effective alternatives to terbufos for controlling billbugs in North Carolina fields with high organic matter soil. Therefore, considering that engineering controls are in place for this activity and there are significant benefits associated with this use, the Agency concludes that no additional exposure reduction is warranted.

The MOEs for loading Counter 15G on sugar beets at the maximum rate (1.97 lbs ai/acre) and acreage (213 acres) is also below the target MOE of 100. However, based on a survey the

Agency determined the acreage treated per day to be 130 acres for sugar beets. The analysis conducted using this acreage assumption results in an acceptable MOE of 114.

The MOEs for loading Counter 15G on sorghum at the maximum rate (1.97 lbs ai/acre) and acreage (213 acres) is below the target MOE of 100. The registrant has agreed to reduce the maximum application rate to 1.7 lbs ai/acre which would result in a MOE of 81. This does not reach the target MOE of 100, however, it is believed that reducing the rate further would reduce the chemical's efficacy against sorghum pests. The primary alternative to terbufos, aldicarb, is expensive compared to terbufos and the Agency has determined that choosing this alternative would reduce the growers net revenues by as much as 78% if used. In addition, other alternatives are not as efficacious in controlling wireworms, a pest of sorghum. Therefore, based on the benefits of terbufos use on sorghum, the Agency concludes that no additional exposure reduction is warranted.

For the Counter 20CR product, the Agency has some risk concerns when the product is handled in open bags. Specifically, the Agency is concerned about risks to agricultural workers handling Counter CR in open bags under the Special Local Need (SLN) registration in North Carolina and loading for sugar beets and sorghum. There are no risk concerns when Counter CR is handled in closed systems (Lock-N-Load) and open or enclosed cabs.

The MOE for handling Counter 20CR in open bags under the Special Local Need (SLN) registration, which permits terbufos use on corn at twice the labeled maximum application rate, is 64. This risk concern can be mitigated if the SLN registration is amended to require the use of closed loading systems. The North Carolina Department of Agriculture and Consumer Services, the department responsible for managing state registrations, and the registrant have agreed to amend the SLN registration to make this a requirement on the label.

The MOEs for loading Counter 20CR in open bags on sugar beets at the maximum rate (1.97 lbs ai/acre) and acreage (213 acres) are below the target MOE of 100. As with the Counter 15G product, a survey of acreage treated per day determined the maximum to be 130 acres for sugar beets which results in an acceptable MOE of 140.

The MOEs for loading Counter 20 CR in open bags on sorghum at the maximum rate (1.97 lbs ai/acre) and acreage (213 acres) are also below the target MOE of 100. BASF has agreed to reduce the maximum rate to 1.7 lbs ai/acre which gives a MOE of 98.

Table 11 describes the necessary PPE and engineering controls to mitigate worker risks.

Table 9. Agricultural Uses: Handler Risk Concerns and Mitigation

Scenario	PPE	Engineering Controls
Loading granular in lock-n-load containers (15G and 20 CR formulation)	long-sleeved shirt and long pants, shoes plus socks chemical-resistant gloves and chemical-resistant apron	lock-n-load container

Loading granular in open bags (20 CR formulation)	coveralls over long-sleeved shirt and long pants, chemical-resistant apron, chemical resistant gloves, chemical resistant footwear plus socks, and OV respirator	none
Applying 15G granular formulation	long-sleeved shirt and long pants, shoes plus socks	enclosed cab
Applying 20 CR granular formulation	coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical resistant footwear plus socks	none

2) Post-Application Risk

There is a low potential for occupational post-application exposure when pre-emergent insecticides are used. Terbufos is applied to the soil directly and is soil incorporated well before the crops are mature. The timing of the application of terbufos can greatly reduce the potential for post-application exposure. Also, most agricultural operations mechanically plant corn early in the season, which minimizes the potential for dermal contact. Minimal exposure during harvesting or any other late season activities is expected since terbufos is primarily applied pre-emergent. Therefore, the Agency does not require a post-application occupational exposure assessment (HED Exposure Science Advisory Council Policy No. 008). The REI for crops treated with terbufos is 48 hours and 72 hours in areas where average annual rainfall is less than 25 inches per years. Early entry PPE for crops treated with terbufos is: coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves made of any waterproof material, chemical-resistant footwear plus socks, and protective eyewear.

c. Homeowner Risk Mitigation

Terbufos is not registered for use in residential settings.

2. Environmental Risk Mitigation

The Agency has determined that these risks can be reduced to an acceptable level taking into consideration the benefits by a reducing the total amount of terbufos that can be applied through imposing an annual sales cap and buffers. The registrant has agreed to a phased approach that will ultimately reduce sales of terbufos by more than 55% by 2008 based on 2000 sales figures. By reducing the amount of terbufos applied in this way the Agency expects that risks to aquatic and terrestrial organisms will be reduced.

The buffers to be implemented are; 1) a 500 ft. vegetative buffer between treated area and surface water on neighboring land, 2) a 500 ft. vegetative buffer between a standpipe drain outlet and surface water on neighboring land, 3) a 300 ft. setback between the treated area and entry points to surface water bodies on highly erodible soils and 66 ft. on non-highly erodible soils, 4) a 66 ft. setback between treated area and standpipes on terraced fields as well as 66 ft. vegetative buffer between the tile outlet and surface water bodies, and 5) restricting loading, rinsing, and washing equipment within 300 ft. from surface water bodies or within 50 ft. from wells unless

conducted on an impervious surface. All setbacks must be planted to a crop or seeded with grass or other suitable cover. Erosion potential of soils can be determined by consulting with the National Resource Conservation Service (NRCS).

In addition, the registrant has agreed to remove from its labels the "over the top" application on corn for european corn borer control. Banded applications on corn will also require placing granules in a 7 inch band over the row, in front of the press wheel, and incorporated into the soil to a depth of 1 inch. To prevent the flow of rainfall down planted rows, the label text will read "To prevent channeling of surface water run-off, adjust the planter row-cleaners appropriately to prevent rows lower in height than adjacent soil".

The Agency believes that the buffers and other changes in application methods described above will reduce the likelihood that terbufos will contaminate surface water. In so doing, non-target aquatic organisms, especially fish, would be less likely to be exposed to terbufos or its metabolites.

The registrant has also committed to voluntarily remove use from counties where multiple, verifiable fish kills occur in that county over a period of two or more years as the result of the use of terbufos in accordance with the risk management measures set forth in this document. The registrant will conduct product stewardship and educational efforts in counties where an incident occurs to address the cause of the incident and seek to prevent a second incident which would result in the discontinuation of use in that county.

3. Benefits Assessment

Both the preliminary and the revised human health and ecological risk assessments identified risks of concern for occupational handlers and terrestrial and aquatic non-target organisms. Since risks of concern in these areas are regulated under FIFRA's requirement that the Agency consider the risks and benefits of pesticide use in making its regulatory decision, the Agency has conducted a benefits assessment for use in determining the appropriate risk management steps to be taken to address these risks. This assessment was aimed at quantifying, to the extent possible, the benefits derived from the use of terbufos on corn primarily for control of corn rootworm.

The benefits of terbufos on corn were estimated using a comparative product performance assessment (BEAD Memo-Product Performance Assessment Methodology as Applied to Terbufos Use on Field Corn, 12/15/2000). This assessment relied on data from numerous product performance studies available in the open scientific literature. These data were analyzed using statistical methods to determine the relative effects on corn yields of using terbufos and other corn insecticides especially tefluthrin. The benefits assessment concluded that under most conditions the alternative insecticides produced similar or greater yields than fields where terbufos was used. Terbufos did show an advantage over the alternatives in controlling billbugs in North Carolina and controlling corn rootworm in the Northeast. Terbufos also performed more effectively on some secondary corn pests. However, there are uncertainties associated with the assessment that were taken into consideration when developing the risk management measures.

The benefits assessment was reviewed by several independent external experts and the United States Department of Agriculture. The registrant was also provided a courtesy copy. The university researchers who provided an independent peer review of the assessment to the Agency noted, in some instances, limitations or uncertainties that are associated with the assessment. These include the use of yields versus root ratings in determining benefits, the use of small plot studies to extrapolate to larger fields, and limitations of the statistical methods used to compare and analyze the available data sets.

The Agency considered the results of the benefits assessment together with the uncertainties present in the analysis when developing its risk reduction measures to address occupational and ecological risks especially with regard to determining the appropriate level for the sales limits considered to be a key aspect of risk management.

E. Other Labeling

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

1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, EPA puts basic toxicity and exposure data developed for REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticides uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. These Pamphlets are available for voluntary use by pesticide applicators, on EPA's web site at www.EPA.gov/espp . A final Endangered Species Protection Program, which may be altered from the interim program, is scheduled to be proposed for public comment in the Federal Register before the end of 2001.

V. What Registrants Needs to Do

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

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

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

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

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

Within the time limit specified in the generic DCI:

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

Please contact Eric R. Olson at (703) 308-8067 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

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

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

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

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

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

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

Within eight months from the receipt of the PDCI:

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

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

(3) five copies of the draft label incorporating all label amendments outlined in Table 12 of this document;

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

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

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

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

By US mail:
Document Processing Desk (PDCI/PRB)

By express or courier service only:
Document Processing Desk(PDCI/PRB)

Karen Jones
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

Karen Jones
Office of Pesticide Programs(7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

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

- Drinking water monitoring data for both surface and groundwater sources for terbufos and metabolite levels in corn, sorghum, and sugar beet growing regions. This data is requested in order to confirm that the levels of these compounds are lower than predicted in the Agency's water models (OPPTS 167-1-SS).

- Neurotoxic esterase (NTE) data on the hen to support the hen delayed neurotoxicity study. (OPPTS 870.6100)

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR 42945-42947, August 18 1999 64FR 44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies; due dates are 9/2001. Registrant responses are under review.

2. Labeling Requirements for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in Table 10 at the end of this section.

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 Requirements 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 Table 10 at the end of this section.

C. Existing Stocks

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

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

D. Required Labeling Changes Summary Table

Table 10: Summary of Required Labeling Changes for Terbufos		
Description	**Required Labeling**	**Placement on Label**
Manufacturing Use Products		
Formulation Instructions required on all MUP's	"Only for formulation into an insecticide for use on corn, sugar beets, and grain sorghum."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	**"Environmental Hazards**" "This chemical is highly toxic to aquatic organisms (fish and invertebrates) and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA"	Directions for Use

Description	Required Labeling	Placement on Label
End Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide	"RESTRICTED USE PESTICIDE" "Due to Acute Oral and Dermal Toxicity and Risks to Wildlife and Aquatic Organisms." "For retail sale to, and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's certification."	Top of front panel
Handler PPE requirements (all formulations)	Note the following information when preparing labeling for all end use products: For **sole-active-ingredient** end-use products that contain terbufos the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed. For **multiple-active-ingredient** end-use products that contain terbufos, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7. PPE that is established on the basis of Acute Toxicity testing with the end-use products must be compared with the active ingredient PPE specified below in this document. The more protective PPE must be placed in the product labeling. For example, the Handler PPE in this RED does not require protective eyewear which may be required by the Acute Toxicity testing for the end-use product. For guidance on which PPE is considered more protective, see PR Notice 93-7.	Precautionary Statements Under PPE Requirements

Description	Required Labeling	Placement on Label
PPE Requirements Established by the RED for the polymer based Granular Formulations (20 CR) **not** marketed in a closed loading system (Lock 'n Load), or any other system that meets the specifications of the WPS. Note: SLN products are not eligible for reregistration if they are **not** marketed in a closed loading system.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category [*registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." "Loaders applicators and other handlers must wear: – coveralls over long-sleeved shirt and long pants, – chemical resistant gloves, – chemical resistant footwear plus socks." "In addition to the above, loaders and persons cleaning equipment must wear: - chemical resistant apron - a non-powered air purifying cartridge respirator equipped with an organic vapor (OV) removing cartridge or canister plus an N-, R- or P- series filter." *Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.*	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Required Labeling	Placement on Label
PPE Requirements Established by the RED for the polymer based Granular Formulations (20 CR) marketed in a closed loading system (Lock 'n Load) or any other system that meets the specifications of the WPS. Note: SLN products are only eligible for reregistration if they are marketed in a closed loading system.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category [*registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." "Loaders must wear: - long-sleeved shirt and long pants, - shoes plus socks - chemical resistant gloves - chemical resistant apron" "See engineering controls for additional requirements" "Applicators and other handlers must wear: - coveralls over long-sleeved shirt and long pants, - chemical resistant gloves, - chemical resistant footwear plus socks." "In addition to the above, persons cleaning equipment must use a non-powered air purifying cartridge respirator equipped with an organic vapor (OV) removing cartridge or canister plus an N-, R- or P- series filter." *Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.*	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Required Labeling	Placement on Label
PPE Requirements Established by the RED for the clay based Granular Formulations (15 G) marketed in a closed loading system (Lock 'n Load) or any other system that meet the specifications of the WPS	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category [*registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." "Loaders and applicators must wear: - long-sleeved shirt and long pants, - shoes plus socks." "In addition to the above, loaders must wear: - chemical resistant gloves - chemical resistant apron." "See engineering controls for additional requirements." "Handlers engaged in those activities for which use of an engineering control is not possible, such as cleaning up a spill or cleaning or repairing contaminated equipment, must wear: - coveralls over long-sleeved shirt and long pants, - chemical resistant gloves, - chemical resistant footwear plus socks, - a non-powered air purifying cartridge respirator equipped with an organic vapor (OV) removing cartridge or canister plus an N-, R- or P- series filter." *Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.*	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Required Labeling	Placement on Label
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering controls for the polymer based Granular Formulation (20 CR) marketed in a closed loading system (Lock 'n Load) or any other closed system that meets the specifications of the WPS	**"Engineering Controls"** "This product is formulated into a Lock 'N Load system that meets the definition of a closed loading system in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. In addition to wearing the required PPE specified above, loaders must be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: coveralls, chemical resistant footwear plus socks, a non-powered air purifying cartridge respirator equipped with an organic vapor (OV) removing cartridge or canister plus an N-, R- or P- series filter." "When handlers use enclosed cabs, in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS." *Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.*	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the User Safety Requirements

Description	Required Labeling	Placement on Label
Engineering controls for the polymer based Granular Formulation (20 CR) **not** marketed in a closed loading system (Lock ‘n Load) or any other closed system that meets the specifications of the WPS	“When handlers use enclosed cabs, in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Description	Required Labeling	Placement on Label
Engineering Controls for the clay based Granular Formulations (15 G) marketed in a closed loading system (Lock 'n Load), that meets the specifications of the WPS	**"Engineering Controls**" "This product is formulated into a Lock 'N Load system that meets the definition of a closed loading system in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. In addition to wearing the required PPE specified above, loaders must be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: coveralls, chemical resistant footwear plus socks, a non-powered air purifying cartridge respirator equipped with an organic vapor (OV) removing cartridge or canister plus an N-, R- or P- series filter." "Applicators using motorized ground equipment must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, such applicators must: -- wear the personal protective equipment required above for applicators; -- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, and a non-powered air purifying cartridge respirator equipped with an organic vapor (OV) removing cartridge or canister plus an N-, R- or P- series filter; -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Description	Required Labeling	Placement on Label
User Safety Recommendations	**"User Safety Recommendations"** "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing*. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	**"Environmental Hazards**" "This pesticide is highly toxic to fish and wildlife and has been known to cause fish kills. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Keep out of lakes, ponds, and streams. Do not contaminate water when disposing of equipment wastewater or rinsate. See Directions for Use for required buffer zones or setbacks. 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. Cover, incorporate or clean up product that is spilled during loading or that is visible on the soil surface in turn areas. Do not apply in wet soil conditions that may prevent the equipment from covering pesticide granules. Do not apply in frequently flooded areas. Under certain field and weather conditions, terbufos and its degradates have a potential for runoff into surface water for several weeks post-application."	Precautionary Statements immediately following the User Safety Recommendations

Description	Required Labeling	Placement on Label
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. The REI is 72 hours in areas where average rainfall is less than 25 inches per year."	Directions for Use, Agricultural Use Requirements Box
Early Re-entry Personal Protective Equipment established by the RED.	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: - coveralls worn over long-sleeve shirt and long pants, - chemical-resistant gloves made of any waterproof material, - chemical-resistant footwear plus socks, and - protective eyewear"	
Notification Statement	"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."	Directions for Use, Agricultural Use Requirements Box
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or tribe, consult the agency responsible for pesticide regulation."	Place in the Direction for Use directly above the Agricultural Use Box.

Description	Required Labeling	Placement on Label
Other Application Restrictions	*Labels must be revised to reflect the reduced the application rate on sorghum from 1.96 lbs. a.i. per acre to 1.70 lbs. a.i. per acre.* *Labels must be revise to reflect the following loader and applicator requirements to minimize the potential for run-off to surface water:* "- maintain a 500 ft. vegetative buffer between treated area and surface water on neighboring land, - maintain a 500 ft. vegetative buffer between a standpipe drain outlet and surface water on neighboring land, - maintain a 66 ft. setback between the treated area and entry points to surface water bodies on **non**-highly erodible soils, - maintain a 300 ft. setback between the treated area and entry points to surface water bodies on highly erodible soils, - maintain a 66 ft. setback between treated area and standpipes on terraced fields as well as 66 ft. vegetative buffer between the tile outlet and surface water bodies. - No loading, rinsing, and washing equipment within 300 ft. from surface water bodies or within 50 ft. from wells unless conducted on an impervious surface. - all setbacks must be planted to a crop or seeded with grass or other suitable cover and all vegetative buffers must be seeded with grass or other suitable cover, - place granules in a 7 inch band over the row, in front of the press wheel, and incorporate into the top 1 inch of soil for banded applications on corn, - no over the top applications for European corn borer control, - to prevent channeling of surface water run-off, adjust the planter row-cleaners appropriately to prevent rows lower in height than adjacent soil."	Place in the Direction for Use Under Application Restrictions

Instructions in the Labeling Required section appearing in quotations represent the exact language that must appear on the label.

Instructions in the Labeling Required section not in quotes represents actions that the registrant must 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 August 7, 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 September 1, 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/op."

VI. APPENDICES

Appendix A. TABLE OF USE PATTERNS ELIGIBLE FOR REREGISTRATION

Site Application Type Application Timing Application Equipment	Formulation	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Minimum Spray Interval (days)	Preharvest Interval, (days)	Reentry Interval (days)	Use Directions and Limitations
Food/Feed Crop Uses								
Corn, field, pop, sweet								

Site Application Type Application Timing Application Equipment	Formulation	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Minimum Spray Interval (days)	Preharvest Interval, (days)	Reentry Interval (days)	Use Directions and Limitations
Banded, In furrow At plant Ground	15% granular 20% granular	1.3 lb/A	1	1.3 lb/A	NA[1]	NA	2 days	Buffers to be implemented are; 1) a 500 ft. vegetative buffer between treated area and surface water on neighboring land, 2) a 500 ft. vegetative buffer between a standpipe drain outlet and surface water on neighboring land, 3) a 66 ft. setback between the treated area and entry points to surface water bodies on non-highly erodible soils and 300 ft. on highly erodible soils, 4) a 66 ft. setback between treated area and standpipes on terraced fields as well as 66 ft. vegetative buffer between the tile outlet and surface water bodies, 5) restricting loading, rinsing, and washing equipment within 300 ft. from surface water bodies or within 50 ft. from wells unless conducted on an impervious surface, 6) remove the "over the top" application for European corn borer control, 7) require placing granules for banded applications on corn in a 7 inch band over the row, in front of the press wheel, and incorporate into the top 1 inch of soil, and 8) the label text will be required to read "To prevent channeling of surface water run-off, adjust the planter row-cleaners appropriately to prevent rows lower in height than adjacent soil". All setbacks must be planted to a crop or seeded with grass or other suitable cover. Require that the Counter 15G label be amended to indicate that applications must be made using enclosed cab tractors. Amend the North Carolina SLN registration of Counter 20CR to require the use of a closed loading system.
Sorghum, grain								

Site Application Type Application Timing Application Equipment	Formulation	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Minimum Spray Interval (days)	Preharvest Interval, (days)	Reentry Interval (days)	Use Directions and Limitations
Banded, Knifed In At bedding, at plant Ground	15% granular 20% granular	1.7 lb/A	1	1.7 lb/A	NA	NA	2 days	Buffers to be implemented are; 1) a 500 ft. vegetative buffer between treated area and surface water on neighboring land, 2) a 500 ft. vegetative buffer between a standpipe drain outlet and surface water on neighboring land, 3) a 66 ft. setback between the treated area and entry points to surface water bodies on non-highly erodible soils and 300 ft. on highly erodible soils, 4) a 66 ft. setback between treated area and standpipes on terraced fields as well as 66 ft. vegetative buffer between the tile outlet and surface water bodies, 5) restricting loading, rinsing, and washing equipment within 300 ft. from surface water bodies or within 50 ft. from wells unless conducted on an impervious surface, 6) the label text will be required to read "To prevent channeling of surface water run-off, adjust the planter row-cleaners appropriately to prevent rows lower in height than adjacent soil". All setbacks must be planted to a crop or seeded with grass or other suitable cover. Require that the Counter 15G label be amended to indicate that applications must be made using enclosed cab tractors.
Sugar beets								

Site Application Type Application Timing Application Equipment	Formulation	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Minimum Spray Interval (days)	Preharvest Interval, (days)	Reentry Interval (days)	Use Directions and Limitations
Banded, Modified In furrow, Knifed In At plant Ground	15% granular 20% granular	1.97 lb/A	1	1.97 lb/A	NA	NA	2 days	Buffers to be implemented are; 1) a 500 ft. vegetative buffer between treated area and surface water on neighboring land, 2) a 500 ft. vegetative buffer between a standpipe drain outlet and surface water on neighboring land, 3) a 66 ft. setback between the treated area and entry points to surface water bodies on non-highly erodible soils and 300 ft. on highly erodible soils,4) a 66 ft. setback between treated area and standpipes on terraced fields as well as 66 ft. vegetative buffer between the tile outlet and surface water bodies, 5) restricting loading, rinsing, and washing equipment within 300 ft. from surface water bodies or within 50 ft. from wells unless conducted on an impervious surface, 6) the label text will be required to read "To prevent channeling of surface water run-off, adjust the planter row-cleaners appropriately to prevent rows lower in height than adjacent soil". All setbacks must be planted to a crop or seeded with grass or other suitable cover. Require that the Counter 15G label be amended to indicate that applications must be made using enclosed cab tractors.
Non-Food/Non-Feed Crop Uses								
Corn, field grown for seed								

Site Application Type Application Timing Application Equipment	Formulation	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Minimum Spray Interval (days)	Preharvest Interval, (days)	Reentry Interval (days)	Use Directions and Limitations
Banded, In furrow At plant Ground	15% granular 20% granular	1.3 lb/A	1	1.3 lb/A	NA	NA	2 days	Buffers to be implemented are; 1) a 500 ft. vegetative buffer between treated area and surface water on neighboring land, 2) a 500 ft. vegetative buffer between a standpipe drain outlet and surface water on neighboring land, 3) a 66 ft. setback between the treated area and entry points to surface water bodies on non-highly erodible soils and 300 ft. on highly erodible soils, 4) a 66 ft. setback between treated area and standpipes on terraced fields as well as 66 ft. vegetative buffer between the tile outlet and surface water bodies, 5) restricting loading, rinsing, and washing equipment within 300 ft. from surface water bodies or within 50 ft. from wells unless conducted on an impervious surface, 6) remove the "over the top" application for European corn borer control, 7) require placing granules for banded applications on corn in a 7 inch band over the row, in front of the press wheel, and incorporate into the top 1 inch of soil, and 8) the label text will be required to read "To prevent channeling of surface water run-off, adjust the planter row-cleaners appropriately to prevent rows lower in height than adjacent soil". All setbacks must be planted to a crop or seeded with grass or other suitable cover. Require that the Counter 15G label be amended to indicate that applications must be made using enclosed cab tractors. Amend the North Carolina SLN registration of Counter 20CR to require the use of a closed loading system.

[1] NA: Not applicable

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 terbufos covered by this RED. It contains generic data requirements that apply terbufos 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 Terbufos

New Guideline Number	Old Guideline Number	REQUIREMENT	USE PATTERN	CITATION(S)
		PRODUCT CHEMISTRY		
830.1550	61-1	Product Identity and Composition	All	43147501, 41297901
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	41049501
830.1670	61-2B	Formation of Impurities	All	41049501
830.1700	62-1	Preliminary Analysis	All	41297902
830.1750	62-2	Certification of limits	All	43147502, 41297902
830.1800	62-3	Analytical Method	All	43147503, 41297902
830.6302	63-2	Color	All	41049502
830.6303	63-3	Physical State	All	41049502
830.6304	63-4	Odor	All	41049502
830.7050	None	UV/Visable Absorption	All	
830.7200	63-5	Melting Point	All	41049502

Data Supporting Guideline Requirements for the Reregistration of Terbufos

REQUIREMENT			USE PATTERN	CITATION(S)
830.7220	63-6	Boiling Point	All	41049502
830.7300	63-7	Density	All	41049502
830.7840 830.7860	63-8	Solubility	All	41049502
830.7950	63-9	Vapor Pressure	All	41049502
830.7370	63-10	Dissociation Constant	All	41049502
830.7550	63-11	Octanol/Water Partition Coefficient	All	41049502
830.7000	63-12	pH	All	41049502
830.6313	63-13	Stability	All	41049502
830.6314	63-14	Oxidizing/Reducing Action	All	41049502, 43147503
830.6315	63-15	Flammability	All	41049502
830.6316	63-16	Explodability	All	41049502
830.6317	63-17	Storage Stability	All	41049502
830.7100	63-18	Viscosity	All	41049502
830.6319	63-19	Miscibility	All	41049502
830.6320	63-20	Corrosion characteristics	All	41049502

ECOLOGICAL EFFECTS

Data Supporting Guideline Requirements for the Reregistration of Terbufos

REQUIREMENT			USE PATTERN	CITATION(S)
850.2100	71-1	Avian Acute Oral Toxicity Test		FEOTER02
850.2200	71-2	Avian Dietary Toxicity Test		00035120, 00087717, 00160387
850.2300	71-4	Avian Reproduction Test		00097892, 00161574, 00191573
None	71-5A	Simulated Field Study		*FEOTER01*, 00085179, 00085183, 40985501, 40993501, 41475801, 41508801, 41849201
None	71-5B	Terrestrial Field Study		*BAOTER01*, 00085178, 00085180, 00087726
850.1075	72-1	Fish Acute Toxicity		FEOTER04, FEOTER05, 00037483, 00085176, 00087718
950.1010	72-2	Aquatic Invertebrate		FEOTER03, 00085176
None	72-3A	Estuarine/Marine Toxicity - Fish		41373602, 41373603
None	72-3B	Estuarine/Marine Toxicity - Mollusk		00162524, 42381501
None	72-3C	Estuarine/Marine Toxicity - Shrimp		00162523, 41297903
None	72-4A	Fish- Early Life Stage		00162525, 40009301, 41475802
850.1500	72-5	Life Cycle Fish		Reserved

Data Supporting Guideline Requirements for the Reregistration of Terbufos

REQUIREMENT			USE PATTERN	CITATION(S)
None	72-6	Aquatic Org. Accumulation		Waived, 41373603
850.1950	72-7A	Simulated Field-Aquatic Organisms		Waived
	TOXICOLOGY			
870.1100	81.1	Acute Oral-Rat		00029863
870.1200	81-2	Acute Dermal-Rabbit		258710
870.1300	81-3	Acute Inhalation-Rat		41538101
870.2400	81-4	Primary Eye Irritation		0044957
870.2500	81-5	Primary Skin Irritation		00044957
870.2600	81-6	Dermal Sensitization		44942302
870.6100	81-7	Delayed Neurotoxicity		00037472
870.6200	81-8	Acute Neurotoxicity		44672003
870.3100	82-1	Subchronic 90 Day Oral Toxicity		44842302
870.3200	82-2	21-Day Dermal - Rabbit/Rat		00085169, 40374701, 44450600, 44450601, 44520501, 44690501
870.3465	82-4	Subchronic Inhalation Toxicity		00258710

Data Supporting Guideline Requirements for the Reregistration of Terbufos

REQUIREMENT			USE PATTERN	CITATION(S)
870.4100	83-1	Chronic Toxicity		00263678, 40374701
870.3700	83-3A	Developmental Toxicity-Rat		00147533
870.3700	83-3B	Developmental Toxicity - Rabbit		00147533, 40886301, 40966401
870.3800	83-4	2-Generation Reproduction - Rat		00085172, 43649402
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity		00049236, 40089602, 40089603
870.7485	85-1	General Metabolism		42348801
		OCCUPATIONAL/RESIDENTIAL EXPOSURE		
875.2100	132-1A	Foliar Residue Dissipation		
875.2400	133-3	Dermal Passive Dosimetry Exposure		
875.2500	133-4	Inhalation Passive Dosimetry Exposure		Waived
		ENVIRONMENTAL FATE		
835.2120	161-1	Hydrolysis of Parent and Degradates		44862501

Data Supporting Guideline Requirements for the Reregistration of Terbufos

REQUIREMENT			USE PATTERN	CITATION(S)
835.2240	161-2	Photodegradation - Water		00161567, 41181101
835.2410	161-3	Photodegradation - Soil		Waived
835.2370	161-4	Photodegradation - Air		Waived
835.4100	162-1	Aerobic Soil Metabolism		00156853
835.4200	162-2	Anaerobic Soil Metabolism		41749801
835.4300	162-4	Aerobic Aquatic Metabolism		44672004, 44862502
835.1240	163-1	Leaching/Adsorption/Desorption		41373604
835-1410	163-2	Volatility-Lab		Waived
835-8100	163-3	Volatility-Soil		Reserved
835.6100	164-1	Terrestrial Field Dissipation		41883100, 44381201
835-6500	164-5	Long-Term Soil Dissipation		Reserved
860-1900	165-2	Field Rotational Crop		40940701

Data Supporting Guideline Requirements for the Reregistration of Terbufos

REQUIREMENT			USE PATTERN	CITATION(S)
None	165-4	Bioaccumulation in Fish		41373603, 41373605
RESIDUE CHEMISTRY				
860-1200	171-3	Directions for Use		
860.1300	171-4B	Nature of Residue - Livestock		41475803, 41475804, 42576900
860.1340	171-4C	Residue Analytical Method - Plants		41475804
860.1340	171-4D	Residue Analytical Method - Animals		Reserved
860.1380	171-4E	Storage Stability		40940701, 41373606, 43237800, 43649401, 44464601
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry /Egg		Reserved
860.1500	171-4K	Crop Field Trials (Sugar Beets)		41569401, 442679
860.1500	171-4K	Crop Field Trials (Corn-Field)		41955601
860.1500	171-4K	Crop Field Trials (Sorghum)		41569402, 42661801

Data Supporting Guideline Requirements for the Reregistration of Terbufos

REQUIREMENT			USE PATTERN	CITATION(S)
860.1520	171-4L	Processed Foods (Corn, Field)		41955601, 43237800
860.1520	171-4L	Processed Foods (Sorghum, Grain)		41569402, 43237800
OTHER				
None	82-3SS	Human Incident Data		
None	163-A-SS	Monitoring Studies-Soil		
870-6200	None	Neurotox Screening Battery-Acute		
870,6200	None	Neurotox Screening Battery-Acute		
870-6300	None	Developmental Neurotox		

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:

3. Organophosphate Pesticides: Terbufos Availability of Revised Risk Assessment (FR Notice)
4. Human Health Risk Assessment: Terbufos
5. Terbufos Toxicology Chapter for RED
6. Terbufos: Revised Acute and Chronic Dietary Exposure Analyses for the HED Revised Risk Assessment
7. Terbufos: Revised Probabilistic (Monte Carlo) Dietary Exposure Analysis and Supporting Documentation
8. Terbufos: Revised Probabilistic (Monte Carlo) Acute Dietary Exposure and Risk
9. Terbufos: Comprehensive Report of the Toxicological Endpoints Selection Report of the Hazard Identification Assessment Review Committee (HIARC)
10. Terbufos: Report of the FQPA Safety Factor Committee
11. The Revised Occupational and Residential Exposure Aspects of the HED Chapter of the RED for Terbufos

EFED Documents:

12. Terbufos: Revised EFED RED Chapter Revision of Fate and Transport and Water Resources

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.

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Appendix E. GENERIC DATA CALL-IN

See table in docket 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 table in docket 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 TERBUFOS 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 terbufos 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.

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

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

- The products in Batch 3 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	241-241	85.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	241-314	20.0	Solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	241-238	15.0	Solid

Appendix H. LIST OF REGISTRANTS SENT THIS DATA CALL-IN

1) BASF Corporation

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

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

1. The Office of Pesticide Programs' Web Site

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

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

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

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This

service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

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

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

Date of receipt
EPA identifying number
Product Manager assignment

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

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

Documents Associated with this RED

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

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