United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-00-022
September 2000

Interim Reregistraion Eligibility Decision (IRED)

Tribufos

United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPAF-00-020 October 2000

EPA Tribufos Facts

EPA has assessed the risks of tribufos and reached an Interim Reregistration Eligibility Decision (IRED) for this organophosphate (OP) pesticide. Tribufos is eligible for reregistration, pending a full reassessment of the cumulative risk from all OPs.

Used only on cotton crops, tribufos residues in food and drinking water do not pose risk concerns. Tribufos has no residential uses. With the implementation of certain risk mitigation measures, worker and ecological risks from tribufos use are believed to be significantly reduced. Additional data are also to be submitted to the Agency to confirm this conclusion.

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. OPs need decisions about their eligibility for reregistration under FIFRA. Additional OPs with residues in food, drinking water, and other non-occupational exposures also must be reassessed to make sure they meet the new Food Quality Protection Act (FQPA) safety standard.

The OP Pilot Public Participation Process

The organophosphates are a group of related pesticides that affect the functioning of the nervous system. They are among EPA's highest priority for review under the Food Quality Protection Act.

EPA is encouraging the public to participate in the review of the OP pesticides. Through a six-phased pilot public participation process, the Agency is releasing for review and comment its preliminary and revised scientific risk assessments for individual OPs. (Please contact the OP Docket, telephone 703-305-5805, or see EPA's web site, www.epa.gov/pesticides/op .)

EPA is exchanging information with stakeholders and the public about the OPs, their uses, and risks through Technical Briefings, stakeholder meetings, and other fora. USDA is coordinating input from growers and other OP pesticide users.

Based on current information from interested stakeholders and the public, EPA is making interim risk management decisions for individual OP pesticides, and will make final decisions through a cumulative OP assessment.

EPA's next step under the FQPA is to complete a cumulative risk assessment and risk management decision encompassing all the OP pesticides, which share a common mechanism of toxicity. The interim decision on tribufos cannot be considered final until this cumulative assessment is complete. Further risk mitigation may be necessary at that time.

The tribufos IRED was made through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in EPA's development of risk assessments and risk management decisions. EPA worked extensively with affected parties to reach the decisions presented in this interim decision document, which concludes the OP pilot process for tribufos.

Uses

- Tribufos is an organophosphate defoliant used for cotton crops. It is specifically used to defoliate cotton in preparation for machine harvesting.

- There are about 4,500,000 pounds of active ingredient (ai) applied annually to between 4 and 5 million acres (A) or about 35% of planted cotton acreage in the United States. The typical rate of application varies from 0.50 lb ai/A to1.875 lb ai/A. Tribufos is most often applied in a tank-mix. When it is tank-mixed, the application rate is typically significantly lower than the maximum label rate.

- There are no residential uses of tribufos.

Health Effects

- Tribufos can cause cholinesterase inhibition in humans; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death.

Risks

- Dietary risks from food and drinking water are not of concern to the Agency for all segments of the population, including children.

- The current occupational risk assessment indicates risk concerns for aerial mixers/loaders and aerial applicators (with closed mixing/loading systems and enclosed cockpits). However, the Agency believes actual exposures are lower. Risks to workers who mix, load, and apply tribufos via groundboom are not of concern to the Agency but risks to workers who enter fields shortly after treatment are of concern.

- Ecological risks include acute and chronic concerns for both birds and mammals. The Agency is also concerned with acute risks to marine fish. Several studies conducted in a variety of climates where tribufos is used resulted in risks of concern to freshwater and marine invertebrates.

Risk Mitigation

To mitigate risks to workers, the following measures are necessary:

1) The maximum application rate is to be reduced to 1.5 pints/A (1.125 lbs ai/A) in all states, except California and Arizona, which would remain at the higher rate of 2.5 pints/A (1.875 lb ai/A). California and Arizona grow hardier varieties of cotton, which require more defoliant.

2) The restricted entry interval (REI) is to be increased from 24 hours to 7 days;
3) Tribufos products are to be distributed in closed systems starting with the 2002 season.
4) Aerial applicators are to be in enclosed cockpits.
5) A biomonitoring study is to be conducted to confirm the Agency's risk management decision that occupational risks associated with the use of tribufos are not of concern. The biomonitoring study will be submitted to the Agency by September 2003.

- The Agency also examines the benefits associated the use of a chemical when worker and ecological risks are of concern to the Agency. For tribufos, the Agency has received and reviewed benefits analyses from several stakeholders that ascertain the benefits from the use of tribufos are numerous, including its efficacy at lower temperatures. The Agency has considered these submissions and concurs that the benefits from tribufos are numerous and its loss to the cotton industry would be substantial.

- Although the Agency's analyses indicate concern for several ecological species, the Agency is confident that the above mitigation measures that will be implemented to address human health risks will also reduce ecological risks. For instance, it is expected that a reduction in the application rate, largely through tank-mixing, will result in less pesticide availability in the ecosystem.

Next Steps

- Numerous opportunities for public comment were offered as this decision was being developed. The tribufos IRED, therefore, is issued in final (see www.epa.gov/REDs/ or www.epa.gov/pesticides/op), without a formal public comment period. The docket remains open, however, and any comments submitted in the future will be placed in this public docket.

- To implement risk mitigation as quickly as possible, time frames for making the changes required by the Tribufos IRED are shorter than those in a usual RED. Tribufos labels must be amended to include the above mitigation and submitted to the Agency within 90 days after issuance of this IRED.

- When the cumulative risk assessment for all organophosphate pesticides is completed, EPA will issue its final tolerance reassessment decision for tribufos and may result in further risk mitigation measures. Similarly, the Agency may reconsider any part of this interim decision based on new information which may come to the Agency's attention. The Agency will revoke one tolerance because there are no registered uses and amend one tolerance. For all OPs, raising and/or establishing tolerances will be considered once a cumulative assessment is completed.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OCT 24 2000

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 tribufos. 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 24, 1999. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. This public participation and comment period commenced on September 24, 1999, and closed on November 24, 1999.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of tribufos. The EPA is now publishing its interim decision on the reregistration eligibility of and risk management decision for the current uses of tribufos and its associated human health and environmental risks. The reregistration eligibility and tolerance reassessment decisions for tribufos will be finalized once the cumulative assessment for all of the organophosphate pesticides is complete. The Agency's decision on the individual chemical tribufos can be found in the attached document entitled, "Interim Reregistration Eligibility Decision" which was approved on September 28, 2000, contains the Agency's decision on the individual chemical tribufos .

A Notice of Availability for this Interim Reregistration Eligibility Decision for tribufos is being published in the *Federal Register*. To obtain a copy of the interim RED (IRED) 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 IRED is based on the updated technical information found in the tribufos public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessments for tribufos (revised as of June 26, 2000), and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For tribufos, a proposal was submitted by Bayer, the technical registrant. Comments on mitigation or mitigation suggestions were submitted by the National Cotton Council and the USDA.

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

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 registrants of tribufos must respond to DCIs issued by the Agency within 90 days of receipt of this letter.

In this IRED, the Agency has determined that tribufos will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of tribufos may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this IRED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Section IV of this IRED describes labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

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

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Anne Overstreet, at (703) 308-8068. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Bonnie Adler at (703) 308-8523.

Lois A. Rossi

Lois A. Rossi, Director
Special Review and
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Attachment

Interim Reregistration Eligibility Decision for Tribufos

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
ChE	Cholinesterase
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DAT	Days After treatment
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration.
EP or EUP	End-Use Product
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
IRED	Interim Reregistration Eligibility Decision
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.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MUP or MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System

Glossary of Terms and Abbreviations

NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PCA	Percent Crop Area
PAD	Population Adjusted Dose
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
PRZM/EXAMS	Tier II Surface Water Computer Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
WPS	Worker Protection Standard

Executive Summary

Tribufos is an organophosphate defoliant used for cotton crops. It is specifically used to defoliate cotton in preparation for machine harvesting. It was first registered in the United States in 1961. There are about 4,500,000 pounds of active ingredient (ai) applied annually to between 4 and 5 million acres (A) or about 35% of planted cotton acreage in the United States. The typical rate of application varies from 0.50 lb ai/A to1.875 lb ai/A. Tribufos is most often applied in a tank-mix. When it is tank-mixed, the application rate is typically significantly lower than the maximum label rate. Even though the maximum registered rate for tribufos is 1.875 lbs ai/A, the Agency acknowledges that there is a relatively small population of aerial mixers, loaders, and applicators who need to apply this rate in California and Arizona. The total percentage of cotton acres treated with tribufos in California and Arizona is 13% and 17%, respectively.

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for tribufos. The decisions outlined in this document do not include the final tolerance reassessment decision for tribufos; however, a single tolerance on cottonseed hulls will be revoked now, because it is not warranted based on the results of an acceptable cottonseed processing study. The final tolerance reassessment decision for this chemical will be issued once the cumulative assessment for all of the organophosphates is complete. The Agency may need to pursue further risk management measures for tribufos once the cumulative assessment is finalized.

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

Dietary Risk

The Agency's human health risk assessment for tribufos indicates that there are no concerns for dietary risks from residues of tribufos in food. Acute dietary risk (food only) for the most highly exposed sub-population, children (1-6 years old), is 9% of the Population Adjusted Dose (PAD) at the 99.9th percentile. Chronic dietary risk for the most highly exposed population, (children 1-6 years), is 3% of the Population Adjusted Dose (PAD) at the 99.9th percentile. Risk less than 100% of the PAD is not of concern to the Agency.

The Agency also evaluates dietary risks from residues in drinking water. For tribufos, the acute and chronic modeled surface drinking water concentrations of tribufos are below the Drinking Water Levels of Comparison (DWLOCs) for all sub-populations, and the chronic concentrations are

slightly exceeded for only the most highly exposed sub-population, children (1-6 years old), and are below the DWLOCs for all others. The Agency considers the surface drinking water values to be screening level assessments that may overestimate exposure. Moreover, the Agency has determined that residues of tribufos are not expected to reach ground water, and therefore, has no concern for acute or chronic effects from tribufos in ground water sources of drinking water. As a result, aggregate risks from tribufos exposure in food and water do not exceed the Agency's level of concern. There are no residential uses of tribufos, therefore, aggregate risks were based only on dietary food and water exposures.

Occupational Risk

The Agency's human health risk assessment for tribufos indicates that there are risk concerns for occupational mixers, loaders, applicators for aerial applications, and reentry personnel. For groundboom applications, the risk concerns are low. The target occupational Margins of Exposure (MOEs) are 300 for dermal and 100 for inhalation exposure. Restricted entry intervals, as well as the risks for the mixers, loaders, and applicators were based on a chemical-specific study submitted by the registrant, Bayer. This chemical-specific study was designed to determine the dermal and inhalation exposures to workers.

Inhalation MOEs for all worker scenarios exceed the target MOE of 100. Many of the dermal risk estimates for handlers using engineering controls (closed systems for mixers, loaders, and applicators) fall below the dermal target MOE of 300. Dermal MOEs below the target range from 49 to 150 for aerial mixers, loaders, and applicators. Flagger dermal MOEs supporting aerial application up to 1,200 acres per day were 2,000 or greater. Dermal MOEs for mixers, loaders, and applicators using groundboom equipment with baseline attire (long-sleeved shirt, long pants, shoes, and socks) are all above 300, while engineering controls are necessary for scenarios supporting aerial application.

The occupational aggregate risk assessment combined dermal and inhalation risks for handlers who were exposed to tribufos by both routes. An Aggregate Risk Index (ARI) method was used because the dermal and inhalation target MOEs were different. A target ARI of greater than or equal to 1 is not of concern to the Agency. When assuming engineering controls, the combined ARIs are below 1 for all aerial mixing, loading and application scenarios. Therefore, occupational risks are of concern to the Agency and warrant further mitigation measures.

The Agency identified four scenarios for post-application exposure: picker operator, module-builder operator, raker, and tramper. A chemical-specific study was used to determine the dermal and inhalation exposures for these scenarios. MOEs at the current restricted entry interval (REI) of 24 hours at the current label rate of 1.875 lbs ai/A, as well as the lower proposed maximum rate of 1.125 lbs ai/A, range from 45 to 180. These MOEs are less than the target MOE of 300 and, therefore, are of concern to the Agency. MOEs at the proposed REI of 7 days at both the current label rate of 1.875 lb ai/A and the lower rate of 1.125 lb ai/A range from 210 to 820. At an REI of 7 days, MOEs for the

pickers, rakers, and trampers at the current label rate (1.875 lb ai/A) are less than 300 and, therefore, are of concern to the Agency, but are above 300 for all workers at the rate of 1.125 lbs ai/A.

Ecological Risks

In addition to the human health effects, the Agency also assessed ecological risks potentially caused by the use of tribufos under all use scenarios. Overall, ecological risk concerns for some species exist but the exceedences are relatively low. The Agency is concerned with acute and chronic risks to birds and mammals when both single and multiple applications of tribufos are used. Risk Quotients (RQs) ranged from 0.01 to 13.94. The Agency is requiring an additional avian study to more comprehensively assess risks to birds (refer to Section V for data requirements).

The Agency is not concerned with acute risk to freshwater fish associated with the use of tribufos (RQs ranged from 0.03 to 0.06). However, acute risks to estuarine/marine fish are of concern to the Agency with RQs ranging from 0.06 to 0.11. Data to assess chronic risks to both freshwater and estuarine/marine fish are lacking and therefore will be required (refer to Section V of this document).

With regards to freshwater and estuarine/marine invertebrates, the Agency has concerns for both acute and chronic risks associated with the use of tribufos (RQs ranged from 1.6 to 23.3). The Agency is also requiring a chronic estuarine/marine study to better characterize risks to invertebrates (refer to Section V).

Exposure to non-target vascular aquatic plants is possible through the use of tribufos. Acute RQs ranged from 0.05 to 0.09. These RQs indicate that the acute LOCs are not exceeded for any use rate. RQs for exposure to non-vascular plants range from 0.07 to 0.12. The Agency is, therefore, not concerned with risks to non-target aquatic plants.

The risks to non-target terrestrial and aquatic plants cannot be fully assessed because pertinent plant studies are lacking. The Agency is requiring confirmatory data to better characterize potential risks. Refer to section V for particular studies required.

Risk Mitigation

The Agency has adopted several measures to help mitigate occupational risks to aerial mixers, loaders, and applicators, as well as ecological risks. These mitigation options have been included in the risk calculations for this IRED and are as follows:

1) The maximum application rate is to be reduced to 1.5 pints/A (1.125 lbs ai/A) in all states, except California and Arizona, which would remain at the higher rate of 2.5 pints/A/year (1.875 lb ai/A). California and Arizona grow hardier varieties of cotton, which require more defoliant.

2) The restricted entry interval (REI) is to be increased from 24 hours to 7 days;

3) Tribufos products are to be distributed in closed systems starting with the 2002 season.

4) The Agency is also requiring closed systems for aerial applicators (enclosed cockpits).

5) A biomonitoring study will be required to confirm the Agency's risk management decision. The biomonitoring study will be submitted to the Agency by September 2003.

The Agency has incorporated the first four mitigation measures in the current risk assessment. However, risk concern still remains for workers who mix, load, and apply tribufos by aerial application.

In this IRED occupational risks associated with the use of tribufos were calculated at two rates, the proposed rate of 1.125 lbs ai/A, and the current maximum rate of 1.875 lbs ai/A. Typically, tribufos is tank-mixed in the majority of applications with other defoliants at a much lower rate (0.50 to 0.75 lbs ai/A). The Agency is, therefore, confident that the occupational and ecological risks associated with the use of tribufos are generally lower than those discussed in this IRED.

In conclusion, based on experience with other biomonitoring studies, the Agency is confident that occupational risks associated with tribufos will not be of concern. A determination has been made that the continued use of tribufos is critical to the cotton industry and should remain available to growers. The factors leading to this conclusion are discussed in further detail in section IV of this document.

Benefits

Under FIFRA, benefits associated with the use of a chemical are considered when worker and ecological risks are of concern to the Agency. The Agency has received and reviewed benefits analyses from both the USDA and the National Cotton Council that ascertain the benefits from the use of tribufos are numerous, including its efficacy at lower temperatures. The Agency has considered these submissions and concurs that the benefits from tribufos are numerous and its loss to the cotton industry would be substantial.

An alternative analysis was also conducted for tribufos. The Agency reviews alternatives to a pesticide, by considering efficacy against target pests, costs, ease of use, potential resistance development to the pesticide, impacts on existing integrated pest management (IPM) programs, and several other characteristics. The Agency determined that tribufos serves a vital role in the cotton industry and there currently are no suitable replacements under the conditions which tribufos is most effective. Furthermore, as outlined in Section IV of this document, tribufos exhibits a synergistic effect when mixed with other defoliants. That is, tribufos alone is less effective than when mixed with other defoliants. This synergism is of great benefit to the cotton industry and its loss would create a void

which other chemicals could not fill. In summary, the Agency has determined that the continued use of tribufos is critical to the cotton industry and, therefore, should remain available to growers.

The Agency is issuing this IRED for tribufos, as announced in a Notice of Availability published in the *Federal Register*. This IRED document includes guidance and time frames for complying with any label changes for products containing tribufos. As part of the process discussed by the Tolerance Reassessment Advisory Committee (TRAC), which sought to open up the process to interested parties, the Agency's risk assessments for tribufos have already been subject to public comment periods. The Phase 6 of the pilot process did not include a public comment period. With regard to complying with the risk mitigation options outlined in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for tribufos can be considered final, however, until the cumulative risk assessment for all organophosphate pesticides is complete. The cumulative assessment may result in further risk mitigation measures for tribufos.

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

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 "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 has 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 Federal Food, Drug, and Cosmetic Act (FFDCA), to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Tribufos belongs to a group of pesticides called organophosphates, which share a common mechanism of toxicity - they all affect the nervous system by inhibiting cholinesterase. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

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

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be established. These issues were developed and refined through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which 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. Most issue papers have already been published for comment in the *Federal Register* and others will be published shortly.

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

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's interim decision on reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list uses that are eligible for interim reregistration, guideline, and other data used to conduct the assessments outlined in this document as well as 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.

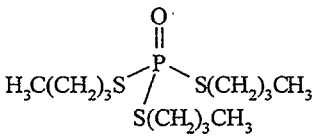
II. Chemical Overview

A. Regulatory History

Tribufos was first registered by the United States Environmental Protection Agency in 1961 for use on cotton as a total defoliant and as a bottom defoliant to reduce or prevent losses from boll rot organisms. A Registration Standard was not issued for tribufos.

B. Chemical Identification

Tribufos:



S,S,S-tributyl phosphorotrithioate

- **Common Name:** Tribufos
- **Chemical Name:** *S,S,S*-tributyl phosphorotrithioate
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 78-48-8
- **OPP Chemical Code:** 074801
- **Empirical Formula:** $C_{12}H_{27}OPS_3$
- **Molecular Weight:** 314.5 g/mole
- **Trade and Other Names:** DEF, DEF6, Folex
- **Basic Manufacturer:** Bayer Corporation

Tribufos is a colorless to yellow liquid with a mercaptan-like odor and a boiling point of ~150°C. Tribufos is practically insoluble in water (2.3×10^{-4} g/100 ml), but is completely miscible in dichloromethane, n-hexane, 2-propanol, and toluene. Tribufos is relatively stable to heat and under acidic conditions, but slowly hydrolyzes under alkaline conditions.

C. Use Profile

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

Type of Pesticide: Defoliant

Summary of Use:

Sites: Cotton

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

Residential: None

Other Nonfood: None

Formulation Types:

Registered: There are two technical products of tribufos presently registered. One technical (98.0% ai, liquid) is registered to Bayer Corporation (EPA Reg. No. 3125-96) and one to Micro Flo Company (98.1% ai with an EPA Reg. No. 51036-324). There are three liquid end-use products: one registered to Bayer (EPA Reg. No. 3125-282 - 71.5% ai); one registered to Aventis Crop Science (EPA Reg. No. 264-498 - 70.5% ai); and one registered to Micro Flo (EPA Reg. No. 51036-320 - 70.5% ai). There is also one Special Local Need (SLN) product registered in Texas, (SLN No. TX810045) which Bayer has recently requested a cancellation on July 24, 2000.

Method and Rates of Application:

Equipment: Aircraft (fixed wing aircraft) and groundboom.

Rate: Application rates vary from 0.50 lbs ai/A (tank-mixed) to 1.875 lbs ai/A (tribufos used alone). Tribufos is most typically used in a tank-mix with other defoliants at a rate between 0.50 lbs ai/A to 0.75 lbs ai/A.

Timing: Pre-harvest application

Trend: In 1999, tribufos was applied to between 4 and 5 million acres or about 35% of planted cotton acreage. This is an increase from 1990 when less than 15% of total cotton acreage was treated with tribufos.

Use Classification: General Use Pesticide

D. Estimated Usage of Pesticide

Based on information available to the Agency and from consultation with the USDA, the Agency estimates that approximately four and a half million pounds of tribufos are applied to approximately 35% of the estimated fourteen million acres of cotton grown in the United States each year. Tribufos is used throughout the cotton belt which extends from California to Florida and as far north as Missouri, Tennessee, and Virginia.

Tribufos is generally used only once per growing season. It is very often tank-mixed with other defoliants at a rate ranging from 0.50 lbs ai/A to 0.75 lbs ai/A to achieve maximum results. On occasion, a second application of tribufos may be applied to complete the defoliation process.

III. Summary of Risk Assessment

The following discussion summarizes EPA's revised human health and ecological risk assessments as fully presented in the documents, "Tribufos Revised HED Chapter for the Reregistration Eligibility Decision Document," dated June 26, 2000, "EFED Chapter for Tribufos," dated November 8, 1996, and an addendum to the EFED chapter "Updated Drinking Water EECs for Tribufos." Electronic copies of these supporting documents are available on the Internet; see http:www.epa.gov/pesticides/op. Public comment was solicited on the preliminary and revised risk assessments. In addition, the Agency invited all interested stakeholders to submit risk mitigation proposals. The risk assessments and risk mitigation measures presented in this IRED considered stakeholder input.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessment for tribufos in March of 1999. Since that time, the Agency has refined the preliminary risk assessment using a probablistic (Monte Carlo) analysis. The

registrant also submitted a dermal absorption study in the monkey, which the Agency used to obtain a conversion factor to further refine the risk assessment. Finally, the Agency determined the additional 3X, which was applied in the preliminary Human Health Risk Assessment for severity of effects, should be removed because the effects were observed at very high doses and that the conventional uncertainty factors (i.e., 10X for interspecies differences, 10X for intraspecies differences, and the 3X for the use of a Lowest-Observed-Adverse-Effect-Level (LOAEL) in the 21-day dermal rabbit study) would be sufficient to adequately characterize the risks associated with the use of tribufos. Further details on the human health effects of tribufos can be found in the June 26, 2000, Human Health Risk Assessment (See the EPA public docket for tribufos or http:www.epa.gov/pesticides/op).

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 to support an interim reregistration eligibility determination for the currently registered uses of tribufos. A brief overview of the studies used to assess dietary risk are provided in Table 1.

b. FQPA Safety Factor

The FQPA Safety Factor is intended to provide up to an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food or to compensate for an incomplete database. Although no increased sensitivity of fetuses as compared to maternal animals was observed in developmental toxicity studies in rats and rabbits and no increased sensitivity of pups was observed in a multi-generation reproduction study in rats, the Agency retained a 10X FQPA Safety Factor for tribufos due to the following toxicity data gaps. The Agency has called in the following studies:

(a) Acute and subchronic neurotoxicity studies in rats. Data on cholinesterase (ChE) inhibition, functional observation battery, as well as histopathology of the central and peripheral nervous systems are not available for evaluation after single or repeated exposures to tribufos.

(b) A developmental neurotoxicity study is required, based on organophosphate induced delayed neuropathy (OPIDN). The concern for the developmental neurotoxic potential of tribufos was elicited by neuropathological lesions in the subchronic study with hens (MRID 42007202) and in the combined chronic toxicity/carcinogenicity study in rats (MRID 42335101).

A Data Call-In (DCI) requiring the above studies was sent to registrants of OP pesticides currently registered under FIFRA on August 6, 1999. The DCI requirements included acute, subchronic, and developmental neurotoxicity studies. The due date for these studies is September 2001.

c. Population Adjusted Dose (PAD)

The Population Adjusted Dose (PAD), is a relatively new term that reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor. For the acute dietary risk assessment, risk is calculated by comparing what is eaten in one day (consumption) with maximum, high-end residue values in food. For chronic exposures, dietary risk is calculated using the average consumption value for food over a 70-year lifetime and average residues found in food. When the FQPA Safety Factor is applied to the risk assessment, the RfD is divided by the FQPA Safety Factor, which results in a potentially different figure, the PAD. The PAD is now referred to in regulatory decisions rather than the RfD. In the case of tribufos, the FQPA Safety Factor is 10, which results in a PAD that is 10 times more protective than the acute or chronic RfD. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern. A brief overview of the studies used to assess dietary risk is outlined in Table 1.

Table 1: Summary of Toxicological Endpoints and Other Factors Used in the Human Health Risk Assessment of Tribufos

Type of Exposure (duration and route)	Endpoint and Effect Level		Study
Acute Dietary	Plasma and red blood cell (RBC) ChE inhibition; No-Observed-Adverse-Effect-Level (NOAEL) of 1 mg/kg/day		Prenatal Developmental Toxicity study in rats (MRID 40190601)
	Acute RfD: 0.01 mg/kg/day		
	Uncertainty Factor (UF): 100	**FQPA Safety Factor:** 10	
	Acute PAD: 0.001 mg/kg/day		
Chronic Dietary	Plasma ChE inhibition; NOAEL of 0.1 mg/kg/day		Chronic study in the dog (MRID 42007203)
	Chronic RfD: 0.001 mg/kg/day		
	Uncertainty Factor (UF) UF: 100	**FQPA Safety Factor:** 10	
	Chronic PAD: 0.0001 mg/kg/day		

d. Exposure Assumptions

The Agency's dietary risk assessment for tribufos uses the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. The acute and chronic exposure analysis was

conducted using DEEM software and a probabilistic (Monte Carlo) technique. The Monte Carlo analysis provides a more realistic assessment due to the use of a distribution of residues, rather than single residues, to calculate a range of exposures and risks.

This exposure estimate, for both the acute and chronic dietary, has been extensively refined. No further refinements can be made to these anticipated residues as the USDA Pesticide Data Program (PDP) and the Food and Drug Administration (FDA) monitoring programs do not analyze for tribufos at this time.

e. Acute Dietary (Food)

The assessment was based on anticipated residue (AR) values which were calculated using field trial data, reduction factors from processing studies, and percent of crop treated data (35%). Residues in meat and milk were estimated using data from livestock metabolism and feeding studies. The endpoint used to assess acute dietary risk is cholinesterase inhibition in plasma and RBCs, at 1mg/kg/day (NOAEL) in the prenatal developmental toxicity study in rats (MRID 40190601). The Agency applied an uncertainty factor (UF) of 100 to account for both interspecies extrapolation (10X), an intraspecies variability (10X), and the FQPA Safety Factor (10X). Therefore, the acute Population Adjusted Dose (aPAD) is calculated to be 0.001 mg/kg. At the 99.9th percentile exposure, the most highly exposed population subgroup is children (1-6 years) at 9% of the aPAD. The acute dietary risk (from food) of tribufos does not exceed the Agency's level of risk concern (i.e., less than 100% of the aPAD is utilized). The results for the general population and the most sensitive subgroups are summarized in Table 2.

Table 2. Acute Dietary (Food) Exposure and Risk Estimates

Population	99.9th Percentile	
	Exposure (mg/kg/day)	% aPAD
U.S. Population	0.000050	5
Non-nursing Infants (<1 year)	0.000060	6
Children (1-6 years)	0.000085	9
Females (13+ years)	0.000026	3

f. Chronic Dietary (Food)

The chronic dietary exposure analysis (from food sources) was conducted using anticipated residues (ARs) from field trial studies and 35% crop treated for cottonseed oil and cottonseed meal. Residues in meat and milk were estimated using data from livestock metabolism and feeding studies. The endpoint used in the chronic dietary risk assessment is cholinesterase inhibition in plasma from a chronic dog study with a NOAEL of 0.1 mg/kg/day (MRID 42007203). As in the acute assessment, the Agency applied a UF of 100 for both interspecies extrapolation (10X) and intraspecies variability (10X). The FQPA 10X Safety Factor was retained (10X). Therefore, the chronic Population

Adjusted Dose (cPAD) is calculated to be 0.0001 mg/kg. The most highly exposed population subgroup is children (1 - 6 years), at 6% of the cPAD. The chronic dietary risk (from food) of tribufos does not exceed the Agency's level of risk concern (i.e., less than 100% of the cPAD is utilized). The results for the general population and the various subgroups are summarized in Table 3.

Table 3. Chronic Dietary (Food) Exposure and Risk Estimates

Population	99.9th Percentile	
	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000003	3
Non-nursing infants <1 yr	0.000001	1
Children (ages 1-6 years)	0.000006	6
Females (13-19)	0.000003	3

g. Cancer Risks

Tribufos is classified as an unlikely human carcinogen at low doses but is a likely carcinogen at high doses. However, the cancer risk from dietary exposure is not of concern to the Agency for the following reasons:

(1) although the chronic NOAEL was 0.1 mg/kg/day for plasma ChE inhibition (in the chronic dog study), tumors were seen in mice only at the highest dose tested (48 mg/kg/day), which is a wide span in dosing between the NOAEL and the tumors;

(2) the dose of 0.1 mg/kg/day used for deriving the chronic RfD is approximately 500-fold lower than the dose that caused tumors (i.e., 48 mg/kg/day);

(3) the primary concern is the non-cancer risk, which manifests as ChE inhibition at a very low dose; and

(4) the application of the 10X FQPA Safety Factor to the chronic RfD yields a cPAD that provides even more protection than for non-cancer dietary risk (i.e., the cPAD of 0.0001mg/kg/day is 500,000 times lower than the dose at which tumors were seen).

For these reasons, the Agency has determined that a quantitative dietary cancer risk assessment was not necessary for tribufos.

2. Dietary Risk From Drinking Water

Drinking water exposure to pesticides can occur through ground and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, when available, to estimate those risks. To determine the maximum contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a drinking water level of comparison

(DWLOC) to ascertain whether the amount estimated in water exceeds this level. If the estimated water concentration is less than the DWLOC, the Agency is not concerned about tribufos consumption in drinking water. If model estimates are greater than the DWLOC, the Agency must further evaluate the potential for drinking water exposure. The Agency uses ground and surface water monitoring data, when available and of sufficient quantity and reliability, as part of a more in-depth evaluation.

There are no environmental degradates of tribufos that are of toxicological concern. The drinking water assessment is based on parent tribufos only. Table 4 below summarizes the DWLOCs and estimated environmental concentrations (EECs) for ground and surface water (acute and chronic).

a. Surface Water

Tribufos spray drift can potentially contaminate surface water. Substantial amounts of applied tribufos may remain available for runoff for many months after application due to the aerobic soil metabolism half-life of 745 days. The relatively high soil/water partitioning of tribufos indicates that runoff will generally occur primarily via adsorption to eroding soil as opposed to dissolution in runoff water.

Tribufos is stable to abiotic hydrolysis at pHs 5 and 7, and stable to direct aqueous photolysis. It has a relatively low volatilization potential, undergoes slow abiotic hydrolysis at pH 9, and appears to undergo extremely slow biodegradation under aerobic conditions. Consequently, tribufos will probably be persistent in the water column of most surface waters within which it occurs, except those with short hydrologic residence times for which flow out of the system may be the major dissipation pathway. The results of the anaerobic soil and the anaerobic aquatic metabolism studies indicate that tribufos may be a little less persistent under the anaerobic conditions found in most sediments, but is still relatively persistent.

Because the Agency does not have any surface water monitoring data fro tribufos, surface drinking water concentrations were estimated using the PRZM 2/EXAMS II (Tier II) computer model with the Index Reservoir and Percent Crop Area. Based on the model scenarios, the estimated peak (acute) concentration of tribufos in surface water is 5.8 ppb and the annual average concentration of tribufos in surface water over a 36-year period (chronic) is 1.8 ppb. Table 5 below summarizes the DWLOCs and EECs for surface water (acute and chronic).

b. Ground Water

According to the *EPA Pesticide in Ground water Database: A Compilation of Monitoring Studies, 1971-1991, A National Summary* (EPA 734-12-92-001 September,1992), between 1984 and 1988, 569 wells were tested for tribufos in California and Texas. Tribufos was not detected in any of these samples. Although an absence of detections of tribufos residues does not necessarily mean

there is no exposure potential, data indicate that tribufos should not be a concern in ground water, because environmental fate testing indicates that tribufos binds to the soil and appears to be immobile. Based on the physical/chemical characteristics of tribufos, the Agency determined that residues of tribufos are not expected to reach ground water and were, therefore, not estimated. The Agency has no concern for acute or chronic effects from tribufos in ground water-sourced drinking water.

c. Drinking Water Levels of Comparison (DWLOC)

To determine the maximum allowable contribution of tribufos from water in the diet, the Agency first looks at how much of the overall allowable risk is contributed by food and then determines a DWLOC to ascertain whether expected concentrations exceed this level.

Table 4. DWLOC and EEC Comparisons

Population Subgroup	DWLOCs (ppb)		EECs (ppb)		
	Acute	Chronic	Ground Water	Surface Water (PRZM2/EXAMS II)	
				Acute	Chronic
Males	33	3	Residues Not Expected*	5.8	1.8
Children (1-6 years)	10	1			
Females (13+ nursing)	29	3			

* Due to the environmental fate characteristics, residues of tribufos are not expected, therefore, a ground water assessment is not necessary

The chronic modeled surface drinking water concentrations (1.8 ppb) of tribufos slightly exceeded the DWLOCs for the most highly exposed sub-population, children 1-6 years old (1 ppb), and are below the DWLOCs for all others. The Agency considers the estimates to be conservative for the following reasons:

1) The estimates are based on a scenario (i.e., high rainfall, spray drift, and soils with maximum runoff potential) that is upper bound for site characteristics.

2) Drinking water treatment effects are not included. It is possible that with a compound like tribufos, the primary treatment effects such as flocculation, sedimentation, and filtering could remove tribufos.

3) The maximum application rate was used (1.875 lbs ai/A). The Agency acknowledges that this rate is very seldom used. The tank-mix rates of 0.50 lbs ai/A to 0.75 lbs ai/A are more commonly used.

4) The modeled chronic surface water estimated concentration only exceeds the DWLOC by 0.8 ppb. Because the sensitivity of this model (PRZM2/EXAMS

II) is limited, the differentiation between these two numbers is considered negligible.

3. Aggregate Risks

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and non-occupational exposure sources. Because there are no residential or other non-occupational uses of tribufos to consider in an acute or chronic aggregate assessment, the aggregate assessment only includes dietary risks from food and water. The Agency has no concern for residues of tribufos in ground water and little concern about exposure to tribufos in surface water sources of drinking water because the drinking water EECs slightly exceed the chronic DWLOCs and for reasons discussed above. Therefore, the aggregate risk of tribufos is not of concern.

4. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of tribufos include individual farmers or growers who mix, load, and/or apply pesticides or professional or custom agricultural applicators. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational or residential exposure comes to a NOAEL.

Inhalation and dermal exposure to tribufos can result from occupational use. The Agency assessed dermal and inhalation risks for mixers, loaders and applicators during aerial and groundboom applications, as well as flaggers during aerial application. Tribufos is not expected to be used on a continuous long-term basis (greater than 6 months a year) that would result in chronic exposure. Therefore, the occupational risk assessments were conducted for short- (1-7 days) and intermediate- (one week to several months) term occupational exposure scenarios. The Agency also calculated risks for reentry workers or others entering a treated site.

The Agency considers the following tasks in assessing exposure (e.g., mixing, loading, and applying): pesticide formulation (e.g., liquid, granular), application method (e.g., aerial, groundboom), amount applied or handled, and similar activities. The Agency also reviews any incident data for occupational handlers if available and applicable.

a. Toxicity

The toxicity of tribufos is integral to assessing the occupational risk. The toxicology database provides evidence confirming that tribufos, like other organophosphates, has anticholinesterase activity in all species tested, which include hen, mice, rats, dogs and rabbits. Toxicity Category I is considered the most toxic, and Toxicity Category IV is considered the least toxic. Technical tribufos is placed in Toxicity Category II by the oral and dermal routes, and Category III by the inhalation route. No data

are available on the eye irritation potential of tribufos. Dermal irritation is mild to moderate and tribufos is placed in Toxicity Category IV. Tribufos is not a dermal sensitizer. Inhibition of plasma, erythrocyte and/or brain ChE activity occurs by all routes (oral, dermal and inhalation) and duration (acute, subchronic, and chronic) of exposures. In addition to its ChE inhibitory effects, tribufos, at a high dose, displayed organophosphate-type delayed neuropatholgy in the hen. Tribufos also displayed ocular toxicity in the rat following either oral or inhalation exposure. Refer to the Human Health Risk Assessment for Tribufos, dated June 26, 2000, and Table 5 for additional information regarding the toxicity of tribufos.

Table 5. Acute Toxicity of Tribufos

Guideline Number	Study Type	MRID	Results	Toxicity Category
81-1	Acute Oral -Rat	41954903	LD_{50} = 195-235 mg/kg	II
81-2	Acute Dermal - Rabbit	41954902	LD_{50} = >1000 mg/kg (m) <2000 mg/kg (f)	II
81-3	Acute Inhalation - Rat	41782301	LC_{50} = 4650 mg/m^3 (m) 2460 mg/m^3 (f)	III
81-4	Primary Eye Irritation -Rat	None	Data required (irritation likely)	NA
81-5	Primary Skin Irritation - Rat	41896203	Mild to moderate erythema, dry cracked skin, edema	IV
81-6	Dermal Sensitization	41618812	Negative	N/A

i. Dermal Exposure (Short- and Intermediate-Term)

In the preliminary human health risk assessment dated September 14, 1999, (available through both the EPA public docket and at http:www.epa.gov/opp/op), the Agency determined an MOE of 1000 was required for occupational exposure. This was based on the standard use of 10X for interspecies variability, 10X for intraspecies variability, and an additional 3X Uncertainty Factor (UF) which was applied because a NOAEL was not established in the 21-day rabbit dermal study (use of a LOAEL), and an additional 3X UF due to concern for severe neurotoxic effects seen in the hen study. Additionally, the ocular lesions seen at 17 mg/kg/day in the chronic study in rats and the retinal toxicity seen at 22 mg/kg/day in the 90-day inhalation study in rats were also seen at the highest dose tested in those studies.

The Agency reconsidered this position in June of 2000, and determined that a target MOE of 300 is appropriate (i.e., an additional 3X for the use of the LOAEL) and no additional UFs, such as the additional 3X for severity of effects (as previously determined) are required for the neurotoxic effects seen in the hen study ("Tribufos - Reassessment of the Toxicity Endpoint Selection - Report of the Hazard Identification Assessment Review Committee", June 27, 2000). This determination was made

based on the following factors: 1) in the hen study, Organophosphate Induced Delayed Neuropathy (OPIDN) occurred only at the highest dose tested (42 mg/kg/day) and a NOAEL (11 mg/kg/day) was established for this effect; and 2) application of the 3X factor to the 2 mg/kg/day LOAEL (in the 21-day rabbit dermal study) yields a dose of 0.7 mg/kg/day, which is 60 times lower than the dose (42 mg/kg/day) that induced the OPIDN in the hens. Therefore, 3X is sufficient to protect against the OPIDN as observed in the hen study. For short and intermediate-term dermal exposure risk assessments, the target dermal MOE is 300 and dermal MOEs greater than 300 are not of concern to the Agency.

ii. Inhalation Exposure (Short- and Intermediate-Term)

The NOAEL of 0.9 mg/kg/day established in the 90-day inhalation study in rats was selected for short and intermediate-term inhalation exposure assessments. The NOAEL is based on the inhibition of plasma and erythrocyte cholinesterase activity observed at 4.5 mg/kg/day (LOAEL). The inhalation target MOE is 100. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for tribufos are listed in Table 6.

Table 6: Summary of Toxicological Endpoints and Other Factors used in the Human Occupational Risk Assessment for Tribufos.

Type of Exposure (duration and route)	Endpoint and Effect Level	Study
Short and Intermediate-Term Dermal	**Endpoint and Effect Level:** Plasma, erythrocyte and brain ChE inhibition; dermal LOAEL of 2 mg/kg/day. This assessment incorporates the use of a 7X conversion factor to account for the differences in dermal absorption between rabbit and human skin. Applying the conversion factor results in a dose of 14 mg/kg/day (LOAEL), which is then compared to occupational exposure data for calculating MOEs. Refer to the section below for further explanation. **Target MOE:** Due to the use of a LOAEL, an additional 3X is applied to the risk assessment (in addition to the 10X interspecies and the 10X intraspecies). Therefore, the target MOE is 300	21-Day Dermal Toxicity study in the Rabbit (MRID 42007201)
Short and Intermediate-Term Inhalation	**Endpoint and Effect Level:** Plasma and erythrocyte ChE inhibition; inhalation NOAEL of 2.43 mg/L (0.9 mg/kg/day) **Target MOE:** Because a NOAEL was established, an additional 3X was not applicable in this assessment. Therefore, the target MOE is 100 (10X interspecies and the 10X intraspecies differences).	90-Day Inhalation Study in the Rat (MRID 42399801)
Long-Term Dermal and Inhalation	Long-term dermal or inhalation occupational exposure are not expected to occur for the registered uses of tribufos.	N/A

b. Adjustment for Species Differences in Dermal Absorption

The previous Human Health Risk Assessment Chapter, dated September 14, 1999, located on the internet at http:www.epa.gov/pesticides/op) established a LOAEL in the 21-day dermal toxicity study in rabbits. The revised risk assessment, dated June 26, 2000, considered a new dermal absorption study in monkeys submitted by the registrant. This study demonstrated that tribufos is poorly absorbed through the skin of monkeys. After eight hours of dermal exposure, only 7% of the applied dose had been absorbed through the skin into the systemic circulation. The Agency considered this new data and revised the risk assessment to reflect the changes discussed below.

With the availability of this new monkey dermal absorption data, the dermal toxicity in rabbits relative to the poor dermal absorption shown in monkeys was re-evaluated because: 1) in general, the skin of rabbits is more permeable to chemicals than human skin, and 2) the penetration of a chemical through the skin of primates (monkeys) can be used as a better surrogate for penetration through human skin. A dermal absorption study in rats showed absorption is greater in the rat than in the monkey. At a comparable dose, 48% of the applied dose was absorbed in the rat.

It is presumed that rat and rabbit dermal absorption rates are comparable. However, monkey dermal absorption is presumed to be a better surrogate for human skin. Therefore, an adjustment can be made to the dose (LOAEL) used for risk assessment to account for species differences in dermal absorption. Consequently, using the dermal absorption rates of 48% in rats and 7% in monkeys, a 6.9 conversion factor was obtained to account for species differences in dermal absorption:

$$\frac{\text{Dermal Absorption in Rats (48\%)}}{\text{Dermal Absorption in Monkeys (7\%)}} = 6.9$$

The Agency determined that a conversion factor of 7 (rounded up from 6.9) should be applied to the LOAEL of 2 mg/kg/day selected for short- and intermediate-term dermal exposure assessments. This resulted in a LOAEL of 14 mg/kg/day to assess occupational dermal risk.

c. Occupational Handler Exposure

Data from the Pesticide Handlers Exposure Database (PHED) as well as a chemical-specific study were used to estimate occupational exposure risks. PHED is a comprehensive generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposures for pesticide workers (e.g., mixers, loaders, and applicators) involved in handling or applying of pesticides. The database currently contains data for over 1700 monitored exposure events.

A chemical-specific handler exposure study was also performed for tribufos (MRID 42685901) using passive dosimetry methodologies. It was designed to determine the dermal and inhalation exposures to the workers. These data were combined with the PHED data to assess the use

on cotton with a more robust database. By combining the chemical-specific data with PHED, the Agency was able to increase the sample size and number of studies. This allows the Agency to better characterize the variety of equipment used throughout the country and accounts for the large variability of exposures among handlers.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest level of PPE is baseline. MOEs are less than the target MOE (target dermal MOE is 300 and target inhalation MOE is 100), increasing levels of risk mitigation (personal protective equipment (PPE) are applied. If MOEs are still less than the target MOE, engineering controls (EC) are applied. In some cases, EPA will conduct an assessment using PPE or ECs taken from a current label. The levels of protection that formed the basis for calculations of exposure from tribufos activities include:

- **Baseline:** Long-sleeved shirt and long pants, shoes and socks.
- **Minimum PPE:** Baseline + chemical resistant gloves and a respirator.
- **Maximum PPE:** Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical footwear plus socks, chemical resistant headgear for overhead exposures, and a respirator if risk is driven by inhalation.
- **Engineering controls:** Engineering controls such as a closed cab tractor for application scenarios, or a closed mixing/loading system, such as a closed mechanical transfer system for liquids or a packaged based system (e.g., Lock N Load for granulars or water soluble packaging for wettable powders). Some engineering controls are not applicable for certain scenarios (e.g., for handheld application methods there are no known devices that can be used to routinely lower the exposures).

In reviewing the use patterns of tribufos, the Agency identified four major application exposure scenarios: (1) mixing/loading liquid formulations for aerial and groundboom equipment; (2) aerial application (3) groundboom application; and (4) flagging during aerial spray applications. The Agency assessed the aerial and ground scenarios using surrogate data from PHED version 1.1 as well as incorporating a tribufos-specific handler study as discussed above. The Agency also assumed that an applicator applies tribufos to 1,200 acres per day aerially, and 80 acres per day by groundboom at the maximum label rate of 1.875 lb ai (pounds of active ingredient) per acre and at 1.125 lbs ai per acre. Mixing/loading, and application are assumed to be performed by different individuals. The Agency normally uses 350 acres as a typical value for the number of acres treated aerially in a single day. However, the Agency has determined that 1,200 acres is more representative for the following reasons:

1. A survey by the National Agricultural Aviation Administration (NAAA) indicates on a good day when weather conditions are extremely favorable, more than 2000 acres of cotton can be treated.

2. Unlike insecticidal uses, which may be limited to areas of infestation, harvest aids are typically applied to the entire crop.

3. Fields where cotton is grown may cover very large areas where growers have only a short window to apply tribufos to an entire crop for defoliation.

i. Dermal Risk

The MOEs listed in Tables 7 and 8 for aerial scenarios are assuming the maximum level of engineering controls. The resulting MOEs for the proposed rate of 1.125 lbs ai/A (Table 7) range from 82 (mixing and loading to support aerial application to 1,200 acres per day) to 3,300 (flaggers supporting aerial application to 1,200 acres per day). For the current maximum label rate of 1.875 lbs ai/A (Table 8), MOEs range from 49 (mixing/loading for aerial application to 1,200 acres) to 2,000 (flagging to support aerial application to 1,200 acres per day). Therefore, several of the handler scenarios are below the dermal target MOE of 300 and are of concern to the Agency.

In the revised human health effects chapter, the MOE for flagger scenarios were calculated with engineering controls. Because these MOEs (2000 and 3200) were so high at both the 1.125 lbs ai/A rate and the 1.875 lbs ai/A rate, the calculations have since been conducted with baseline and additional PPE. MOEs for dermal exposure ranged from 40 (flaggers with baseline attire at a rate of 1.875 lbs ai/A) to 73 (flaggers with additional PPE at a rate of 1.125 lbs ai/A). These MOEs are below the target MOE of 300, therefore, the Agency concludes that engineering controls are necessary to protect flaggers supporting aerial applications of tribufos at any rate.

The MOEs associated with the use of groundboom equipment, performed at baseline, range from 760 (mixing and loading at a rate of 1.875 lbs ai/A) to 780 (applying tribufos at a rate of 1.125 lbs ai/A. At baseline, the MOEs for dermal exposure to tribufos are all greater than the target MOE of 300. The Agency, therefore, has no concern for workers who, mix, load, and apply tribufos via groundboom.

The aerial scenarios for tribufos are based on the maximum level of engineering controls and the groundboom scenarios are based on baseline assumptions (long sleeved-shirt, long pants, shoes, and socks). MOEs for dermal exposure are less than the target MOE 300, despite maximum mitigation measures (engineering controls) for the identified aerial exposure scenarios listed above. One of these five scenarios is below 100. In summary, when engineering controls are used, the MOEs for the aerial mixer, loader, and applicator are below the target MOE of 300 and, therefore, are of concern to the Agency.

ii. Inhalation Risk

Tables 7 and 8 summarize inhalation risks from tribufos use. The inhalation MOEs are as follows: at the current label rate of 1.875 lbs ai/A, MOEs range from 330 (mixing and loading to support aerial application to 1,200 acres per day) to 5,100 at baseline (mixing and loading liquids for groundboom application); at the proposed label rate of 1.125 lbs ai per acre, MOEs range from 560 (mixing and loading for aerial application to 1,200 acres per day) to 8,400 at baseline (mixing and loading liquids for groundboom application). With engineering controls for aerial scenarios and baseline for groundboom equipment, the inhalation MOEs are significantly above the target MOE of 100 (refer to Tables 7 and 8).

d. Combined Dermal and Inhalation Risks

The Agency also performed an occupational risk assessment combining both the dermal and inhalation risk for workers who are exposed to tribufos by both routes. An Aggregate Risk Index (ARI) method was used because the dermal target MOE is 300 and the inhalation target MOE is 100. An ARI of greater than 1 is not of concern to the Agency, whereas, an ARI less than 1 is of concern to the Agency. The combined dermal and inhalation risks which reflect the current maximum label rate of 1.875 lbs ai/A range from 0.16 (mixing and loading to support application 1,200 acres per day) to 5 (flaggers supporting aerial application to 1,200 acres per day).

The combined dermal and inhalation ARIs reflecting the proposed amended label rate of 1.125 lbs ai/A range from 0.26 (mixing and loading to support aerial application to 1,200 acres per day) to 9.5 (flaggers supporting aerial application to 1,200 acres per day). These scenarios are accurate with the exception of California and Arizona, which use the higher rate of 1.875 lbs ai/A for defoliation for reasons discussed in chapter IV of this document. Two of the five combined inhalation and dermal scenarios yield ARIs below 1, and therefore, are of concern even when engineering controls are used. Tables 7 and 8 list the scenarios applicable to tribufos as well as MOEs and ARIs.

Table 7. Short- and Intermediate-Term Dermal, Inhalation, and Total MOEs for Tribufos at 1.125 lb ai/A

Exposure Scenario	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (μg/lb ai)	Acres Treated	Dermal - Eng. Controls[a] for aerial scenarios only (Baseline - groundboom)[b, e, f]		Inhalation - Eng. Controls for aerial scenarios only (Baseline - groundboom)[c, e]		ARI[d]
				Daily Dose (mg/kg/day)	MOE[g] (target300)	Daily Dose (mg/kg/day)	MOE[h] (target100)	
Mixer/Loader Exposure								
Miixing/Loading for aerial application - PHED and Chemical-Specific study	0.0086	0.083	1200	0.17	82	0.0016	560	0.26
Mixing/loading liquids for groundboom application -- PHED and Chemical-Specific study	0.0086	0.083	80	0.011	1300	0.0001	8400	4.1
Applicator Exposure								
Application for aerial - PHED and Chemical-Specific Data	0.005	0.068	1200	0.096	150	0.0013	690	0.47
Groundboom Tractor –(Open Cab) PHED V1.1[f]	0.014	0.74	80	0.018	780	0.0010	950	2.5
Flagger Exposure								
Flagging to Support Aerial Application	0.00022	0.007	1200	0.0042	3300	0.00014	6700	9.5

Note: Proposed reduction in application rate reduces the maximum rate from 2.5 pts/acre formulated product to 1.5 pts/acre formulated product (DEF6 is 6 lb ai/gal or 1.125 lb ai per 1.5 pts product). Memo from J. Thornton, Bayer Corp., to A. Overstreet, EPA/OPP/SRRD, dated January 5, 2000.

[a]Engineering control unit exposures represent the use of closed systems (e.g., closed loading and enclosed cab tractors/cockpit) long pants, long sleeved shirt, and no gloves (except for closed loading which is based on the use of chemical-resistant gloves).

[b]Potential dermal daily dose (mg/kg/day) = [dermal unit exposure (mg/lb ai) * Appl. rate (lb ai/acre) * Acres treated * 1 dermal absorption]/Body weight (70 kg). Dermal absorption is not factored into the dose because it is compared to the 21-day dermal study, and therefore, it is a "potential" dose.

[c]Potential inhalation daily dose (mg/kg/day) = [inhalation unit exposure (mg/lb ai) * 0.001 μg/mg unit conversion * max appl rate (lb ai/A or lb ai/gal) * area treated (acres or gal) * 1 inhalation absorption]/Body weight (70 kg).

[d]An ARI of greater than one is not of concern. ARI = 1/((1/dermal MOE/300UF)) + (1/(inhalation MOE/100UF))

[e]MOEs greater than 300 for the dermal route and 100 for the inhalation route are not of concern.

[f]Baseline attire for groundboom applicators consists of a single layer of clothing, no gloves, and no respirator.

[g] Dermal MOE = (LOAEL of 2 mg/kg/day x 7 absorption correction factor)/dermal dose (mg/kg/day)

[h] Inhalation MOE= (NOAEL of 0.9 mg/kg/day)/inhalation dose (mg/kg/day)

Table 8. Dermal, Inhalation and Aggregate MOEs at 1.875 lb ai/A (For CA and AZ)

Exposure Scenario	Acres Treated	Dermal MOE [a] with Eng. Controls for aerial - Baseline for groundboom scenarios	Inhalation MOE[b] with Eng. Controls for aerial - and Baseline for groundboom scenarios	ARI[c]
Mixer/Loader Exposure				
Mixing/Loading Liquids for Aerial Application	1200	49	330	0.16
Mixing/Loading Liquids for Groundboom Application	80	760	5100	2.4
Applicator Exposure				
Applying Spray via Aerial Application	1200	90	410	0.2
Groundboom Tractor -- PHED V1.1(3) -at Baseline	80	470	570	1.2
Flagger Exposure				
Flagging Aerial Applications -- PHED V1.1 (4)	1200	2000	4000	5.9

[a] MOEs greater than 300 for the dermal route are not of concern.
[b] MOEs greater than 100 for the inhalation route are not of concern.
[c] ARIs greater or equal to 1 are not of concern.

e. Post-Application Risks

The Agency also assessed post-application risks to workers. Post-application workers who enter previously treated fields may be exposed because their skin contacts treated surfaces in the area where they are working. Exposures are directly related to the tasks which are performed. The Agency examines the amount of pesticide residue found on the workers over time in various studies. The Agency then evaluates this information to determine the number of days following application that must elapse before the pesticide residues dissipate to a level where worker MOEs equal or exceed 300 while wearing baseline attire. Baseline attire, consisting of long-sleeved shirt, long pants, shoes and socks, was used to assess post-application risks to reentry workers. Based on the results of the post-application worker assessment, the Agency decides if there is a need to establish early entry restrictions to allow reentry into treated fields for nonroutine hand labor activities using a specified set of PPE, rather than totally restricting entry for a period of time. For tribufos, restricted entry intervals (REIs) have been established for post-application activities. These include: raking, picking, tramping, and the module builder operator.

The Agency also reviewed a chemical-specific post-application worker exposure study. This chemical-specific study was conducted to determine the dermal and inhalation exposures of workers engaged in post-application activities. Inhalation exposure is a negligible contributor to the overall risks associated with the use of tribufos. Table 9 lists the post-application dermal MOEs, based on the

current maximum application rate of 1.875 lb ai/A, as well as the more typical application rate of 1.125 lbs ai/A (except CA and AZ which use the 1.875 lbs ai/A).

The post-application assessment is based on exposures to the pickers, module builders, rakers, and trampers. The exposure assessment is based solely on the data submitted by the registrant. Based on a recent Agency site visit to Arizona to observe cotton harvesting activities, the assessment is believed to accurately represent the application and harvesting activities performed.

The Agency used a chemical-specific, passive dosimetry study (MRID 42685901) to determine the exposure to workers engaged in post-application activities (subsequent REIs were determined from passive dosimetry data). The study subjects were monitored at the maximum application rate of 1.875 lb ai/acre and reduced by a factor of 0.6 to the proposed application rate of 1.125 lb ai/acre. The Agency also applied a linear extrapolation of the exposure to an 8 hour work day because the registrant study monitored for a 4.8 hour work day. Moreover, the average exposure of the 3 or 4 replicates were used, not the highest one monitored.

A transfer coefficient was used to estimate the dermal MOEs 24 hours after application (current REI) and 7 days after treatment (DAT). Table 9 below provides the results of the dermal MOEs at 24 hours and newly proposed 7 DAT. The resulting MOEs for 24 hours post-treatment at the current application rate of 1.875 lbs ai/A ranged from 45 (rakers) to110 (module builder operators). The current label rate at 7 days post-application yielded MOEs ranging from 200 (rakers) to 480 (module builder operator). At the proposed rate of 1.125 lbs/ai/A, the MOEs at 24 hours after application ranged from 74 (rakers) to 180 (module builder operator). MOEs at 7 days post-application ranged from 340 (rakers) to 840 (module builder operator).

The Agency therefore concludes that there are still risk concerns for three of the four scenarios (rakers, trampers, and pickers) at the current label rate even after 7 days post-treatment (MOEs below 300); however, it has no risk concerns at the lower proposed application rate with a 7-day REI.

Table 9. Tribufos Dermal Exposures for Picker Operators, Module Builder Operators, Rakers, and Trampers (Target MOE=300)

	Worker Categories [a]			
	Pickers	Module	Rakers	Trampers
Results at 24 hours after treatment				
Average dermal dose @ 1.875 lb ai/acre (mg/kg/day)[b]	0.30	0.13	0.31	0.27
MOEs at 1.875 lbs ai/acre [d]	**47**	**110**	**45**	**52**
Average dermal dose (mg/kg/day) corrected for the lower (1.125 lb ai A) application rate [c]	0.18	0.078	0.19	0.16
MOE@ 1.125 lb ai/acre [d]	**78**	**180**	**74**	**88**
Results at Seven Days After Treatment (DAT)				
Average dermal dose @ 1.875 (mg/kg/day)[b]	0.066	0.029	0.069	0.060
MOEs at 1.875 lbs ai/acre [d]	**210**	**480**	**200**	**230**
Average dermal dose (mg/kg/day) corrected for the lower (1.125 lb ai A) application rate [c]	0.040	0.017	0.041	0.036
MOE @ 1.125 lb ai/acre [d]	**350**	**820**	**340**	**390**

[a]Passive dosimetry monitoring data were collected at the California sites (DAT 15 and 17 are from the aerially treated field and DAT 20 is from the ground-treated field).

[b]The dermal exposure represents workers wearing cotton/polyester coveralls over the whole body dosimeters. The average dermal dose is calculated from the data reported in MRID 427016-01 at an application rate of 1.875 lb ai/acre. The dermal exposure data were collected on 15, 17, and 20 DAT and corresponding cotton boll residues were also collected. Based on thes data, transfer coefficients were calculated to extrapolate the dose from 15, 17, and 20 DAT down to 24 hours and 7 DAT.

[c]Corrected Average dermal exposure (mg/kg/day) = Avg dermal exposure@1.875 lb ai/A (mg/kg/day) x 0.6correction factor for new application rate (*i.e.*, 1.125 lb ai/A/1.875 lb ai/A). Where the Avg. Daily Dermal Dose (mg/kg/day) = (Avg. Dermal exposure(μg/hr) x 8 hrs/day x 0.001 mg/ug unit conversion)/70 kg BW.

[d]MOE = 14 mg/kg/day (LOAEL of 2 mg/kg/day x a conversion factor of 7)/Dermal Dose mg/kg/day. Target MOE is 300.

f. Human Incident Reports

The Office of Pesticide Programs (OPP) Incident Data System (IDS), Poison Control Centers database, California Department of Food and Agriculture database, and the National Pesticide Telecommunications Network (NPTN) have been consulted for poisoning incident data on tribufos. From the review of the IDS and reports from California, it appears that a significant number of spray drift cases result from the use of tribufos. It is not clear from the information collected how many of these cases are due to anticholinergic effects versus the odor of the pesticide. Some cases reportedly resulted in flu-like symptoms as a result of spraying tribufos near residential areas. There were too few incidents involving mixer/loader workers that applied tribufos for the Agency to make any conclusions.

The Minnesota Department of Agriculture surveyed 32 states about spray drift and found a total of 2,681 complaints from 1993 through 1995. Tribufos was involved in 27 of these complaints, which is only 1% of the total complaints but it ranked 10 out of the 38 pesticides for which incidents were reported. In a survey by the California Department of Health Services in 1987, a total of 232 exposed residents and 175 controls were interviewed. Those with high likelihood of exposure to tribufos complained of fatigue, eye irritation, rhinitis, throat irritation, difficulty in breathing, wheezing, nausea and diarrhea. California no longer allows tribufos to be used within one-half mile of residential areas for reasons of odor.

Since the Agency's 1997 review, there have been two drift complaints: one from Georgia in 1996 when a person with flu-like symptoms did not seek medical attention and one from North Carolina in 1998 where a woman was outdoors when a crop duster flew over. The woman reported feeling the mist on her skin as well as inhaling it. She also reported nausea, headache, and developed hypertension. Her physician felt tribufos was likely the cause of her symptoms.

B. Environmental Risk Assessment

1. Environmental Fate

The Agency has determined that ground and surface water contamination are not likely to occur through runoff. The environmental fate of tribufos has been well characterized in the laboratory; however, its behavior in the field is not yet clearly understood. Based on the laboratory data, it appears that tribufos could accumulate in soil with repeated applications. The primary route of dissipation appears to be degradation in flooded soil under anaerobic conditions, with a half-life of 4-6 months. In general, tribufos may be described as a persistent and immobile compound. It is also only moderately soluble, with an aqueous solubility of 2.3 ppm. Tribufos can contaminate surface water at application by spray drift. Substantial fractions of applied tribufos may remain available for runoff for many months after application. The relatively high soil/water partitioning of tribufos indicates that runoff will generally occur primarily via adsorption to eroding soil as oppossed to dissolution in runoff water. In addition, the concentration of tribufos adsorbed to suspended and bottom sediment will be much greater than its concentration in sediment pore water or the water column. Based on the tendency to bind to soil, ground water contamination as a result of tribufos use is not expected.

2. Ecological Assessment

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics, pesticide use, and/or monitoring data. To evaluate the potential risk to nontarget organisms from the use of tribufos products, EPA calculates a Risk Quotient (RQ), which is the ratio of the estimated exposure concentration to the toxicity endpoint values, such as LD_{50} (the median lethal dose at which 50% of the test animals die) or LC_{50} (the median concentration of a substance which causes death to 50% of the

test animals). The RQ is a means of integrating the results of ecological exposure and ecological toxicity. These RQ values are compared to levels of concern (LOCs), which provide an indication of the relative risk the particular pesticide and/or use may pose for nontarget organisms. If the RQ does not exceed the LOC, it is unlikely that the pesticide will pose a significant risk. Similarly, when RQs are equal to or greater than the LOC, additional refinements or mitigation may be necessary. Use, toxicity, fate, and exposure are considered to characterize the risk as well as the level of certainty and uncertainty in the assessment. Refer to the Ecological Effects and Fate Chapter for the Tribufos IRED for additional information located on the internet at http:www.epa.gov/pesticides/op.

a. Risks To Birds

For calculating risks to birds associated with the use of tribufos, an exposure scenario of 10 days was assumed. The LOCs used for comparison to the RQs were 0.5 for acute high risk, 0.2 for restricted use risk, and 0.1 for concerns to endangered species. The LOC for chronic risk is 1.0. The Agency assessed both acute and chronic risks to birds using a Bobwhite Quail study. Therefore, the Agency is requiring a mallard duck study to more comprehensively assess risks to birds (refer to Section V for data requirements).

i. Single Application

The results indicate that for a single, broadcast application of tribufos, the acute high risk LOC is not exceeded for any use rate. RQs ranged from 0.01 for birds foraging on seeds at an application rate of .75 lbs ai/A, to an RQ of 0.18 for birds foraging on short grass at an application rate of 1.125 lbs ai/A. The acute endangered species LOC is exceeded at 1.875 lbs ai/A, and the 1.125 labs ai/A rate for birds foraging on short grass.

Furthermore, the results indicate that for a single, broadcast application of tribufos, the chronic risk to birds (LOC=1.0), is exceeded for different food items at all use rates. RQs ranged from 0.07 for birds foraging on seeds at an application rate of 0.75 lbs ai/A, to 3.04 for birds foraging on short grass at an application rate of 1.875 lbs ai/A.

The Agency, therefore, has no concern for acute high risk to bird species, but chronic risks are possible to bird species that feed on particular food items. Endangered species may be affected both acutely and chronically.

ii. Multiple Applications

The results indicate that for multiple broadcast applications of tribufos (0.75 lbs ai/A applied twice), the avian acute high risk (0.5) is not exceeded for any use rate or food item. RQs ranged from 0.01 for birds foraging on seeds to 0.24 for birds foraging on short grass. However, the acute

restricted use LOC (0.2) and endangered species LOC (0.1) are slightly exceeded for some food items.

The acute endangered species LOC (0.1), the restricted use LOC (0.2), and the chronic LOC (1.0) are exceeded for some food items. The RQs for chronic risks range from 0.08 for birds foraging on seeds, to 1.32 for birds foraging on short grass. In conclusion, the Agency is concerned with chronic risk to bird species resulting from multiple applications of tribufos, as well as risks to endangered bird species, which may be acutely affected.

b. Risks To Mammals

For calculating risks to mammals associated with the use of tribufos, two exposure scenarios were assumed (10 days and 21 days). The LOCs used for comparison to the RQs were 0.5 for acute high risk, 0.2 for restricted use risk, and 0.1 for concerns to endangered species. The LOC for chronic risk is 1.0.

i. Single Application

The results indicate that for a single, broadcast application of tribufos, the acute high risk, the acute restricted use, and the endangered species LOCs are exceeded for all use rates for herbivores and insectivores that feed on short grass or forage on small insects. Acute RQs for both herbivores and insectivores ranged from 0.01 to 1.34. The acute endangered species LOC is exceeded when mammals feed on large insects at both the 1.875 lbs ai/A rate and the 1.125 lbs ai/A rate. Therefore, the Agency is concerned with acute high risks to herbivores and insectivores.

Acute RQs for single, broadcast applications involving granivores (mammals which feed on seeds) ranged from 0.01 at an application rate of 0.75 lbs ai/A, to 0.03 at an application rate of 1.875 lbs ai/A. The Agency, therefore, has no acute concerns for these scenarios at any application rate.

For chronic risks to mammals, the Agency examined a lower (average) exposure scenario because, typically, mammals will not be exposed to maximum residues of tribufos throughout their breeding cycle. More likely, such animals would be exposed to initial maximum residues followed by declining residues. To address this scenario, the Agency used an average of such residues for a time period of 21 days, a period that would account for the shortest gestation period of a representative small mammal. RQs for this scenario ranged from 0.34 for seed foraging mammals at an application rate of 0.75 lbs ai/A, to 13.94 for mammals feeding on short grass at a maximum application rate of 1.875 lbs ai/A. The Agency, therefore, has chronic risk concern for these scenarios at all application rates.

ii. Multiple Applications

The results indicate that for multiple applications of tribufos (0.75 lbs ai/A applied twice), the acute LOC for mammals (0.5), the acute restricted use LOC (0.2), and the acute endangered species LOC (0.1) are exceeded for herbivores and insectivores that feed on short grass or insects. The RQs ranged from 0.02 for mammals foraging on large insects, to 1.77 for mammals foraging on short grass. Therefore, acute high risks to herbivores and insectivores are likely and endangered species may be acutely affected. The Agency is, therefore, concerned with acute risk to mammals when multiple applications of tribufos are used.

For granivorous mammals, which forage on seeds, multiple applications of tribufos are not of concern to the Agency. RQs ranged from 0.01 to 0.02 and, therefore, did not exceed the acute high risk, restricted use, or endangered species LOC.

In regard to chronic risk, multiple applications (0.75 lbs ai/A applied twice), resulted in risk concerns to mammals. As discussed previously, the Agency examined a lower (average) exposure scenario because, typically, mammals will not be exposed to maximum residues of tribufos throughout their breeding cycle. RQs for this scenario ranged from 0.53 for mammals feeding on seeds to 8.63 for mammals feeding on short grass and, therefore, has concern for chronic risks to mammals.

c. Risks to Insects

A honeybee study was conducted and results showed that tribufos is practically nontoxic to bees on an acute contact basis. The Agency, therefore, has no concern with risks to honeybees associated with the use of tribufos.

d. Risks To Aquatic Species

To assess risks to aquatic species associated with tribufos use, the Agency used estimated environmental concentrations predicted from the PRZM2/EXAMS II surface water model. However, the PRZM2/EXAMS II estimates for potential exposure to aquatic organisms do not include the Index Reservoir (IR) and Percent Crop Area refinements that are part of the human drinking water assessment. The IR was developed from a real watershed in western Illinois to be used as a standard watershed to estimate surface drinking water concentrations, and is not appropriate for use to estimate pesticide concentrations in water bodies available to aquatic organisms. For freshwater fish, acute RQs ranged from 0.03 to 0.06 at a single application rate of 1.875 lbs ai/A. The Agency is not concerned with acute risk to fish.

In regard to chronic risks to freshwater as well as estuarine fish, data are lacking. The Agency is requiring further data to better characterize potential risks. Refer to section V for particular studies required.

For estuarine and marine fish, the results indicate that the aquatic acute restricted use, and the acute endangered species LOCs are very slightly exceeded. RQs ranged from 0.06 to 0.11 at an application rate of 1.875 lbs ai/A. The Agency is, therefore, concerned with acute risks to estuarine and marine fish.

In regards to freshwater invertebrates, the results indicate that the aquatic acute restricted use LOC, the acute endangered species LOC, and the chronic LOC are exceeded for freshwater invertebrates at the 1.875 lbs ai/A rate. Acute RQs ranged from 0.01 to 0.52 and the chronic RQs ranged from 0.05 to 3.50. The Agency, therefore, has concerns with acute and chronic risk to freshwater invertebrates.

For estuarine and marine invertebrates, the acute high risk LOC (0.5), the acute endangered species (0.05), the acute restricted use (0.1), and the chronic LOC (1.0) are exceeded for estuarine/marine invertebrates at an application rate of 1.875 lbs ai/A. Acute RQs ranged from 1.60 to 2.80 and, chronic RQs ranged from 10.0 to 23.3. The Agency, therefore, has concerns with acute and chronic risks to estuarine and marine invertebrates. The Agency is also requiring a chronic estuarine/marine study to better characterize risks to invertebrates (refer to Section V).

e. Risks To Plants

Terrestrial, aquatic, and semi-aquatic plants may be exposed to tribufos from runoff or spray drift from adjacent treated sites. Semi-aquatic plants are those that inhabit low-lying wet areas that may be dry at certain times of the year. Spray drift exposure from ground application is assumed to be 1% of the application rate. Spray drift from aerial application is assumed to be 5% of the application rate.

Exposure to non-target vascular aquatic plants is possible through the use of tribufos. Acute RQs ranged from 0.05 to 0.09. These RQs indicate that the acute LOCs are not exceeded for any use rate. RQs for exposure to non-vascular plants range from 0.07 to 0.12. The Agency is, therefore, not concerned with risks to non-target aquatic plants.

The risks to non-target terrestrial plants cannot be assessed because pertinent plant studies are lacking. The Agency is requiring further data to better characterize potential risks. Refer to section V for particular studies required.

IV. Interim Reregistration Eligibility and Risk Management Decisions

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 are 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 tribufos.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient tribufos , as well as a tribufos -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 tribufos, EPA has sufficient information on the human health and ecological effects of tribufos to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that tribufos is eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) the cumulative risk assessment for the organophosphates support a final reregistration eligibility decision. Label changes are described in Section IV. Appendix B identifies the generic data requirements that the Agency reviewed as part of its interim determination of reregistration eligibility of tribufos, and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet completed its cumulative risk assessment for the organophosphates, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to support the continued use of tribufos. Based on its current evaluation of tribufos alone, the Agency has determined that tribufos 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 tribufos.

At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. For tribufos, if all changes outlined in this document are incorporated into the labels, then all current risks will be mitigated to an acceptable level. But, because this is an interim RED, the Agency may take further actions, if warranted, to finalize the reregistration eligibility decision for tribufos after assessing the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

Because the Agency has not yet completed the cumulative risk assessment for the organophosphates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing tribufos food residue tolerances as called for by the Food Quality Protection Act (FQPA). When the Agency has completed the cumulative assessment, tribufos tolerances will be reassessed in that light. At that time, the Agency will reassess tribufos along with the other organophosphate pesticides to complete the FQPA requirements and make a final reregistration eligibility determination.

By publishing this interim decision on reregistration eligibility and requesting mitigation measures now for the individual chemical tribufos , 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.

Summary of Phase Five Comments and Responses

When making its interim decision, the Agency reviewed all comments received during Phase 5 of the Organophosphate Pilot Process. As stated previously, a mitigation proposal was received from the Bayer Corporation; details of this proposal are discussed in the next section. Several other comments were received including those from the National Cotton Council, which described the benefits of tribufos and impact of loss to the industry in the absence of tribufos. These comments helped the Agency in understanding the benefits associated with the use of tribufos and the loss that would be incurred by the cotton industry as a result of removing tribufos from the market. Many of these comments are addressed below where the Agency's additional considerations are listed. These comments and their responses are available in the public docket.

B. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. The assessment was for this individual organophosphate, and does not attempt to fully reassess 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.

The Agency has determined that risk from exposure to tribufos is within its own "risk cup." That is, if tribufos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for tribufos 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 acute and chronic food exposure. An aggregate assessment was conducted for exposures through food and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to tribufos "fit" within the individual risk cup.

b. Tolerance Summary

This tolerance discussion is limited to tribufos. The tolerances listed in 40 CFR §180.272 are expressed in terms of tribufos. The Agency has concluded that tribufos *per se* is the compound of toxicological concern. The current tolerance expression is adequate. It should be noted that the Agency will commence proceedings to revoke one tolerance, cottonseed hulls. Seven tolerances will remain the same (cattle meat and byproducts, cottonseed, goat meat and byproducts, and sheep meat and byproducts. The remaining eleven tolerances (seven to be added and four to be raised) will remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is completed.

i. Tolerances To Be Proposed Under 40 CFR §180.272

Tolerances for residues of tribufos in the meat and meat byproducts of hogs and horses at 0.02 ppm are to be proposed, as well as tolerances for residues of tribufos in meat fat of hogs and horses at 0.15 ppm. Once adequate data concerning tribufos residues in cotton gin byproducts from cotton harvested at the established preharvest interval (PHI) are submitted, a tolerance of 40 ppm (as determined by field trial data) for cotton gin byproducts will be proposed.

ii. Tolerances Listed Under 40 CFR §180.272

Ruminant metabolism and feeding studies indicate that the established tolerances for the meat, and meat byproducts of cattle, goats, and sheep are adequate. The existing tolerance for residues of tribufos in milk is 0.002 ppm. Based on maximum theoretical dietary burden using the recommended cotton gin byproducts tolerance, the existing tolerance for tribufos residues in milk needs to be raised. Based on the data currently available, milk and fat tolerances have been reassessed at 0.01 and 0.15 ppm, respectively. The registrant may petition to lower the recommended milk tolerance by submitting analyses of samples from the animal feeding studies using a method with greater sensitivity than 0.01 ppm that quantitatively shows that tribufos residues in milk are less than 0.01 ppm. It should also be noted, consistent with FQPA, that a milk tolerance can not be set lower than the limit of quantification (LOQ). Therefore, the existing tolerance of 0.002 is to be increased.

The registrant may petition to lower the tolerance in meat and meat byproducts if they submit an analytical enforcement method capable of quantifying residues at the proposed lower tolerance levels. The term "negligible residues" is to be removed from the tolerance expressions for fat, meat, and meat

byproducts of cattle, goats, and sheep, and milk to conform to current Agency administrative practice. Table 10 lists the current tolerances along with proposed changes. Based on FQPA and the results of an acceptable cottonseed processing study, the established feed additive tolerance for cottonseed hulls is to be revoked.

Table 10. Tolerance Summary for Tribufos

Commodity	Current Tolerance (ppm)	Tolerance Reassessment * (ppm)	Comment/ *(Correct Commodity Definition)*
Tolerances Listed Under 40 CFR §180.272(a):			
Cattle, fat	0.02[1]	0.15	Tolerance to be raised (see text above)
Cattle, meat	0.02[1]	0.02	
Cattle, meat byproducts	0.02[1]	0.02	
Cottonseed	4	4	(Cotton, undelinted seed)
Cottonseed hulls	6	Revoke	Not warranted based on the results of an acceptable cottonseed processing study.
Goats, fat	0.02[1]	0.15	(Goat, fat)
Goats, meat	0.02[1]	0.02	(Goat, meat)
Goats, meat byproducts	0.02[1]	0.02	(Goat, meat byproducts)
Milk	0.002[1]	0.01	Tolerance to be raised (see text above)
Sheep, fat	0.02[1]	0.15	Tolerance to be raised (see text above)
Sheep, meat	0.02[1]	0.02	
Sheep, meat byproducts	0.02[1]	0.02	
Tolerances to Be Proposed Under 40 CFR §180.272(a):			
Cotton Gin byproducts	None	40	(Cotton, gin byproducts)
Hog, fat	None	0.15	
Hog, meat	None	0.02	
Hog, meat byproducts	None	0.02	
Horse, fat	None	0.15	
Horse, meat	None	0.02	
Horse, meat byproducts	None	0.02	

[1]Negligible residues

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

2. Endocrine Disruptor Effects

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

C. Regulatory Rationale

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

1. Human Health Risk Mitigation

a. Dietary Risk Mitigation

The Agency has no concern for dietary risks from food and water. Therefore no mitigation measures for dietary food and water risks are required.

i. Acute Dietary (Food)

Acute dietary exposure is below the Agency's level of concern of all population subgroups. Infants and children (1-6 years) are exposed to tribufos at a level less than or equal to 9% of the aPAD (0.005 mg/kg/day) at the 99.9th exposure percentile. Therefore, no mitigation for acute dietary food risks is required.

ii. Chronic Dietary (Food)

The chronic dietary risk is below the Agency's level of concern and is estimated to be less than 6% of the cPAD for all population subgroups including infants and children (1-6 years). Therefore, no mitigation for chronic dietary food risks is required.

iii. Acute Drinking Water

The acute DWLOC for the most highly exposed subpopulation, children 1-6 years, is 10 ppb. The modeled estimate for tribufos is 5.8 ppb in surface sources of drinking water. Based on the physical/chemical characteristics of tribufos, the Agency determined that residues of tribufos are not expected to reach ground water and were, therefore, not estimated. The Agency has no concern for acute effects from tribufos in surface or ground water-sourced drinking water; therefore, no mitigation is required.

iv. Chronic Drinking Water

The DWLOC for the most highly exposed subpopulation, children 1-6 years, is 1 ppb. In a worst case scenario, the modeled annual mean estimate for chronic exposure to tribufos in water is 1-2 ppb. Even though the modeled surface water figures slightly exceed the DWLOCs for only the most highly exposed sub-population, the Agency believes the modeled drinking water concentrations are considered high-end estimates and do not represent tribufos levels that people actually consume in finished drinking water for reasons discussed earlier in the drinking water section of this document. Based on the physical/chemical characteristics of tribufos, the Agency determined that residues of tribufos are not expected to reach ground water and were, therefore, not estimated. The Agency has no concern and is, therefore, not proposing any mitigation for chronic drinking water risks from surface or ground water sources of drinking water.

b. Occupational Risk Mitigation

Based on the Agency's revised occupational risk assessment, mixers, loaders, and handlers of tribufos are exposed dermally at levels that pose risk concerns and require mitigation. With the addition of engineering controls for aerial scenarios to mitigate dermal occupational risks, estimated MOEs for inhalation exposure are above the target MOE of 100 for all scenarios. Therefore, inhalation risks are not a main risk driver or concern for this assessment.

The target MOE for dermal exposure is 300. Dermal MOEs for mixers, loaders, and applicators supporting groundboom operations range from 780 to 1,300 at baseline (long-sleeved shirt, long pants, shoes, and socks) at the proposed rate of 1.125 lbs ai/A and from 470 to 760 at baseline at the higher application rate of 1.875 lbs ai/A. These MOEs do not exceed the Agency's level of concern and no further mitigation is necessary.

The Agency finds that mixers/loaders and applicators involved in aerial applications at typical 1,200 acres per day currently are at risk levels that exceed the Agency's level of concern. Risk to post-application workers also exceed the Agency's level of concern at the higher use rate of 1.875 lbs ai/A. To address these concerns, the following mitigation measures are necessary:

1) The maximum application rate will be reduced to 1.125 lbs ai/A in all states except California and Arizona (which comprise a very small part of the use at the higher rate of 1.875 lb ai/A). California and Arizona grow hardier varieties of cotton which require the higher rate for defoliation (also refer to the below discussion regarding the benefits of tribufos). The total percentage of cotton acres treated with tribufos in California and Arizona are 13% and 17%, respectively.

2) The restricted entry interval will be increased from 24 hours to 7 days.

3) Tribufos products will be distributed in closed loading systems starting with the 2002 growing season.

4) Enclosed cockpits.

5) A biomonitoring study will be conducted to confirm the Agency's risk management decision that the occupational risks will not be of concern. The biomonitoring study will be submitted to the Agency by September 2003.

The Agency has incorporated the first four mitigation measures in the current risk assessment. However, concern still remains for workers who mix, load, and apply tribufos by aerial application.

In this IRED occupational risks associated with the use of tribufos were calculated at two rates, the proposed rate of 1.125 lbs ai/A, and the current maximum rate of 1.875 lbs ai/A. In reality, tribufos is tank-mixed in the majority of applications with other defoliants at a much lower rate (0.50 to 0.75 lbs ai/A). The Agency is therefore confident that the occupational and ecological risks associated with the use of tribufos are generally lower than those discussed in this IRED.

In conclusion, based on the Agency's experience with other biomonitoring studies, the Agency is confident that occupational risks associated with tribufos will not be of concern. A determination has been made that the continued use of tribufos is critical to the cotton industry and therefore should remain available to growers. The factors leading to this conclusion are discussed below.

2. Additional Considerations

The Agency has extensively examined other areas of possible refinement to the risk assessment. The following is a more detailed description of the Agency's refinement of the risk assessment and options for additional refinement considered by the Agency.

a. Chemical-Specific Exposure Data

The registrant has submitted a tribufos-specific passive dosimetry worker exposure study. This data was used in conjunction with the PHED V1.1 to assess occupational exposure. The chemical-specific data were combined with PHED to increase the sample size and number of studies in the database. The Agency determined worker exposures based on the chemical specific study and using enhanced PHED (i.e., combining the chemical-specific data with PHED).

b. Levels of Dermal Absorption Versus Other Test Species

For occupational exposure risk assessments, a NOAEL or LOAEL (when a NOAEL is not established) derived by the same route as the human exposure is used to calculate the MOEs. In this process, unless proven otherwise, it is presumed that human and animal absorption of the chemical is identical for the same route of exposure.

The toxicity endpoint used to estimate worker risk was derived from a 21-day dermal toxicity study in rabbits. In this study, a NOAEL was not established. Therefore, the risks were based on a LOAEL (2 mg/kg/day). The MOEs were calculated using the assumption that dermal penetration of tribufos through rabbit and human skin is largely equivalent. Since then, Bayer has submitted a dermal absorption study in monkeys. This study demonstrated that tribufos is poorly absorbed through the skin of monkeys. After eight hours of dermal exposure, only 7% of the applied dose had been absorbed through the skin into the systemic circulation.

With the availability of this new monkey dermal absorption data, the dermal toxicity in rabbits relative to the poor dermal absorption shown in monkeys was re-evaluated because: 1) in general, the skin of rabbits is more permeable to chemicals than human skin, and 2) the penetration of a chemical through the skin of primates (monkeys) can be used as a better surrogate for penetration through human skin.

The Agency accepted that the dermal absorption data in monkeys can be used as a surrogate for penetration through human skin. Because it is presumed that rat dermal absorption is comparable to rabbit dermal absorption, an adjustment can be made to the dose (LOAEL) used for risk assessment to account for species differences in dermal absorption. Consequently, using the dermal absorption rates of 48% in rats and 7% in monkeys, a 6.9 conversion factor (rounded to 7) was obtained, to account for species differences in dermal absorption.

Therefore, the rabbit LOAEL (2 mg/kg/day) was adjusted by the conversion factor (7) to yield a more realistic toxicity endpoint of 14 mg/kg/day for the risk assessment. This significantly refined the risk assessment and groundboom workers are now below the Agency's level of concern. Reentry of workers into tribufos treated fields at the 1.125 lbs ai/A rate are below the Agency's level of concern with a 7-day REI.

c. Information from Bayer

A repeated 21-day dermal study was considered, given that the current study yielded a LOAEL without establishing a NOAEL. If the study was repeated and a NOAEL was established, the target MOE would be 100 rather than the current 300. The newly established NOAEL would essentially need to equal the LOAEL for there to be any improvement to the risk assessment. For example, if the study were repeated and the determined NOAEL was 2 mg/kg/day, MOEs of concern for aerial mixers, loaders, and applicators for both the 1.125 lbs ai/A rate as well as the 1.875 lbs ai/A (for CA and AZ) rate would range from 17 to 50 with a target MOE of 100. These MOEs would still exceed the Agency's level of concern.

The registrant proposed that the most appropriate toxicological endpoint for dermal risk assessment is provided by the 90-day inhalation toxicity study in rats. This study provides a systemic NOAEL of 0.9 mg/kg/day based on inhibition of plasma and erythrocyte ChE activities at the LOAEL of 4.5 mg/kg/day. The registrant contends that the NOAEL for systemic exposure in an animal study should be compared with the systemic dose workers may encounter, and therefore, the inhalation study with the systemic NOAEL is the most appropriate to assess worker dermal risk assessments. The Agency evaluated this proposal and concluded that the inhalation toxicity study is not appropriate for use in dermal risk assessments for the following reasons: 1) when a route-specific toxicity study (i.e., 21-day dermal study) is available for the route of exposure of concern (dermal) for workers the dermal should be used rather than a study with a different route of exposure (i.e., inhalation), as proposed by the Registrant; 2) in the dermal study, systemic absorption was demonstrated as evidenced by ChE inhibition in males (plasma) and females (RBC) at the lowest dose tested and therefore is a systemic LOAEL; and 3) the dermal study with the systemic toxicity endpoint (cholinesterase inhibition) of concern is the most appropriate for regulations.

Additionally, as shown below, the NOAEL in the inhalation study is essentially the same as the effect level (i.e., LOAEL) in the dermal study when an adjustment is made for dermal absorption for both routes (i,e, dermal and inhalation). Therefore, a dose that was shown to be an effect level can not be used as a no effect effect level.

- Inhalation NOAEL of 0.9 mg/kg/day when adjusted for 7% dermal absorption rate (as shown in monkeys) results in a equivalent dermal dose of 13 mg/kg/day
(0.9 mg/kg/day ÷ 0.07 = 13 mg/kg/day)

- Dermal LOAEL of 2 mg/kg/day when adjusted for 7% dermal absorption rate (as shown in monkeys), results in a equivalent dermal dose is 14 mg/kg/day
(2 mg/kg/day ÷ 0.07 = 14 mg/kg/day).

d. Other Issues

The incident profile for tribufos is as follows: The Minnesota Department of Agriculture surveyed 32 states about spray drift and found a total of 2,681 complaints from 1993 through 1995. Tribufos was involved in 27 of these complaints and ranked 10th of 38 of the pesticides reported. Another survey was conducted by the California Department of Health Services in 1987. A total of 232 exposed residents were interviewed and 175 controls. People with high likelihood of exposure to tribufos complained of fatigue, eye irritation, rhinitis, throat irritation, difficulty in breathing, wheezing, nausea, and diarrhea.

The Agency has worked with the California Department of Pesticide Regulation on its review of tribufos. California regulates on brain cholinesterase inhibition; the Agency regulates on plasma or RBC cholinesterase inhibition. California considers the 2 mg/kg/day dose in the 21-day rabbit dermal study to be a NOAEL because cholinesterase inhibition was observed in plasma and red blood cells only, not brain. The Agency regulates this dose as a LOAEL and applied an additional 3X uncertainty factor to account for the lack of a NOAEL in this study.

e. Alternatives and Benefits of Tribufos

Tribufos is applied to cotton prior to harvest. The Agency estimates that approximately 4.5 million pounds of tribufos are applied to approximately 35% of the estimated fourteen million acres of cotton grown in the U.S. per year. Application rates vary from 0.50 lbs ai/A (tank-mixed) to 1.875 lbs ai/A (tribufos used alone). Tribufos is most typically used in a tank-mix with other defoliants and at a rate between 0.50 lbs ai/A to 0.75 lbs ai/A.

Tribufos is used throughout the cotton belt, which extends from California to Florida and as far north as Missouri, Tennessee, and Virginia. As stated above, tribufos is applied to more than 35% of planted cotton acreage, which is an increase from 1991 when less than 1 million acres (<10% of total acreage) was treated with tribufos.

Alternatives

An alternative analysis was conducted for tribufos. The Agency reviews alternatives to a pesticide, by considering efficacy against target pests, costs, ease of use, potential resistance development to the pesticide,impacts on existing integrated pest management (IPM) programs, and several other characteristics. Although there are other defoliants available, the Agency has concluded that tribufos exhibits greater efficacy at lower night temperatures than other defoliants. Also, when

tribufos is tank-mixed with other defoliants, a synergistic effect is exhibited which results in better defoliation with less staining and harvest debris, as opposed to when tribufos or these alternatives are used alone. These factors are further explained in the benefits discussion below.

Benefits

The Agency has considered numerous submissions from both USDA and the National Cotton Council and believes that the benefits of tribufos are numerous and its loss to the cotton industry would be substantial. Below are several factors the Agency considered in its benefits analysis.

1) **How defoliants work.** Defoliants, used on cotton, cause leaves to abscise, or fall off the plant. Abscission is controlled in the plant by the amount of ethylene available in the plant for this process to occur. Ethylene is produced in plants but is usually inhibited in its action by plant hormones (auxins). There are basically two types of defoliants, herbicidal and hormonal. Herbicidal defoliants act by causing slight injury to leaves, which causes an increase in ethylene production within the plant as an injury response. This increase in ethylene overrides the effects of auxin and causes the abscission process to occur and therefore defoliation. Tribufos is a herbicidal defoliant. Hormonal defoliants also cause an increase in ethylene production through a similar enzymatic induction process, which occurs more slowly than with the herbicidal defoliants. Dimethipin and thidiazuron are hormonal defoliants. Thidiazuron is also known to inhibit auxin transport, which results in inhibition of regrowth in defoliated cotton, and, therefore performs well when tank mixed with tribufos.

2) **The importance of weather conditions.** Cotton defoliant performance is affected by the condition of the plant at application, weather variables at application time, and ambient temperature within a week following application. In order to work, the defoliant must penetrate the leaf surface. Humid weather and high light promote the greatest uptake of the defoliant. Therefore, best performance is obtained when leaf cuticles (the waxy layer surrounding the leaf) are thinner and light intensity and humidity are high. High light intensity and humidity result in more open stomates (tiny openings on the leaves which regulate moisture exchange between the plant and its environment), which, along with thinner leaf cuticles, allow maximum uptake through the leaf surface. Thick leaf cuticles, which occur in drier climates and low humidity, result in lower uptake through leaves. This explains why higher rates (1.875 lbs ai/A) of tribufos are required in California and Arizona than in other cotton growing areas. In regard to the use of the higher rate of 1.875 lbs ai/A, the Agency acknowledges that there is a relatively small population of aerial mixers, loaders, and applicators who will actually use such a rate in Arizona and California.

Temperature after application is an important factor in performance. Overnight temperatures below 60^0F will limit the effectiveness of defoliants by slowing their activity. Herbicidal defoliants such as tribufos, are less affected by cool night temperature than

hormonal defoliants, and therefore, are able to achieve faster defoliation. Generally, hormonal defoliants work at night temperatures of 65^{0}F or above and herbicidal defoliants are effective to temperatures as low as 50^{0}F.

3) The importance of tank mixing. Most cotton producers today use tank-mix combinations of defoliants to get best results. Many times, other materials are also used at defoliation time, including boll openers and regrowth inhibitors, which increase the yield and quality of cotton. Ethephon is a boll opening accelerant which causes bolls to open more rapidly when used in combination with defoliants. Ethephon, however, is not a very effective defoliant on it own. It is often used in combination with tribufos and thidiazuron. One of the most widely used combinations of materials used in defoliation is ethephon + tribufos + thidiazuron. This combination promotes more rapid boll opening, provides the most consistent defoliation, and provides for regrowth suppression. Suppressing regrowth is important in limiting the amount of green stain that will be introduced into the cotton during harvest. In addition to promoting boll opening, ethephon synergizes or enhances defoliation of both tribufos and thidiazuron. Tribufos provides consistency in defoliation, especially at lower night temperatures, and thidiazuron contributes to defoliation under warmer condition, as well as providing regrowth suppression. This combination has proven very effective and necessary for maintaining both the yield and quality of cotton, thus providing growers with a suite of tank mixes to chose from based on environmental conditions present at time of harvest.

4) Timing of harvest. The choice of a defoliant is influenced by several factors, one of which is how quickly a grower anticipates picking can be accomplished. Larger acreage growers usually have their own harvesting equipment and, barring weather interference, can usually plan fairly accurately when they will pick their cotton. They typically would apply ethephon + tribufos or tribufos alone, depending on the need for a boll opener, and pick their cotton about 12 to 14 days later. Growers would not be very concerned about regrowth suppression, because regrowth normally does not become a problem until 21 or so days after defoliation. Smaller acreage growers, or those who depend on contracted harvesting, would more typically use tribufos + thidiazuron with or without ethephon. The growers cannot predict as accurately when the crop will be harvested and are more concerned with regrowth problems.

5) The rate necessary to maintain efficacy. As mentioned above, the efficacy of defoliants and desiccants is dependent upon a number of factors. Tribufos is the only defoliant currently available which can achieve maximum defoliation in a variety of conditions. Tribufos is most often tank mixed to achieve the most efficacious results. Most growers who use combination defoliants use 0.75 pints of DEF 6 (0.56 lb ai tribufos) and 0.1 lb of Dropp (thidiazuron) per acre. A common term cotton growers use in referring to

defoliant rate is "1 + 1 to 10". This term refers to 1 gallon of DEF 6 + 1 pound of Dropp to 10 acres of cotton.

6) Loss to the cotton industry. The Agency has had a tremendous amount of input in regards to the incurrence of cost and loss to the cotton industry if tribufos were unavailable. It is well understood that tribufos is critical to achieving good defoliation in adverse weather conditions, as well as its improved efficacy in tank mixes. The docket contains more detailed information submitted by both the National Cotton Council and USDA, including a comprehensive analysis of cost replacement and losses to yield and fiber quality. In a typical year of cotton production, it is estimated that the total loss to the cotton industry as a result of losing tribfuos would exceed $156 million per year. This cost estimate takes into account the impact of losing tribufos as a defoliant as well as the impact to quality and quantity of cotton yields.

3. Environmental Risk Mitigation

In addition to the human health risks, the Agency is also concerned with ecological risks potentially caused by the use of tribufos. Overall, ecological risk concerns for some species exist but the exceedences are relatively low. The Agency is concerned with acute and chronic risks to birds and mammals when both single and multiple applications of tribufos are used (RQs ranged from 0.01 to 13.94). The Agency assessed both acute and chronic risks to birds using a Bobwhite Quail study. Therefore, the Agency is requiring a mallard duck study to more comprehensively assess risks to birds (refer to Section V for data requirements).

The Agency is not concerned with acute risk to freshwater fish associated with the use of tribufos (RQs ranged from 0.03 to 0.06). However, acute risks to estuarine/marine fish are of concern to the Agency with RQs ranging from 0.06 to 0.11. Data to assess chronic risks to both freshwater and estuarine/marine fish are lacking and therefore will be required in Section V of this document.

With regards to freshwater and estuarine/marine invertebrates, the Agency has concerns for both acute and chronic risks associated with the use of tribufos (RQs ranged from 1.6 to 23.3). The Agency is also requiring a chronic estuarine/marine study to better characterize risks to invertebrates (refer to Section V).

Exposure to non-target vascular aquatic plants is possible through the use of tribufos. Acute RQs ranged from 0.05 to 0.09. These RQs indicate that the acute LOCs are not exceeded for any use rate. RQs for exposure to non-vascular plants range from 0.07 to 0.12. The Agency is, therefore, not concerned with risks to non-target aquatic plants.

The risks to non-target terrestrial and aquatic plants cannot be fully assessed because pertinent plant studies are lacking. The Agency is requiring further data to better characterize potential risks. Refer to section V for particular studies required.

Although the Agency's analyses indicate concern for several ecological species (RQs ranging from 0.01 to 23.3), RQs are relatively low. Measures discussed above that will be implemented to address human health risks will also reduce ecological risks. The Agency has not attempted to quantify the relative risk reduction resulting from the implementation of these mitigation measures. For instance, because tribufos is usually tank-mixed at a much lower application rate than was assessed in the IRED, it is expected that this reduction in the application rate will result in less pesticide availability in the ecosystem. Therefore, no mitigation measures to address ecological risks are required.

D. Labeling Modifications

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 tribufos. For the specific labeling statements, refer to Section V of this document

1. Endangered Species Statement

The Agency has developed a program "The Endangered Species Protection Program" to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. At present, the program provides information to users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program will be described in a future *Federal Register* notice. The Agency is not imposing label modifications at this time through the IRED. Rather, any requirements for product use modification will occur in the future under the Endangered Species Protection Program.

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now proposing interim mitigation measures for aerial applications that should be placed on product labels/labeling, as specified in section V of this document. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants. The Agency is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks

associated with aerial as well as other application types where appropriate. In the interim, labels should be amended to include the following spray drift related language.

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

"Do not allow this product to drift"

For outdoor liquid products that are applied aerially, further label language is necessary for spray drift management. Specific label language is outlined in Table 11, "Summary of Labeling Changes for Tribufos."

3. Other Label Modifications

Provided the following risk mitigation measures are incorporated in their entirety into labels for tribufos-containing products, the Agency finds that all currently registered uses of tribufos would be eligible for reregistration, pending a cumulative assessment of the organophosphates.

- Increased Restricted Entry Interval to 7 days
- Reduction in maximum label rate to 1.125 lbs ai/A with the exception of California and Arizona, which retain the maximum current label rate of 1.875 lbs ai/A
- Distribute tribufos in a closed loading systems by 2002
- Closed systems for aerial applicators

V. What Registrants Need To Do

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV, by submitting label amendments and meeting the data requirements described in this section.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of tribufos has been reviewed and determined to be substantially complete. Based on a need to further refine the occupational and ecological risk assessments, the Agency is requiring the following confirmatory data.

- Eye Irritation - (§ 870.2400)
- Magnitude of Residues - Crop Field Trials for ULV Applications (§ 860.1500)
- Residue in Analytical Method - ILV of milk (§ 860.1340)
- Avian Reproduction - mallard duck (§ 850.2300)
- Freshwater Fish Early Life Stage Study - rainbow trout (§ 850.1400)
- Estuarine /Marine Fish Early Life Stage Study - (sheepshead minnow) (§ 850.1400)
- An Estuarine/Marine Invertebrate Life Cycle Study (mysid species preferred) (§850.1350)
- Nontarget Terrestrial Plant Studies (§850.4250)
- Nontarget Aquatic Plant Studies (§850.4400)
- Field Dissipation (§835.6100)

Also, a DCI was sent to registrants of OP pesticides currently registered under FIFRA [August 6, 1999 (64FR42945-42947), and August 18 (64FR44922-44923)]. DCI requirements included acute, subchronic, and developmental neurotoxicity studies; due dates are 9/2001.

2. Labeling for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies.

All registrants need to submit applications for amended registration. This application should include the following items: completed EPA application form 8570-1, five copies of the draft label with all label amendments outlined in Table 11 of this document incorporated, and a description on the application, such as "Responding to Interim Reregistration Eligibility Decision" document. All amended labels need to be submitted within 8 months of signature of this document. The Product Reregistration Division (PRB) contact is Bonnie Adler at (703) 308-8523.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then 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 DCI, outlining specific data requirements, accompanies this IRED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV, above. Specific language to incorporate these changes is specified in the Table at the end of this section. Registrants need to submit applications for amended registration. This application should include the following items: a completed EPA application form 8570-1, five copies of the draft label with all label amendments outlined in Table 11 of this document incorporated, and a description on the application, such as, "Responding to Interim Reregistration Eligibility Decision" document. All amended labels need to be submitted within 8 months of signature of this document. The Product Reregistration Division (PRB) contact is Bonnie Adler at (703) 308-8523.

C. Existing Stocks

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

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

D. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in section IV. Table 11 describes how language on the labels should be amended.

Table 11: Summary of RED Labeling for Tribufos		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
Formulation Instructions required on all MUPs	"Only for formulation into a defoliant for use on cotton."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statements	**"Environmental Hazards"** "This chemical is toxic to terrestrial and aquatic plants, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements under Environmental Hazards. Buffer zones also must appear in directions for use.

Table 11: Summary of RED Labeling for Tribufos		
Description	**Amended Labeling Language**	**Placement on Label**
End Use Products Intended for Occupational Use (WPS)		
RED PPE Requirements[1]	**"Personal Protective Equipment** **Mixers, loaders, applicators, flaggers, and other handlers (see requirements below) must wear:** - long-sleeve shirt and long pants, - shoes plus socks"	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls	**"Engineering Controls"** "Mixers and loaders supporting aerial applications must use a mechanical transfer system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for providing dermal protection. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to not more than 2 ml. per disconnect point. In addition to wearing the specified PPE, all handlers of this product must wear chemical resistant gloves and a chemical resistant apron." "Persons using a closed system that operates under pressure shall wear protective eyewear." "Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Table 11: Summary of RED Labeling for Tribufos		
Description	**Amended Labeling Language**	**Placement on Label**
User Safety Recommendations	**"User Safety Recommendations"** "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements: Hazards to Humans and Domestic Animals (Must be placed in a box.) (Immediately following Engineering Controls)
Environmental Hazards	**"Environmental Hazards:** "This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Do not apply when weather conditions favor drift from the treated area.	Precautionary Statements under Environmental Hazards
Restricted-Entry Interval	"Do not enter or allow workers entry into treated areas during the restricted entry interval (REI) of 7 days."	Directions for Use, Agricultural Use Requirements Box
Personal protective equipment required for early entry	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is: - Coveralls over short-sleeved shirt and short pants - Protective eyewear - Chemical-resistant gloves - Chemical resistant footwear plus socks	

Table 11: Summary of RED Labeling for Tribufos		
Description	**Amended Labeling Language**	**Placement on Label**
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."For any requirements specific to your State or tribe, consult the agency responsible for pesticide regulation. "Cotton treated with this product must be mechanically harvested. Hand harvesting is prohibited." "Do not allow this product to drift."	Directions for Use
Other Applications Restrictions.	The maximum application rate per acre per year is 1.125 lbs ai/A. The maximum application rate for California and Arizona is 1.875 lbs ai/A.	Directions for Use under General Precautions and Restriction or Application Instructions.
Aerial Spray Drift Label Language	"Aerial Spray Drift Management" "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use
Continued... Aerial Spray Drift Label Language	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations. 1.The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2.Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use

Table 11: Summary of RED Labeling for Tribufos		
Description	**Amended Labeling Language**	**Placement on Label**
Continued..., Aerial Spray Drift Label Language	"Aerial Drift Reduction Advisory" "This section is advisory in nature and does not supersede the mandatory label requirements." **"INFORMATION ON DROPLET SIZE"** "The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"CONTROLLING DROPLET SIZE"** "●Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. ●Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure. ●Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. ●Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. ●Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	Directions for Use

Table 11: Summary of RED Labeling for Tribufos		
Description	**Amended Labeling Language**	**Placement on Label**
Continued... Aerial Spray Drift Label Language	**"BOOM LENGTH"** "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"APPLICATION HEIGHT"** "Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"SWATH ADJUSTMENT"** "When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use
Continued... Aerial Spray Drift Label Language	**"WIND"** "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"TEMPERATURE AND HUMIDITY"** "When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."	Directions for Use

Table 11: Summary of RED Labeling for Tribufos		
Description	**Amended Labeling Language**	**Placement on Label**
Continued... Aerial Spray Drift Label Language	**"TEMPERATURE INVERSIONS"** "Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"SENSITIVE AREAS"** "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

VI. Related Documents and How to Access Them

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

The docket initially contained preliminary risk assessments and related documents as of September 10, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on July 7, 1999.

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

VII. Appendices

Appendix A: Use Patterns Eligible For Reregistration

Application Type Timing Equipment	Formulation [EPA Reg. No.]	Max. Single App. Rate (lb ai/A)	Max. No. of Apps.	Restrictions/Comments
Cotton				
Defoliant Foliar Spray - Groundboom -Aerial	98%Technical-Bayer Corporation Reg. No. 3125-96 70.5% End Use Product - Bayer Reg. No. 3125-282 70.5% End Use Aventis Crop Science Reg No. 264-498 70.5% End Use Product Crystal Chemical Inter-America Reg. No. 67801-3 98.1% Technical - Micro Flo Reg. No. 51036-324 70.5% End Use Product Micro Flo Reg. No. 510360-320	1.875 for CA and AZ and 1.125 for the remaining states	1	Not for residential use, or other non-occupational uses. "Mechanical Harvesting Only"; requires use of closed systems. Do not allow to drift.

Appendix B. Table Of Generic Data Requirements And Studies Used To Make The Interim Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #2145 (tribufos) covered by this Interim RED. It contains generic data requirements that apply to tribufos 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 Tribufos

(Old/New Guideline) REQUIREMENTS			USE PATTERN	CITATION(S)
OLD	NEW	PRODUCT CHEMISTRY		
61-1	830.1550	Product Identity and Disclosure of Ingredients	All	41618801
61-2A	830.1600	Start. Mat. & Mfg. Process	All	41618801
61-2B	830.1670	Formation of Impurities	All	41618801
62-1	830.1700	Preliminary Analysis	All	41618802
62-2	830.1750	Certification of Ingredient Limits	All	41618802
62-3	830.1800	Analytical Methods to Verify the Certified Limits	All	41618802
63-2	830.6302	Color	All	41618803
63-3	830.6303	Physical State	All	41618803, 42382701
63-4	830.6304	Odor	All	41618803
63-6	830.7220	Boiling Point	All	41618803
63-7	830.7300	Density, Bulk Density or Specific Gravity	All	41618803
63-8	830.7840,60	Solubility	All	41618803
63-9	830.7950	Vapor Pressure	All	41618803
63-11	830.7550	Octanol/Water Partition Coefficient	All	41618803
63-12	830.7000	pH	All	42382701
63-13	830.6313	Stability	All	41618803

(Old/New Guideline)	REQUIREMENTS		USE PATTERN	CITATION(S)
		ECOLOGICAL EFFECTS		
71-1A	850.2100	Acute Avian Oral - Quail/Duck	All	00160000, 00049258
71-2A	850.2200	Avian Dietary - Quail	All	00049258, 41618804, 41618805
71-2B	850.2200	Avian Dietary - Duck	All	00049258, 41618804
71-4	850.2300	Avian Reproduction - Bobwhite Quail	All	40757101
71-4	850.2300	Avian Reproduction - Mallard Duck	All	**Data Gap**
71-4B	850.2400	Reproduction toxicity - Mammal	All	40757101
72-1B	850.1075	Fish Toxicity Bluegill	All	40094602, 40098001, 41618808, 41618806
72-1C	850.1075	Fish Toxicity Rainbow Trout	All	41618808
72-2A	850.1010	Invertebrate Toxicity	All	41689901, 41668902, 40098001
72-3A	850.1025	Estuarine/Marine Acute Toxicity - Pinfish, Mysid	All	40228401, 41896302
72-3B	850.1025	Estuarine/Marine Acute Toxicity - Mollusk	All	42083201, 40228401, 41896301
72-3C	850.1035	Estuarine/Marine Acute Toxicity - Pink Shrimp	All	42083201, 40228401, 41896301
72-4A	850.1400	Fish Early Life Stage Toxicity - Rainbow Trout	All	**Data Gap**
72-4A	850.1400	Fish Estuarine/Marine Early Life Stage Toxicity - Sheepshead Minnow	All	**Data Gap**
72-4B	850.1350	Estuarine/Marine Invertebrate Life Cycle Toxicity - Mysid Shrimp	All	**Data Gap**
72-4B	850.1350	Aquatic Invertebrate Life Cycle Toxicity - Daphnia Magna	All	43978201
123-1A	850.4225 850.4230 850.4250	Seed Germination/Seedling Emergence	All	**Data Gap**

(Old/New Guideline)	REQUIREMENTS		USE PATTERN	CITATION(S)
123-1B	850.4250	Vegetative Vigor	All	**Data Gap**
123-2	850.4400	Aquatic Plant Growth - *Lemna gibba*	All	41618813, 40228401 - **Data Gap**
		TOXICOLOGY		
81-1	870.1100	Acute Oral Toxicity - Rat	All	41954903
81-2	870.1200	Acute Dermal Toxicity - Rabbit/Rat	All	41954902
81-3	870.1300	Acute Inhalation Toxicity - Rat	All	41782301
81-4	870.2400	Primary Eye Irritation - Rabbit	All	**Data Gap**
81-5	870.2500	Primary Dermal Irritation - Rabbit	All	41896203
81-6	870.2600	Dermal Sensitization - Guinea Pig	All	41618812
81-7	870.6100	Acute Delayed Neurotoxicity - Hen	N/A	N/A
81-8	870.6200	Acute Neurotoxicity - Rat	All	**Data Gap**
82-2	870.3200	21-Day Dermal - Rabbit	All	42007201
82-4	870.3645	90-Day Inhalation - Rat	All	42399801
82-5	870.6100	Subchronic Neurotoxicity - Rat	All	**Data Gap**
82-5	870.6100	Subchronic Neurotoxicity - Hen	All	42007202
82-5B	870.6100	90-Day Neurotoxicity - Mammal	All	**Data Gap**
83-1A	870.4100	Chronic Feeding Toxicity - Rodent	All	42553601
83-3B	870.3700	Developmental Toxicity - Rabbit	All	40190602
83-4	870.3800	2-Generation Reproduction - Rat	All	42040101, 42040103
83-5	870.4300	Chronic Toxicity/Carcinogenicity - Mice/Rat	All	42335101
83-6	870.6100	Developmental Neurotoxicity	All	**Data Gap**

(Old/New Guideline)	REQUIREMENTS		USE PATTERN	CITATION(S)
85-3	870.7600	Dermal Penetration (rat)	All	42350003
85-3	870.7600	Dermal Penetration (monkey)	All	45019901
84-2A	870.5140	Gene Mutation (Ames Test)	All	41459101
84-2B	870.5375	Structural Chromosomal Aberration	All	41459103
84-4	none	Other Genotoxic Effects	All	41459102
85-1	870.7485	General Metabolism	All	42034501
		OCCUPATIONAL EXPOSURE		
132-1A	875.2100	Foliar Residue Dissipation	All	42685901, 42701601
133-3	875.2400	Dermal Passive Dosimetry Exposure	All	42685901, 42701601
133-4	875.2500	Inhalation Passive Dosimetry Exposure	All	42685901, 42701601
		ENVIRONMENTAL FATE		
160-5	none	Chemical Identity	All	
161-1	835.2120	Hydrolysis	All	41618814
161-2	835.2240	Photodegradation - Water	All	41719401
161-3	835.2410	Photodegradation - Soil	All	41618816
162-1	835.4100	Aerobic Soil Metabolism	All	42007204
162-2	835.4200	Anaerobic Soil Metabolism	All	42007205
162-3	835.4400	Anaerobic Aquatic Metabolism	All	43325504
163-1	835.1240	Leaching/Adsorption/Desorption	All	41618817, 42350004
163-2	835.1410	Volatility - Lab	N/A	N/A
164-1	835.6100	Terrestrial Field Dissipation	All	43325501, 4235005 - **Data Gap**

(Old/New Guideline)		REQUIREMENTS	USE PATTERN	CITATION(S)
165-4	none	Bioaccumulation in Fish	All	41618811, 43080401
		RESIDUE CHEMISTRY		
171-4A	860.1300	Nature of Residue - Plants	All	42350009
171-4B	860.1300	Nature of Residue - Livestock	All	42034502, 42034503, 42350010, 42350011
171-4C	860.1340	Residue Analytical Method - Plants	All	42799001, 42848001, 42848002, 42848003
171-4D	860.1340	Residue Analytical Method - Animals	All	**Data Gap**
171-4E	860.1380	Storage Stability	All	42184701, 42350009, 43821601, 43837801
171-4K	860.1500	Crop Field Trials - Cottonseed and gin byproducts	All	**Data Gap** (For ULV Applications)
171-4 (l)	860.1520	Magnitude of the Residues in Processed Food/Feed	All	43783701
171-4 (j)	860.1480	Magnitude of the Residue in Meat, Milk, Poultry, and Eggs: Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	All	43821601
165-1	835.1850	Rotational Crops (Confined)	All	42184701

Appendix C: Technical Support Documents

Additional documentation in support of this Interim 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 the preliminary risk assessments and related documents as of September 23, 1998. Sixty days later the first public comment period closed. The Agency considered comments on the revised risk assessments and added the formal "Response to Comments" document and the revised risk assessment to the docket on September 24, 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

Appendix D. Citations Considered To Be Part Of The Database Supporting the Interim Reregistration Eligibility 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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00019258	Buchanan, G.A. (1969) Preemergence Weed Control in Soybeans: Research Report CF-4621. (Unpublished study received Nov 13, 1969 under 8192-5; prepared by Auburn Univ., submitted by Ciba Agro-chemical Co., Summit, N.J.; CDL:018027-B)
00049258	Lamb, D.W.; Jones, R.E. (1972) Acute Oral Toxicity of (R)= DEF Technical to Bobwhite Quail and Mallard Ducks: Report No. 35016. (Unpublished study received Mar 22, 1976 under 3125-71; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:224114-P)
00147533	Rodwell, D. (1985) A Teratology Study with AC 92, 100 in Rats: Project No. WIL-35014: Final Report. Unpublished study prepared by WIL Research Laboratories, Inc. 212 p.
00160000	Hudson, R.; Tucker, R.; Haegele, M. (1984) Handbook of toxicity of pesticides to Wildlife: Second edition. US Fish and Wildlife Service: Resource Publication 153. 91 p.
40094602	Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates: Resource Publication 137. US Fish and Wildlife Service, Washington, D.C.106 p.
40098001	Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Interpretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. US Fish & Wildlife Service, Resource Publication 160. 579 p.
40190601	Kowalski, R. (1986) A Teratology Study with DEF Technical in the Rat: Report No. 87320. Unpublished study prepared by Miles Laboratories, Inc. 213 p.

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40228401	Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Interpretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. US Fish & Wildlife Service, Resource Publication 160. 579 p.
40757101	Beavers, J.; Marselas, G.; Jaber, M. (1988) DEF: A One-generation Reproduction Study with the Bobwhite (Colinus virginianus): Wildlife International Ltd. Project No. 149-127. Unpublished study prepared by Wildlife International Ltd. 101 p.
40886301	Hoberman, A. (1988) A Developmental Toxicity (Embryo-fetal Toxicity/Teratogenicity) Study with AC 92,100 in Rabbits: Project ID: Argus Research Laboratories Protocol: 101-008. Unpublished study prepared by Argus Research Laboratories, Inc. 243 p
41171001	Hayes, R. (1989) Oncogenicity Study of Technical Grade Tribufos (DEF) with Mice: Study No. 86-271-01. Unpublished study prepared by Mobay Corp. 2042 p.
41459101	Curren, R.; Gentry, P. (1989) Salmonella/Mammalian-microsome Plate Incorporation Mutagenicity Assay (Ames Test): Lab Project Number T8299.501. Unpublished study prepared by Microbiological Assoc. Inc. 49 p.
41459102	Curren, R. (1990) Unscheduled DNA Synthesis in Rat Primary Hepatocytes: Lab Project Number: T8299.380: 1107. Unpublished study prepared by Microbiological Assoc., Inc. 26 p.
41459103	Putman, D.; Morris, M. (1989) Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: Lab Project Number: T8299.337: 98592. Unpublished study prepared by Microbiological Assoc., Inc. 28 p.
41618801	Talbott, T. (1990) Product Chemistry of DEF Technical: Lab Project Number: VAP0007: JDM0066: 2172. Unpublished study prepared by Mobay Corp. 65 p.
41618802	Talbott, T. (1990) Product Chemistry of DEF Technical: Lab Project Number: 91978: 99857: 99856. Unpublished study prepared by Mobay Corp. 115 p.

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MRID	CITATION
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41618804	Grau, R. (1990) DEF Technical Grade: 5-day Dietary LC50 to Bobwhite Quail: Lab Project Number: BV-007: E2950351-5: 100223. Unpublished study prepared by Bayer Ag. 36 p.
41618805	Grau, R. (1990) DEF Technical Grade: 5-day Dietary LC50 to Mallard Duck: Lab Project Number: VE-002: E2970426-0: 100224. Unpublished study prepared by Bayer Ag. 43 p.
41618806	Grau, R. (1990) DEF Technical Grade: Acute Toxicity to Bluegill Sunfish in a Flow-through Test: Lab Project Number: FB-003: E2860137: 100222. Unpublished study prepared by Bayer Ag. 36 p.
41618807	Grau, R. (1990) DEF 6: Acute Toxicity to Bluegill Sunfish in a Flow-through Test: Lab Project Number: FB-006: E02860355-9: 100219. Unpublished study prepared by Bayer Ag. 40 p.
41618808	Grau, R. (1990) DEF Technical Grade: Acute Toxicity to Rainbow Trout in a Flow-through Test: Lab Project Number: FF-286:2810136-1: 100221. Unpublished study prepared by Bayer Ag 36 p.
41618811	Cohle, P. (1990) Uptake, Depuration and Bioconcentration of (Carbon 14)-DEF by Bluegill (Lepomis macrochirus): Lab Project Number: 38466: 100236. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 48 p.
41618812	Sheets, L. (1990) Dermal Sensitization Study with Technical Grade Tribufos (DEF) in Guinea Pigs: Lab Project Number: 90-324-GK: 100268. Unpublished study prepared by Mobay Corp. 24 p.

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41618816	Jackson, S.; Kesterson, A.; Lawrence, L. (1988) Soil Surface Photolysis of [Carbon 14] DEF in Natural Sunlight: Lab Project Number: 1153: 206: 95673. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 67 p.
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41689901	Heimbach, F. (1989) Acute Toxicity of DEF (Technical) to Waterfleas (Daphnia magna): Lab Project Number: 99630. Unpublished study prepared by Bayer AG. 32 p.
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41954902	Sheets, L.; Phillips, S. (1991) Acute Dermal Toxicity Study with Technical Grade Tribufos (DEF) in Rabbits: Lab Project Number: 90-025-FE: 100698. Unpublished study prepared by Mobay Corp. 20 p.
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42007201	Sheets, L.; Phillips, S. (1991) 21-Day Dermal Toxicity Study with Technical Grade Tribufos (DEF) in Rabbits: Lab Project Number: 90-125-FP. Unpublished study prepared by Mobay Corp., Toxicology Dept. 445 p.
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42007203	Christenson, W. (1991) Chronic Feeding Toxicity Study of Technical Grade Tribufos (DEF) with Dogs: Lab Project Number: 88-274-AB. Unpublished study prepared by Mobay Corp., Toxicology Dept. 585 p.
42007204	Stevenson, T.; Leimkuehler, W.; Mathew, A. (1991) The Metabolism of Tribufos in Soil Under Aerobic Conditions: Lab Project Number DE042101: 100338. Unpublished study prepared by Mobay Corp., R & D Dept. 33 p.

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42034501	Kao, M.; Middien, R.; Bosnak, L.; et al. (1991) Disposition and Metabolism of [Carbon 14]-Tribufos in Rats: Lab Project Number: 101331: DEO41801. Unpublished study prepared by Mobay Corp. 145 p.
42034502	Hall, L. (1991) The Metabolism of [Carbon 14] and [S 35]-Tribufos in Hens: Lab Project Number: DE040501: 101329. Unpublished Study prepared by Mobay Corp. 123 p.
42034503	Sahali, Y. (1991) Metabolism of [Carbon 14]-Tribufos in Lactating Goats: Lab Project Number: DE041001: 101330. Unpublished study prepared by Mobay Corp. 83 p.
42040101	Selman, F. (1991) Responses to the EPA Review of Ciba-Geigy Protocol No. 17-91 for Small-Scale Prospective Ground-Water Monitering Study for Primisulfuron-Methyl (Beacon): Lab Project Number: ABR-91068. Unpublished study prepared by Ciba-Geigy. 80 p.
42184701	Leimkuehler, W.; Moore, K. (1991) Carbon 14 Tribufos Residues in Confined Rotational Crops: Lab Project Number: DE051601. Unpublished study prepared by Mobay Corp. 37 p.
42335101	Christenson, W. (1992) Technical Grade Tribufos (DEF): A Chronic Toxicity/Oncogenicity/ Neurotoxicity Feeding Study in the Fisher 344 Rat: Lab Project Number: 88-271-AA. Unpublished study prepared by Miles Inc. 3672 p.
42350003	Schroeder, R. (1992) Dermal Absorption of Tribufos by Rats from a DEF 6 Emulsifiable Formulation using [carbon 14] Tribufos: Lab Project Number: 91-722-KW. Unpublished study prepared by Miles, Inc. 54 p.

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42350004	Schocken, M.; Parker, G. (1987) Leaching of Aged Soil Residues of DEF in California Sandy Loam: Lab Project Number: 95016. Unpublished study prepared by Mobay Corp. 23 p.
42350005	Grace, T.; Cain, K. (1990) Dissipation of Tribufos in California Soils: Lab Project Number: ML022101: 89. 022: 892010. 1-5K. Unpublished study prepared by Plant Sciences, Inc.; Siemer and Associates, Inc. and PTRL West. 668 p.
42350009	Chopade, H. (1992) Metabolism of [n-Butylthio-1-carbon 14] Tribufos in Cotton: Lab Project Number: DE41601: 102639. Unpublished study prepared by Miles, Inc. 87 p.
42350010	Hall, L. (1992) The Metabolism of [carbon 14] and [sulfur 35] Tribufos in Laying Hens: Lab Project Number: DE040501: 101329-1. Unpublished study prepared by Miles, Inc. 158 p.
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42382701	Fontaine, L. (1992) Supplement to MRID 41618803: Product Chemistry of DEF Technical: Lab Project Number: BR 1804. Unpublished study prepared by Miles Inc. 6 p.
42399801	Pauluhn, J. (1992) DEF (Common Name: Tribufos): Study of the Subchronic Inhalation Toxicity to Rats in Accordance with OECD Guideline No. 413: Lab Project Number: 102697. Unpublished study prepared by Bayer Ag, Wuppertal, Germany. 1050 p.
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42799001	Bajzik, M. (1992) The Independent Laboratory Method Validation for the Analysis of Tribufos in Cottonseed and Soapstock: Lab Project Number: DE111601: 105003. Unpublished study prepared by Huntingdon Analytical Services. 90 p.
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43325501	Valadez, S.; Dehart, B.; Cain, K. (1993) Field Dissipation of Tribufos on Georgia Soil: Lab Project Number: DE022101: 105163: 52373. Unpublished study prepared by Miles Research Farm; Miles Research Park; and Harris Environmental Technologies, Inc. 81 p.

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43649402	Schroeder, R. (1989) A Two-Generation (Two-Litters) Reproduction Study With AC 92,100 to Rats: Lab Project Numbers: 86-3128: 971-87-132. Unpublished study prepared by Bio/dynamics, Inc. 1806 p.
43783701	Grace, T. (1995) DEF 6EC--Magnitude of Residue in Cotton Processed Products: Lab Project Number: DE19CT01: 106988. Unpublished study prepared by Miles Research Park and Bayer Corp. 405 p.
43821601	Mathew, A.; Nguyen, T. (1995) Tribufos--A 28-Day Dairy Cattle Feeding Study: Lab Project Number: 107104: DE060401: DE130401. Unpublished study prepared by Bayer Corp. 508 p.
43837801	Krolski, M. (1995) DEF 6EC--Magnitude of the Residue on Cotton: Lab Project Number 106993: DE19CT02: 351-DE001-94D. Unpublished study prepared by Bayer Corp. 542 p.
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44439101	Ghillebaert, F. (1997) Toxicology File of Mexel 432 Summary of the Studies. Unpublished study prepared by Ecotox. 33 p.

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MRID	CITATION
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45019901	Willis, M. (2000) A Dermal/Intravenous crossover study to determine the dermal absorption of 14C-DEF 6(S, S, S-tributylphosphorotrothioate) in male rhesus monkeys. Sierra biomedical Lab. Study Number: 0834-90. Bayer study Number: 99C-B29-FR.

Appendix E. Generic Data Call-In

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

United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/00

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address	2. Case # and Name 2145 DEF Chemical # and Name 074801 Tribuphos	3. Date and Type of DCI GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/00

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1.

2. Case # and Name
2145 DEF
Chemical # and Name 074801
Tribuphos

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
72-4(a) *	Early life stage fish					AB		12 mos.	
72-4(b) *	Life cycle invertebrate					AB		12 mos.	
81-4	Primary eye irration-rabbit					AB		12 mos.	
123-1(a)	Seed germ/seedling emerg					AB		12 mos.	
123-1(b)	Vegetative vigor					AB		12 mos.	
123-2	Aquatic plant growth					AB		12 mos.	
164-1	Terrestrial field dissipation		Y			AB		24 mos.	
171-4(d) *	Res. analyt. method - animal		Y			AB		24 mos.	
171-4(k) *	Cropfield trials COTTON		Y			AB		24 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
2145 DEF
Chemical # and Name
074801 Tribuphos

GUIDELINE	COMMENT
72-4(a)	Two studies required: 1. Freshwater early life stage with the rainbow trout. 2. Estuarine, marine early life stage study with sheepshead minnow.
72-4(b)	Mysid is the preferred species
171-4(d)	ILV of milk
171-4(k)	COTTON Crop field trials for Ultra-Low-Volume (ULV) applications.

Appendix F: Product Specific Data Call-In

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

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2145 DEF	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claimimg a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNNN		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
2145 DEF

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
830.1550	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1600	Description of materials used to produce the product (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1620	Description of production process (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1650	Description of formulation process (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1670	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1700	Preliminary analysis (1,4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1750	Certified limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1800	Enforcement analytical method (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6302	Color (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6303	Physical state					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6304	Odor (17)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
2145 DEF

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
830.7000	pH	(9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7050	UV/Visible absorption						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7100	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7300	Density						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6314	Oxidation/reduction: chemical incompatability	(10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6315	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6316	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6317	Storage stability						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6319	Miscibility	(14)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6320	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6321	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical									
870.1100	Acute oral toxicity	(1,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.1200	Acute dermal toxicity	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.1300	Acute inhalation toxicity	(3)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2400	Acute eye irritation	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2500	Acute dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2600	Skin sensitization	(4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2145 DEF

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
9 Required if test substances are dispersible with water.
10 Required if product contains an oxidizing or reducing agent.
11 Required if product contains combustible liquids.
12 Required if product is potentially explosive.
13 Required if product is a liquid.
14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
15 Required if end-use product is liquid and is to be used around electrical equipment.
17 Not required unless efficacy data are required.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2145 DEF

Footnotes (cont.):

37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

Appendix G: EPA's Batching of Tribufos Products for Meeting the 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 tribufos as the primary active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note the Agency is not describing batched products as "substantially similar" since some products with in a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-in Response, " asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or

depend on someone else to do so. If the registrant supplies the data to support a batch of products, he/she must select the one of the following options: Developing data (Option 1), Submitting an existing Study (Option 4), Upgrading an existing Study (Option 5), or Citing an Existing Study (Option). If a registrant depends on another's data, he/she must choose among: Cost sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

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

Batch 1	EPA Reg. No.	Percent active ingredient	Formulation Type
	3125-96	98.0	Liquid
	51036-324	98.0	Liquid

Batch 2	EPA Reg. No.	Percent active ingredient	Formulation Type
	264-498	71.5	Liquid
	3125-282	70.5	Liquid
	51036-320	70.5	Liquid
	67801-3	70.5	Liquid

Appendix H: List of Registrants Sent this Data Call-In

List of All Registrants Sent This Data Call-In Notice

Case # and Name
2145 DEF
Chemical # and Name
074801 Tributyl phosphorotrithioate

Company Number	Company Name	Additional Name	Address	City & State	Zip
003125	BAYER CORP	AGRICULTURE DIVISION	8400 HAWTHORN RD BOX 4913	KANSAS CITY MO	64120

Appendix I: List of Related Documents and Electronically Available Forms

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

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

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

Instructions

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

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

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf

8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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

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

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

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

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

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

1. The Office of Pesticide Programs' Web Site

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

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

   The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide

Programs. We anticipate that this publication will become available during the Fall of 1998.

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

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

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

Date of receipt
EPA identifying number
Product Manager assignment

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

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

Documents Associated with this RED

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

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