United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

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September 2001

Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED) for Trichlorfon

United States Environmental Protection Agency

Prevention, Pesticides and Toxic Substances (7508C)

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EPA Trichlorfon Facts

EPA has assessed the risks of trichlorfon and reached a decision presented in the "Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for Trichlorfon" (commonly known as a TRED) for this organophosphate (OP) pesticide. With the risk mitigation measures required, trichlorfon fits within its own "risk cup"; its individual, aggregate risks are within acceptable levels.

EPA's next step under the Food Quality Protection Act (FQPA) is to consider the cumulative risks of all the OP pesticides, which share a common mechanism of toxicity. The interim decision on trichlorfon cannot be considered final until these cumulative risks are considered. Further risk mitigation may be required at that time.

Used primarily on turf, ornamental shrubs and plants, ornamental bait and fish ponds, and pour-on treatment for cattle (import only), trichlorfon residues in food and drinking water are not expected to pose risk concerns due to mitigation requirements. These include reducing the number of applications and reapplication intervals; and limiting broadcast treatment on golf courses. With the mitigation, trichlorfon fits into its own "risk cup"- it does not pose risk concerns.

EPA completed a trichlorfon Reregistration Eligibility Decision (RED) before the Food Quality Protection Act (FQPA) of 1996 was enacted. At present, only food, drinking water, and residential uses of trichlorfon must be reevaluated, and tolerances (legal limits for residues in food) reassessed, to ensure that they meet the new safety standard required by the FQPA. However, the Agency also reevaluated the occupational risks since new data was received and recommends mitigation for risk concerns associated with large ornamental ponds, and application to ornamental plants.

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 in implementing the Food Quality Protection Act.

EPA encourages the public to participate in the review of the OP pesticides. Through a six-phased pilot public participation process, the Agency has released 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. The Agency will make final decisions after considering the cumulative risks of the OP assessment. Please see

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. Other OPs need decisions about their eligibility for reregistration under FIFRA. OPs with food, drinking water, and other non-occupational exposures must be reassessed to make sure they meet the new FFDCA safety standard, brought about by the FQPA.

The trichlorfon TRED was developed 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 TRED document, which concludes the OP pilot process for trichlorfon.

Uses

- An insecticide, trichlorfon is used on golf course turf, home lawns, non-food contact areas of food and meat processing plants, ornamental shrubs and plants, and ornamental and bait fish ponds to control insects such as lepidopteran larvae (caterpillars), white grubs, mole crickets, cattle lice, sod webworms, leaf miners, stink bugs, flies, ants, cockroaches, earwigs, crickets, diving beetle, water scavenger beetle, water boatman backswimmer, water scorpions, giant water bugs and pillbugs. Trichlorfon is also used overseas on cattle as a pour-on treatment.

- Average domestic usage of trichlorfon is about one million pounds active ingredient (a.i.) per year. In terms of pounds a.i., total usage is allocated mainly to lawn care operators (74%) and golf courses (18%). However, on average, less than 2% of all turf sites are treated with trichlorfon. Other sites with small usage include landscaping, institutional turf, turf farms, nursery/greenhouse, livestock and general farm use. Application rates per acre on these sites are generally less than 7 pounds a.i. per acre.

Health Effects

- Trichlorfon 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 alone for both acute and chronic exposure are not of concern to the Agency. When surface water is considered as the source of drinking water, dietary risks (food and water) exceed the Agency's level of concern for children 1 - 6 years. However, the Agency believes that mitigation measures required in this TRED decision, and the fact that trichlorfon has a short half life, will reduce the exposure. Moreover, when the source of drinking water is groundwater, neither the acute nor the chronic dietary risk exceed the

Agency's level of concern. Accordingly, aggregate risk with groundwater also does not exceed Agency concern.

- The current occupational risk assessment indicates risk concerns for pond applicators, applicators using broadcast treatment to golf course fairways, and postapplication worker concerns following foliar treatments of ornamentals. Risks to workers are of concern if personal protective equipment is not used, or application methods are not modified.

- However, the Agency believes that required mitigation will effectively reduce exposure and risk to a level that is not of concern to the Agency.

Risk Mitigation

- To mitigate risks to handlers and workers:
  - Prohibit broadcast treatment to golf course fairways; spot treatment to fairways is permitted.
  - Require 7-day application interval (waiting period between treatments) for application to turf, and limit applications to no more than 3 per calendar year
  - Require applicators to use a truck-drawn spray rig for ornamental fish and bait ponds over 1 acre.
  - Prohibit foliar application to ornamentals; allow only direct soil spray application to base of plant.

Next Steps

- Numerous opportunities for public comment were offered as this decision was being developed. The trichlorfon TRED therefore is issued in final (see www.epa.gov/pesticides/reregistration/status.htm 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.

- When EPA has considered the cumulative risks for of the OP pesticides, the Agency will issue its final tolerance reassessment decision for trichlorfon and may require 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. For all OPs, tolerances will not be raised or established until cumulative risks have been considered.

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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

OCT 10 2001

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as the EPA or the Agency) has completed its review of the available data and public comments received related to the revised risk assessment for the organophosphate pesticide trichlorfon. The public comment period on the revised risk assessment phase of the tolerance reassessment process is closed. Comments were received during the public comment period, and the Agency revised the human health risk assessment and made it available to the public on April 28, 2000. The attached document summarizes the Agency's assessment of the dietary risk from trichlorfon, the related food tolerances for this chemical, revised occupational risks, and provides the Agency's risk management decision.

A Notice of Availability for this "Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for Trichlorfon" is published in the *Federal Register*. This document and the technical documents supporting it are available for viewing in the Office of Pesticide Programs' Public Docket and can also be found on the Agency's web page, www.epa.gov/pesticides/op.

This document is based on the updated technical information found in the trichlorfon public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, but also now includes the revised risk assessment and addenda for trichlorfon, and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessment submitted by the chemical manufacturer, Bayer Corporation, as well as comments submitted by the general public and stakeholders during the comment period.

The process used to develop this document is the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or FQPA tolerance reassessment decisions on pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality

Protection Act of 1996 (FQPA), and to engage the public in the reregistration and tolerance reassessment processes for these chemicals, the Agency is maintaining open public dockets on the organophosphate pesticides. The idea of using such an open process was developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body, which advised the Agency on implementing the new provisions of the FQPA.

Please note that the trichlorfon risk assessment concerns only this particular organophosphate. Because the FQPA directs the Agency to consider available information on 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, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after completing risk assessments for the individual organophosphates. The Agency is working to complete a methodology to assess cumulative risk, and individual assessments of 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 where necessary. The Agency will issue the final tolerance reassessment decision for trichlorfon once the cumulative assessment for all of the organophosphates is complete.

If you have questions regarding this document, please contact the Chemical Review Manager for trichlorfon, Kylie Rothwell, at 703-308-8055.

Sincerely,

Lois A. Rossi

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for Trichlorfon

Case 0104

Table of Contents

Trichlorfon Team i

Glossary Of Terms and Abbreviations iii

I. Introduction 5

II. Chemical Overview 6
- A. Regulatory History 6
- B. Chemical Identification 7
- C. Use Profile 8
- D. Estimated Usage of Pesticide 9

III. Summary of Trichlorfon Risk Assessment 9
- A. Human Health Risk Assessment 10
  - 1. Dietary Risk from Food 10
    - a. Toxicity 10
    - b. FQPA Safety Factor 11
    - c. Reference Dose and Population Adjusted Dose 11
    - d. Exposure Assumptions 12
  - 2. Food Risk Characterization 12
    - a. Acute Dietary (Food) Risk 12
    - b. Chronic Dietary (Food) Risk 12
  - 3. Dietary Risk from Drinking Water 13
    - a. Surface Water 13
    - b. Ground Water 14
    - c. Drinking Water Levels of Comparison (DWLOCs) 14
      - i. Acute DWLOCs 14
      - ii. Chronic DWLOCs 15
  - 4. Residential Handler and Non-Occupational Risk 15
    - a. Toxicity 16
    - b. Residential Handler and Lawn Care Operator Risks 16
    - c. Non-Occupational Post-Application Risk 19
  - 5. Aggregate Risk 21
    - a. Acute Aggregate Risk 21
    - b. Short/Intermediate Term Aggregate Risk 21
    - c. Chronic (Non-Cancer) Aggregate Risk 22
  - 6. Occupational Risk 22
    - a. Toxicity 23
    - b. Occupational Risk Assessment 23

i. Occupational Handler Risk 24
ii. Short/Intermediate-Term Risk 25
7. Post-application Exposure 28
8. Incident Information 30
B. Environmental Risk Assessment 30

IV. FQPA Tolerance Reassessment Progress & Interim Risk Management Decision . . 30
A. Tolerance Reassessment Progress & Interim Risk Management Decision . . 30
B. Phase 5 Comments 31
C. Regulatory Position 31
1. FQPA Assessment 31
a. "Risk Cup" Determination 31
b. Tolerance Summary 32
2. Endocrine Disruptor Effects 33
3. Risk Mitigation 33
a. Ornamental Fish and Bait Pond 35
b. Turf Uses: Occupational and Aggregate 35
c. Ornamentals: Re-entry Worker Risks 35
d. Residential Use 35
e. Summary of Worker Risks and Label Impacts 36
4. Regulatory Rationale 38
5. Codex Harmonization 39
6. Spray Drift Management 39

V. What Manufacturers Must Do 40
A. Additional Data Requirements 40
1. Labeling Requirements for Manufacturing Use Products 40
2. End-Use Products 40
3. Existing Stocks 41
B. Risk Mitigation Requirements 41
C. Labeling Summary Table 41

VI. Related Documents and How To Access Them 48

Appendix A: Trichlorfon (Case 0104): Use Patterns Eligible for Reregistration 49
Appendix B: Data Supporting Guideline Requirements For Reregistration 50
Appendix C: Technical Support Documents 57
Appendix D: Bibliography 59
Appendix E: Generic Data Call-In 67
Appendix F: List Of Registrants Sent this Data Call-In 71

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Glossary Of Terms and Abbreviations

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observational Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.

LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	Pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Database
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by a Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model

SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage Retrieval database
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

The Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996, requires EPA to reassess all tolerances for registered chemicals in effect on or before the date of the enactment of FQPA. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a revocation occurs.

A reregistration eligibility decision (RED) for trichlorfon was completed in September 1995. Therefore, the Agency must reconsider tolerances and tolerance exemptions to ensure they meet the safety standard required by the 1996 amendments.

This FQPA Tolerance Reassessment Progress and Interim Risk Management Decision document (otherwise known as TRED) is based on a thorough review of required data as well as new information received by the Agency as a result of the public participation process. After considering the revised risk assessments; registrant-proposed risk mitigation measures; and stakeholder input; EPA developed its risk management decisions for uses of trichlorfon that pose risks of concern. These decisions are discussed fully in this document.

The Agency is also providing preliminary information on the trichlorfon degradate, dichlorvos (DDVP) in this document. DDVP is a registered organophosphate (OP) pesticide that is currently undergoing reregistration. Once the DDVP interim RED is complete, the Agency will determine whether DDVP exposure resulting from trichlorfon use poses risk concerns and if any of the decisions for trichlorfon require modification.

Since the Agency has not yet completed the cumulative risk assessment for the OPs, this TRED may be revised to reflect a cumulative assessment of all OPs as required by the FQPA. When the Agency completes the cumulative assessment, trichlorfon tolerances will be considered reassessed.

First registered in the United States in 1955, trichlorfon is a systemic insecticide with non-agricultural uses, such as golf course turf, home lawns, non-food contact areas of food and meat processing plants, ornamental shrubs and plants, and ornamental fish and bait ponds. Although there are no agricultural or other registered food uses, trichlorfon is used outside the US as a pour-on treatment for cattle which requires a tolerance (commonly referred to as an import tolerance when there is no US registration). From 1994 to 1999, average domestic use of trichlorfon was about one million pounds of active ingredient (ai) per year, most of which was used by lawn care operators (74% of total ai) and on golf courses (18% of total ai).

Overall Risk Summary

EPA's human health risk assessment for trichlorfon indicates few risk concerns. Neither acute nor chronic dietary risks exceed the Agency's level of concern. Drinking water risk estimates, based on surface and groundwater screening models, do not exceed the Agency's level of concern for any subpopulation, except for children 1-6 years when the source of drinking water is surface water.

The Agency has determined that occupational risks for most uses are not of concern while certain residential use is of concern. Of the ten occupational scenarios evaluated, three exceed the Agency's level of concern. For occupational scenarios that indicated potential risks of concern, the registrant has agreed to modify the use practices to address these concerns. For the residential scenario that indicated potential risks of concern, the registrant has agreed to voluntarily cancel this use.

Dietary Risk (Food and Water)

The population adjusted dose (PAD) characterizes the dietary risk of a chemical and reflects the Reference Dose, either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e, RfD/FQPA safety factor). A risk estimate that is less than 100% of the acute population adjusted dose (aPAD) or chronic population adjusted dose (cPAD) does not exceed the Agency's risk concern.

There is a tolerance for imported beef and beef byproducts that covers cattle treated outside of the US. This is the only food use of trichlorfon. The revised risk assessment for trichlorfon indicates that both the acute and chronic dietary (food) risks associated with trichlorfon exposure are less than 100% of the aPAD (18%) and cPAD (24%) for all population subgroups. Therefore, dietary risks from food for both acute and chronic exposure are not of concern to the Agency, and no mitigation is warranted at this time for any dietary (food) exposure to trichlorfon.

Surface and groundwater assessments were conducted using GENEEC and SCI-GROW computer models. Most trichlorfon use is on turf; however, there is not a surface water model scenario for turf so a refined Tier II surface water assessment could not be conducted. The GENEEC Tier 1 model was moderately refined for surface water. Except for children 1-6 years, the GENEEC model predicted trichlorfon estimated environmental concentrations (EECs) did not exceed the acute dietary drinking water level of comparison (DWLOC). For children 1-6, the surface water EEC is 179 ppb while the acute dietary DWLOC is 82 ppb. Similarly, the chronic surface water EEC is 2.7 ppb and the chronic dietary DWLOC is 1.5 ppb. Conversely, neither acute nor chronic DWLOCs exceed groundwater EECs based on SCI-GROW modeled estimates. Therefore, neither acute or chronic exposure to trichlorfon from food and groundwater sources of drinking water are of concern to the Agency.

Residential and Recreational Risk Summary

Trichlorfon is also used on residential lawns and ornamentals. Residents or homeowners may be exposed to trichlorfon through mixing, loading, or application, or through entering or performing other activities on treated areas. Residential handler and lawn care operator (LCO) exposures to trichlorfon via dermal and inhalation routes were assessed. The Agency used additional data from the Outdoor Re-entry Task Force (ORETF) to further characterize the potential risks to homeowners and LCOs treating residential lawns and house perimeters using a push-type broadcast spreader. The risks to residential handlers and LCOs do not exceed the Agency's level of concern except for the home perimeter and ant mound treatments by homeowners which the registrant has agreed to voluntarily cancel. No additional risk mitigation is warranted at this time to address residential risks.

Non-Occupational Post-Application Risk (Golfers, Homeowners and Residents)

There is potential dermal exposure and inadvertent oral exposure to children from incidental ingestion of trichlorfon-treated lawns and/or granules. Post-application exposure was assessed for adults and children from entering treated lawns, and for golfers playing on treated courses. The exposure assessments indicated that post-application dermal risks are low for adults, as are both oral hand-to-mouth and dermal risk for children, and do not exceed the Agency's level of concern.

Aggregate Risk Summary

An aggregate risk assessment combines risks from dietary exposure (food and water), and nonoccupational exposure (e.g., residential and/or golfer). Except for children 1-6 years, aggregate risks for acute and chronic dietary (food and drinking water) exposure, and short/intermediate-term (dermal, inhalation and incidental oral) exposure do not exceed the Agency's level of concern; therefore, no mitigation is warranted. Acute aggregate risks for food, water and residential may be of concern for children 1-6 years when the source of drinking water is surface water. The Agency is implementing mitigation measures to address this potential risk.

Occupational/Residential Risk Summary

Although trichlorfon is under review for tolerance reassessment only, the Agency received new ORETF exposure data from a registrant-based task force. These data were used to reassess the potential occupational and residential/recreational (non-occupational) human health risks. Therefore, this assessment includes both tolerance reassessment and occupational risk determinations.

Workers can be exposed to a pesticide through mixing, loading, and/or application, or when re-entering treated sites. With the addition of personal protective equipment, combined dermal and inhalation risks to handlers that mix/load and apply trichlorfon products to turf are significantly reduced. Occupational risks from mixing/loading and applying trichlorfon to large ornamental fish and bait ponds exceed the

Agency's level of concern. However, use of a truck drawn spray rig with the on - off switch located inside the truck cab is expected to mitigate risks for large ornamental fish or bait pond uses of trichlorfon.

The hand application of trichlorfon to ant mounds and the house perimeter use pose risks that exceed the Agency's level of concern. In response to risk concerns, the registrant requested voluntarily cancellation of these uses.

The Agency has also determined that there are post-application dermal risk concerns for workers re-entering treated areas following foliar treatment of ornamentals. Conversely, potential exposure to golf course workers while mowing and maintaining the turfgrass on the day of application is not of concern. To mitigate post-application risk concerns following foliar treatment of ornamentals, the use pattern will be revised to prohibit foliar application and allow only direct application to soil for ornamental plants.

Environmental Risk Summary

The scope of this review is limited to consideration of human health risks for trichlorfon as required by FQPA to complete the tolerance reassessment and reassessed the occupational risks based on new data. Ecological risks are not addressed in the TRED. However, the ecological assessment in the RED, which was issued in 1995, may be amended if warranted to account for new data or information that the Agency may receive.

I. Introduction

This trichlorfon tolerance reassessment of is the result of the pilot process developed through the Tolerance Reassessment Advisory Committee (TRAC) to facilitate greater public involvement in the ongoing Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) reregistration, the Federal, Food, Drug and Cosmetic Act (FFDCA), and the Food Quality Protection Act (FQPA) tolerance reassessment initiatives on pesticides. Trichlorfon is subject only to the FQPA because it has tolerances associated with its use outside the U.S. as a pour on treatment for cattle.

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 EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional health and environmental effects data; and to determine whether the pesticide meets the "no unreasonable adverse effects" standard of FIFRA. The Reregistration Eligibility Decision (RED) for trichlorfon was completed in 1995.

On August 3, 1996, FQPA was signed into law. This Act amends the FFDCA to require reassessment of all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the FFDCA to require a safety finding in tolerance assessment based on factors including an assessment of the cumulative effects of chemicals with a common mechanism of toxicity. Although the 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.

The Agency has determined organophosphate (OP) pesticides exhibit or share a common mechanism of toxicity, cholinesterase inhibition. The Agency must, therefore, complete a cumulative assessment of the risks of all OP pesticides before it can complete its reassessment of the trichlorfon tolerances. While the methodology for completing the cumulative assessment for all OPs is being developed, individual risk assessments are being conducted, and risk mitigation measures implemented. The individual dietary assessment will be used in the cumulative assessment of all the OP chemicals.

This Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for Trichlorfon (otherwise know as TRED) considers acute and chronic dietary risks from food and water and risk from occupational sources of pesticide exposure. After the Agency released the *Revised Preliminary Human Risk Assessment for Trichlorfon, dated September 19,2000,* the risk assessments were further refined.

The Agency decided to limit this risk assessment to trichlorfon *per se*, rather than also considering the risks associated with the degradate dichlorvos (DDVP). Although DDVP is a significant environmental degradate of trichlorfon, it is undergoing a separate, parallel reregistration review. If the DDVP risk assessment indicates that the contribution of DDVP from trichlorfon is of concern and additional data are needed (e.g., water monitoring), the Agency will, at that time, issue a Data Call-In (DCI) for these data as part of the trichlorfon reregistration process. Similarly, if the results of the DDVP reregistration assessment indicate that DDVP resulting from the use of trichlorfon could pose significant human health exposure concerns, the Agency may reconsider any or all requirements in this document. The Agency is providing available exposure information on the trichlorfon sources of DDVP residues in this TRED for information purposes only.

In response to biological and environmental fate issues identified in the 1995 RED, the registrant furnished new data on the environmental effects of trichlorfon. The Agency intends to address environmental issues in a separate action, since the intention of this document is to provide an FQPA update and tolerance reassessment.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the usage of the chemical. Section III gives an overview of the dietary risk assessment for trichlorfon, including a discussion of any revisions that were made to the preliminary risk assessment, as well as residential, recreational and occupational exposure assessments. Section IV presents the Agency's progress towards tolerance reassessment including its interim reregistration eligibility decision for trichlorfon. Section V discusses what the manufacturer's obligations are with respect to further actions required, and Section VI provides information on how to access related documents. The entire revised risk assessment is not included in this document, but is available on the Agency's web page www.epa.gov/pesticides/op, and in the Public Docket.

II. Chemical Overview

A. Regulatory History

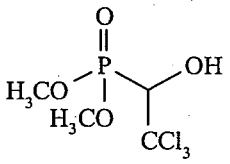
Trichlorfon was originally registered in the United States by the United States Department of Agriculture in 1955. At that time, trichlorfon was registered for use as an insecticide on a variety of vegetable, fruit and field crops as well as livestock, ornamental and forestry plants, agricultural premises and domestic dwellings, and for the control of parasites on fish in designated aquatic environments.

The Agency issued the Registration Standard for trichlorfon in1984, which included a Data Call-In (DCI) requiring studies to support the existing use patterns. Additional data were required in 1991 to complete the database for trichlorfon and to support reregistration. The trichlorfon database is largely complete. Some of the studies were not acceptable or only partially satisfied the requirement. However, the Agency was able to use available information to assess the potential risks as part of this TRED.

The 1995 RED for trichlorfon considered all data submitted in response to the 1984 Registration Standard and the subsequent 1991 DCI. Ornamental and turf uses (excluding sod farm use) were eligible for reregistration. Since issuance of the RED, three states issued Special Local Need registrations for use of trichlorfon in commercial bait and ornamental fish ponds.

Bayer Corporation, the manufacturer of the trichlorfon technical product, requested voluntary cancellation of all food, feed, and field crop uses, poultry packing plants and food areas of food-handling establishments in 1995, but decided to support a "tolerance with no U.S. registration" for beef and beef byproducts. Other trichlorfon registrants agreed to remove the unsupported uses from their product labels. The Agency determined that all tolerances should be revoked except tolerances for beef and beef byproducts imported into this country. Those tolerances are listed in Title 40 of the US Code of Federal Regulations Part 180.198. The Agency recommended that tolerances for beef and beef byproducts be revoked if an adequate nature of the residue study for these commodities was not submitted. Although the registrant submitted the study, the Agency determined that it was unacceptable; however, the Agency was able to propose "reassessed tolerances" using some of the information in the metabolism study.

B. Chemical Identification



Empirical Formula:	$C_4H_8O_4Cl_3P$
Molecular Weight:	257.6
Vapor Pressure (PAI):	2.8×10^{-6} at 20°C
Octanol/Water Partition Coefficient (Kow):	3.3

- **Common Name:** Trichlorfon
- **Chemical Name:** Dimethyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate
- **Chemical Family:** Organophosphate
- **CAS Registry No.:** 52-68-6
- **OPP Chemical Code:** 057901
- **Trade and Other Names:** Dylox

- **Technical Manufacturer:** Bayer Corporation

Technical trichlorfon is a white crystalline solid with a melting point of 75 - 84°C. Trichlorfon is soluble in water, dichloromethane, 2-propanol, and toluene and nearly insoluble in N - hexane. Trichlorfon is expected to have a half-life of 6.4 days in soil and 1.4 days in aqueous conditions. The Agency believes that the short half-life of trichlorfon may limit its persistence in the environment.

C. Use Profile

The trichlorfon use profile has changed dramatically in recent years. The use information provided here is based on the currently registered uses of trichlorfon. The following section summarizes use patterns, application methods, and other technical details on the current pesticidal uses of trichlorfon.

Type of Pesticide: Systemic insecticide.

Summary of Use Sites: Non-agricultural uses such as golf course turf, home lawns, non-food contact areas of food and meat processing plants, ornamental shrubs and plants, and ornamental and bait fish ponds. (Trichlorfon is used overseas as cattle pour-on, which is classified as a food-use).

Target Pests: Insects such as lepidopteran larvae (caterpillars), white grubs, mole crickets, cattle lice, sod webworms, leaf miners, stink bugs, flies, ants, cockroaches, earwigs, crickets, diving beetle, water scavenger beetle, water boatman, backswimmer, water scorpions, giant water bugs, and pillbugs.

Formulation Types:

- Technical product with 98% active ingredient (ai)
- Soluble powder with 80% ai (which may only be applied by commercial applicators)
- Granular products with 5% and 6.2% ai

Application Rates:

- Lawns/recreational turf: 1.1 lb ai/acre to 8.2 lb ai/acre; Ornamentals: 0.01 to 0.015 lb ai/gallon
- Commercial ponds/aquatic tank: 0.64 to 1.4 lb ai/acre-foot of pond water.

Method of Application: Groundboom sprayer, low and high-pressure handwand, backpack sprayer, handgun sprayer, sprinkling can, push-type granular spreader, and irrigation systems.

Timing: Product labels do not give specific timing for application of trichlorfon. For turf and lawns, most labels indicate application can be made monthly beginning in May or June. Two or three applications per week may be necessary for trichlorfon treatment of commercial ponds according to special local need labels.

Use Classification: General use pesticide.

D. Estimated Usage of Pesticide

This section summarizes the best pesticidal usage estimates available for trichlorfon. These estimates are derived from a variety of published and proprietary sources. The data, which are reported on an aggregate and site basis, reflect annual fluctuations in use patterns as well as the variability in using data from different sources.

Based on pesticide usage information mainly for 1994 through 1999, average domestic usage of trichlorfon is about one million pounds ai per year. In terms of pounds ai, total usage is allocated mainly to lawn care operators (74%) and golf courses (18%). Other sites with small usage include landscaping, institutional turf, nursery/greenhouse, and livestock areas. On average less than 2% of all turf sites are treated with trichlorfon. Application rates per acre on these sites are generally less than 7 lbs ai/acre.

III. Summary of Trichlorfon Risk Assessment

The following is a summary of EPA's revised human health risk findings and conclusions as presented in the revised risk assessment document and addenda listed below:

(1) *HED's Revision of the Trichlorfon Residential Exposure/Risk* Assessment. August 09, 2000;

(2) *HED's Insert to the Trichlorfon Risk Assessment: Residential Handler's and Postapplication Ornamental Uses,* August 30, 2000;

(3) HED's Review of *Determination of Transferable Turf Residues on Turf Treated with Trichlorfon,* September 6, 2000;

(4) *HED's Revised Preliminary Human Health Risk Assessment for Trichlorfon,* September 19, 2000;

(5) *HED's Reassessment of the Use of ORETF Granular Push-Type Spreader Studies (LCO and Homeowner) for the Trichlorfon Risk Assessment*, November 1, 2000;

(6) *Trichlorfon: Refined Tier I Surface Water EECs for Use in the Human Health Drinking Water Risk Assessment,* March 23, 2001; and

(7) *HED's Revised Drinking Water Levels of Concern and Aggregate Risk Assessment*

for Trichlorfon, April 24, 2001.

These documents are available in the public docket and on the Internet at www.epa.gov/pesticides/op. During the tolerance reassessment of trichlorfon, the registrant submitted new exposure studies. These new data had a material effect on the occupational and residential risk assessments for trichlorfon which are detailed in the documents listed above.

The Agency received public comments from the Golf Course Superintendents Association of America (GCSAA) and the Natural Resources Defense Council on the trichlorfon risk assessment. These comments and the Agency response can be seen in their entirety in the public docket and are summarized later in Chapter IV.

A. Human Health Risk Assessment

The human health risk assessment for trichlorfon looked at acute dietary, chronic dietary (non-cancer), drinking water, residential, and occupational risks. Since the Agency released its preliminary risk assessment in April 2000, there have been changes in the use profile and application method to ornamentals which impacts both the residential and occupational risk assessments. The ant mound treatment and homeowner building perimeter uses have been voluntarily canceled by the registrant because of Agency exposure concerns.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies and determined that the toxicity database is largely complete, and that it supports tolerance reassessment. Table 1 summarizes the toxicological endpoints and safety and/or uncertainty factors used by EPA for the dietary risk assessments.

Trichlorfon was evaluated for carcinogenicity in mice, rats and monkeys. The Agency's Cancer Assessment Review Committee classified trichlorfon as "not likely to be carcinogenic to humans at low doses, but is likely to be carcinogenic at high doses". Therefore, a quantitative carcinogenicity assessment is not required.

Table 1. Endpoints and Other Factors for Acute and Chronic Dietary Exposure

Exposure Scenario	Dose [1]	Endpoint	Study	UF	FQPA Safety Factor	RfD [1]	PAD [1]
Acute Dietary	10 (NOAEL)	Clinical signs (oral, red nasal, and urine stains; decreased motor activity), plasma, RBC and brain cholinesterase inhibition	Acute Neurotoxicity- Rat (MRID 44578001)	100	10x	0.1	0.01
Chronic Dietary	0.2 (NOAEL)	Brain cholinesterase inhibition in both sexes	Chronic Toxicity-Monkey (MRID 40776001)	100	10x	0.002	0.0002

UF - Uncertainty Factor
1) Expressed in mg/kg/day

b. FQPA Safety Factor

The Agency determined the 10x FQPA safety factor should be retained for the protection of infants and children from acute and chronic dietary exposure to trichlorfon based on the occurrence of neuropathology in animal studies and data gaps. Specifically, neuropathology concerns include: 1) organophosphate induced delayed Neurotoxicity, 2) neuropathology in hens observed in the acute delayed neurotoxicity study, and 3) literature studies in which oral administration of trichlorfon resulted in decreased brain weights in guinea pig fetuses. There are also data gaps for a prenatal developmental toxicity study and a developmental neurotoxicity study. [The Agency has previously issued a separate DCI to all registrants of OPs requiring a developmental neurotoxicity study (DNT)]. Methods to assess dietary and non-occupational exposures are unlikely to underestimate exposure.

c. Reference Dose and Population Adjusted Dose

The acute reference dose (acute RfD) is an estimate of a single oral exposure level for the human population, including the sensitive subpopulation, that is likely to be without an appreciable risk of deleterious effects.

The chronic reference dose (chronic RfD) is an estimate of a daily oral exposure level for the human population, including sensitive subpopulation, that is likely to be without an appreciable risk of deleterious effects during a lifetime.

The acute and chronic RfDs are calculated by dividing the no observed adverse effect level (NOAEL) or the lowest observed adverse effect level (LOAEL) by uncertainty factors. Uncertainty factors are used to account for differences between different humans (intraspecies variability) and for differences between the test animals and humans (interspecies extrapolation). If the LOAEL is used, an additional uncertainty factor is used.

$$RfD = \frac{\text{NOAEL or LOAEL}}{\text{Total UF}}$$

The population adjusted dose (PAD) is the acute RfD or the chronic RfD modified by the FQPA safety factor. The PAD is calculated by dividing the RfD by the FQPA safety factor.

$$PAD = \frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$$

For trichlorfon, the NOAEL was used and the uncertainty factor is 100; the FQPA safety factor is 10x. The chronic and acute PADs and RfDs are shown in Table 1 above. A risk estimate that is less than 100% of the acute or chronic PAD is not a risk of concern.

d. Exposure Assumptions

The revised acute and chronic dietary risk analyses for trichlorfon were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Survey ofFood Intake by Individuals (CSFII), 1989-91. Generally, a dietary risk assessment that is less than 100% of the acute or chronic Population Adjusted Dose is not of concern.

In the dietary exposure analyses, the Agency used tolerance level residues in addition to the assumption that 10 % of beef and beef byproducts consumed in the US is imported. The Agency also assumed that 100% of imported beef is treated with trichlorfon which is a conservative estimate. This is the only food use and only tolerances established for trichlorfon.

2. Food Risk Characterization

a. Acute Dietary (Food) Risk

The Agency conducted an acute probabilistic/Monte Carlo type dietary exposure analysis for trichlorfon. The results of this assessment indicate that dietary exposure from food is below the Agency's level of concern at the 99.9th percentile (<100% aPAD) for all population subgroups. Acute dietary exposure for the general US population from food was estimated be 11% of the aPAD. For the most highly exposed subgroup, children 1-6 years, the dietary exposure was estimated to be 18% of the aPAD.

b. Chronic Dietary (Food) Risk

Use of the assumptions noted above results in chronic dietary exposure that is also below the Agency's level of concern. Dietary exposure for the general US population was estimated to be 12% of the cPAD. For the most highly exposed population subgroup, children 1-6 years, the dietary exposure was estimated to be 24% of the cPAD.

3. Dietary Risk from Drinking Water

Trichlorfon and its degradate, DDVP, may contaminate surface and ground water. However, this TRED addresses exposure and risk for trichlorfon only. The risks associated with DDVP as an environmental degradate of trichlorfon will be assessed in the context of the DDVP interim reregistration eligibility decision, rather than in this document, once toxicity endpoints and other information necessary for risk assessment are determined. However, the existing exposure estimates for DDVP derived from trichlorfon use are provided here for completeness.

Tier 1 surface water and groundwater assessments were completed using GENEEC and SCI-GROW modeling. A Tier II surface water assessment was not conducted because there is no PRZM-EXAMS scenario for turf, which is the predominant use.

a. Surface Water

The surface water assessment indicates that trichlorfon has a high potential to reach surface water. The Agency conducted this assessment using refinements to GENEEC, which is a Tier 1 screening model that provides a high-end estimate. On its own merits, GENEEC is not an ideal tool for drinking water exposure assessments. Surface-water-sourced drinking water tends to come from bodies of water substantially larger than the 1-hectare pond typically used in the model. In addition, GENEEC assumes that essentially the whole basin receives an application of the chemical. In virtually all actual cases, basins large enough to support a drinking water facility will contain a substantial fraction of area that does not receive the chemical. Furthermore, there is always at least some flow (in a river) or turn over (in a reservoir or lake) of the water so the persistence of the chemical near the drinking water facility is usually overestimated by GENEEC. Consequently, GENEEC usually provides an upper bound on the concentration of pesticide that could be found in drinking water and therefore can be appropriately used only in screening calculations.

The Agency used the standard input parameters which include application rate, application interval, persistence, solubility and other factors in the GENEEC model. Then the Agency refined the EECs by incorporating an 87% crop treated area factor (default PCA) and applied an average expectancy that 27% of the golf course is potentially treated (based on golf course characteristics from the GCSAA database), rather than assuming 100% of the golf course is treated. Using this approach, the Agency believes the results are not overly conservative and may be somewhat more representative of the actual concentrations of trichlorfon. The estimated environmental concentrations (EECs) for surface water are based on this refined Tier 1, GENEEC estimate and are shown in Table 2. (The Agency has listed the EECs for DDVP solely as information since it is a degradate of trichlorfon. Drinking water exposure to all sources of DDVP, including trichlorfon, will be addressed as part of the pending DDVP IRED).

Table 2. Estimated Environmental Concentrations Associated With Use of Trichlorfon on Turf

Drinking Water Source (Model)	Estimated Environmental Concentration (EEC) (ppb) for 7-day retreatment interval
Surface Water (GENEEC)	Peak = 179 ppb Average 56-day (chronic value) = 2.7 ppb [1]
	Peak = 81.7 ppb (DDVP)[2] Average 56-day (chronic value) = 11.7 ppb
Groundwater (SCI-GROW)	0.27 ppb
	0.006 ppb (DDVP)[2]

[1] Value reported was 8.2 ppb, current Agency policy states that the average 56 day GENEEC (or chronic) value should be divided by 3 for chronic DWLOC calculation.
[2] For informational purposes, DDVP EECs are provided

b. Ground Water

Very limited groundwater monitoring data for trichlorfon are available. There are no detectable residues reported in the EPA STORET (storage retrieval) database. Consequently, the SCI-GROW model was used to estimate a Tier I screening value for the groundwater EEC. In the absence of a limit on maximum applications per year on the current trichlorfon labels, the Agency ran the model assuming the pesticide was used three (3) times per year with a seven day retreatment intervals a reasonable average estimate. Modeled acute and chronic groundwater EECs are shown above in Table 2.

c. Drinking Water Levels of Comparison (DWLOCs)

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

i. Acute DWLOCs

The acute DWLOC represents the maximum peak concentration of trichlorfon that may occur in water without a risk concern. Acute DWLOCs for trichlorfon were calculated based on the acute dietary (food) exposure and the Agency default values for body weight and drinking water consumption. The assumptions and equation for calculating the acute DWLOC can be found in the *HED's Revised Preliminary Human Health Risk Assessment for Trichlorfon,* dated September 19, 2000, and in the memorandum *Trichlorfon: Refined Tier I Surface Water EECs for Use in the Human Health Drinking Water Risk Assessment*, March 23, 2001.

The acute surface water EEC (179 ppb) for trichlorfon, based on the refined GENEEC model, is greater than the acute DWLOC (82 ppb) for the most highly exposed population subgroup, children 1 - 6 years. This suggests acute exposure to trichlorfon from food and surface water sources of drinking water could exceed the Agency's level of concern.

The acute EEC for trichlorfon in groundwater (0.27 ppb), which is based on SCI-GROW modeling, is less than the acute DWLOC (312 ppb) for the general population and the most highly exposed subpopulation, children 1-6 years (82 ppb). Therefore, acute exposure to trichlorfon from food and groundwater sources of drinking water is not of concern. These results are presented below in Table 3.

Table 3. Drinking Water Levels of Comparison for Acute Dietary Exposure

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	$DWLOC_{acute}$ (ppb)	GENEEC surface water EEC (ppb)	SCI-GROW groundwater EEC (ppb)
US Population	0.01	0.001086	0.008914	312	179	0.27
Children 1-6	0.01	0.001761	0.008239	82	179	0.27

ii. Chronic DWLOCs

Chronic DWLOCs were estimated based on the chronic dietary (food) exposure and default body weights and water consumption. The assumptions and equation for calculating the chronic DWLOC are detailed in the September 19, 2000, *Revised Preliminary Human Health Risk Assessment for Trichlorfon.*

The modeled chronic surface water EEC (2.7 ppb) exceeds the DWLOC (1.5 ppb) for the subpopulation children 1 - 6 years. Therefore, chronic exposure risk to trichlorfon from surface water sources of drinking water appear to exceed the Agency's level of concern. These data are presented in Table 4 below.

The modeled EEC (0.27 ppb) for groundwater is less than the chronic DWLOC for all population groups. Therefore, chronic exposure to trichlorfon in food and water from groundwater sources of drinking water is not of concern for even the most highly exposed subpopulation, children 1 - 6 years old. These data are also presented below in Table 4.

Table 4. Drinking Water Levels of Comparison for Chronic Dietary Exposure

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	$DWLOC_{chronic}$ (ppb)	GENEEC surface water EEC (ppb)	SCI-GROW groundwater EEC (ppb)
US Population	0.0002	0.000025	0.000175	6.1	2.7	0.27
Children 1-6	0.0002	0.000049	0.000151	1.5	2.7	0.27

4. Residential Handler and Non-Occupational Risk

This section addresses residential risk associated with the use of trichlorfon. New data and methodologies are now available to assess these risk scenarios since the RED was completed in 1995.

Residents or homeowners may be exposed to a pesticide through mixing, loading, or applying, or through entering or performing other activities on treated areas. Residential handlers include homeowner applicators treating their own lawns. As mentioned above, trichlorfon exposure to adults and children also occurs from contact with treated lawns or other turf areas. Estimated 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.

a. Toxicity

All risk calculations are based on the most current toxicity information available for trichlorfon. The toxicological endpoints, and other factors used in the residential risk assessment for trichlorfon are shown in Table 5.

Table 5. Endpoints for Assessing Residential Risks for Trichlorfon

Endpoint	NOAEL mg/kg/day	Margin of Exposure and Uncertainty Factor	Study/Effect
Short/ Intermediate-Term Dermal	100	1,000 (residential) UF = 100 FQPA SF = 10x	21-day dermal (rabbit), RBC ChEI (MRIDs 0040369, 40306901)
Long-Term Dermal	A long-term exposure scenario is not expected based on the use patterns of trichlorfon.		
Inhalation Any time period	3.45 (0.0127 mg/L[a])	1,000 (residential) UF = 100 FQPA SF = 10X	21-day inhalation (rats), RBC ChEI (MRID 00256446)

[a] 3.45 mg/kg/day = NOAEL (0.0127 mg/l) x respiration rate of a young adult Wistar rat (8.46 L/hr) x study daily exposure duration (6 hr/day)/body weight of a young adult Wistar rat (0.187 kg).

b. Residential Handler and Lawn Care Operator Risks

Trichlorfon is also used on residential lawns and ornamentals. In determining the residential handler risks, the Agency assumed that homeowners wear only short sleeved shirts and short pants while applying trichlorfon to turf. The professional lawn care operator (LCO) treating residential lawns is assessed at baseline attire, which includes only long sleeved shirt, long pants, shoes and socks (no gloves or respirator). Residential handler exposure to trichlorfon residues via dermal and inhalation routes can occur during handling, mixing, loading, and applying activities. The endpoints for the short-term and intermediate term scenario durations are the same, so the actual time duration of the activity is unimportant in estimating the risk. The areas treated per day in this risk assessment were assumed to be 0.5 and 5 acres for turf broadcast applications for homeowners and LCOs, respectively. The resultant MOEs do not exceed the Agency's level of concern and can be found in Table 6 of this document.

Using the Pesticide Handler Exposure Database (PHED) data and preliminary information from the Occupational and Residential Exposure Task Force (ORETF), the Agency was able to assess risk to handlers loading/applying granules to residential lawns using a "push-type" broadcast spreader. The same assumptions are used to estimate exposures for the LCO and residential handler; therefore, exposure and combined MOEs for the professional LCO (Scenario 8) and residential handler are both presented in Table 6. For residential exposure and risk estimates, an uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability, because the10x FQPA safety factor was retained for the protection of infants and children. The target residential MOE is 1,000 (100 x 10x FQPA safety factor). Neither MOEs for residential handlers or LCOs exceed the Agency's levels of concern.

Table 6. Residential and LCO Dermal, Inhalation, and Combined MOEs for Trichlorfon Based on ORETF Data.

Exposure Scenario	Dermal Unit Exposure[a] (mg/lb ai)	Inhalation Unit Exposure[b] (μg/lb ai)	Use[c]	Application Rate[d] (lb ai/acre)	Amount Handled per Day[e]	Dermal[f,g]		Inhalation[h,i]		Combined[j] MOE
						Daily Dose[f] (mg/kg/day)	MOE[g]	Daily Dose[h] (mg/kg/day)	MOE[i]	
Loader/Applicator Risks: Residential Granular Push-Type Spreader (short-sleeved shirt, short pants, no gloves). **MOE of 1,000** Needed for Combined Dermal and Inhalation Exposures.										
Loading/Applying with a Push Type Spreader (R2)	0.68 (7.6 max)	0.91 (3.7)	turf	8.2 lb ai/acre	0.5 acres	0.040	2,500	0.000053	65,000	2,400
Loader/Applicator Risks: Lawn Care Operator (LCO) Granular Push-Type Spreader (long-sleeved shirt, long pants, no gloves). **MOE of 100** Needed for Combined Dermal and Inhalation Exposures.										
Loading/Applying with a Push Type Spreader (8)	0.31 (max 2.1)	7.1 (max 29)	turf	8.2 lb ai/acre	5 acres	0.18	550	0.0042	830	330

Footnotes:

a,b Dermal and inhalation unit exposure values from the Outdoor Residential Exposure Task Force (ORETF). Residential dermal exposure assumes short pants, short sleeved shirt, shoes and socks and no gloves. LCO dermal exposures assumes long-sleeved shirt, long pants, shoes and socks, no gloves and no respirator.

c "Use" - broadcast turf application.

d Application rate is the maximum application rate presented on EPA registered labels. Rate are taken from the 3125-507 label.

e Amount handled per day values are EPA estimates of acreage treated found in the Residential SOPs draft December 1997.

f Dermal daily dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/acre) x amount handled per day (acres) / body weight (70 kg).

g Dermal MOE = dermal NOAEL (100 mg/kg) / daily dose (mg/kg/day). Target MOE of 1,000 for residential uses and 100 for occupational handlers.

h Inhalation daily dose (mg/kg/day) = inhalation unit exposure (μg/lb ai) x application rate (lb ai/acre) x amount handled per day (acres) x conversion factor (1 mg/1,000 μg) /body weight (70 kg).

i Inhalation MOE = NOAEL (3.45 mg/kg/day) / daily dose (mg/kg/day). Target MOE of 1,000 for residential uses and 100 for occupational handlers.

j Total MOE = 1 / [(1/dermal MOE) + (1/inhalation MOE)].

c. Non-Occupational Post-Application Risk

In addition to residential handler risk, there is potential dermal exposure and inadvertent oral exposure to children from incidental ingestion of trichlorfon from trichlorfon-treated lawns. A chemical-specific turf transferable residue (TTR) study was submitted by the registrant. This study was used by the Agency to refine post-application exposure concerns for toddlers and adults playing on treated lawns.

Table 7 below presents the DDVP TTR data for informational purposes only. Following the table is a discussion of the acute, short/intermediate term, and chronic aggregate risk assessments based on moderate refinements to the GENEEC model.

Table 7. Dermal Post-application Risks to Toddlers and Adults from Granular and Soluble Powder Formulations When Reentering Treated Lawns

Scenario	Application Rate (lb ai/acre)[a]	TTR ($\mu g/cm^2$)		Transfer Coefficient (cm^2/hr)	Exposure Duration (hours)	Daily Dermal Dose[b] (mg/kg/day)		Dermal MOE[c]
		Trichlorfon[a]	DDVP[b]			Trichlorfon	DDVP	Trichlorfon
Toddler	5.4	0.0092	(1) 0.0028	5,200	2	0.0064	(1) 0.00021	16,000
			(2) 0.0065				(2) 0.00050	
	8.2	0.0138	(1) 0.0042	5,200	2	0.0096	(1) 0.00032	10,000
			(2) 0.0097				(2) 0.00074	
Adult	5.4	0.0092	(1) 0.0028	14,500	2	0.0038	(1) 0.00013	26,000
			(2) 0.0065				(2) 0.00030	
	8.2	0.0138	(1) 0.0042	14,500	2	0.0057	(1) 0.00019	17,000
			(2) 0.0097				(2) 0.00044	
Golfer - Adult	5.4	0.0092	(1) 0.0028	500	4	0.00026	(1) 8.8E-6	380,000
			(2) 0.0065				(2) 2.0E-5	
	8.2	0.0138	(1)0.0042	500	4	0.00039	(1) 1.3E-5	250,000
			(2)0.0097				(2) 3.0E-5	

(1) TTRs based on the longest ½ life from the Florida site in the DDVP Turf study (FL is 0.156 days; CA is 0.069 days; Ontario, Canada is 0.022 days) and the longest ½ life of trichlorfon (2.5 days), and

(2) The longest ½ life from the FL site in the DDVP Turf study and the shortest ½ life of trichlorfon (0.93 days).

a The maximum application rate is 8.2 lbs ai/acre based on the turf transferable (TTR) residue from MRID 450672-01 from the GA site (granular formulation) at 12 hours after treatment (0.0138 $\mu g/cm^2$). The Agency also assumed estimated hours exposed as 2 hours for toddlers playing on the lawn and 4-hours for golfers for an 18-hole round of golf. The low application rate is 5.4 lbs ai/acre based on an extrapolation of this study and assumptions.

b Daily Dermal Dose (mg/kg/day) = [TTR ($\mu g/cm^2$) x Transfer Coefficient (cm^2/hr) x unit conversion (1 mg/1000 μg) x Exposure Duration (hrs/day) x absorption factor]/-Body Weight (kg). Trichlorfon is assessed using a dermal toxicological endpoint and therefore the dose is not adjusted for absorption. DDVP dermal absorption is estimated at 11 percent. Inputs and calculations are derived from the SOPs for Residential Exposure Assessments, except for golfers. Golfer transfer coefficient is an estimate.

c Postapplication Trichlorfon Dermal MOE = (100 mg/kg/day)/Daily Dermal Dose (mg/kg/day). Target MOE is 1,000. All pesticide exposure sources of DDVP will be considered in the DDVP IRED.

5. Aggregate Risk

An aggregate risk assessment combines risks from dietary (food and drinking water), and non-occupational exposure (residential exposure: dermal and inhalation for homeowner applicators, and incidental oral for toddlers; and recreational exposures: dermal post-application to golfers). The results of the acute, short/intermediate term, and chronic aggregate risk assessments are discussed below.

Trichlorfon residues from food alone are not of concern. Acute exposure (food only) to trichlorfon was 18 % of the aPAD for the most highly exposed population (children 1-6 years) while chronic exposure (food only) to trichlorfon residues was 24 % of the cPAD. However, risk estimates suggest acute, short/intermediate term and chronic aggregate dietary exposure (food and water) to trichlorfon may be a concern when the source of drinking water is surface water.

a. Acute Aggregate Risk

The acute aggregate risk estimates for trichlorfon address exposure from food and drinking water. Acute exposure is considered to occur in a one-day time frame via the oral route of exposure. Acute dietary risks are below the Agency's level of concern if less than100 % of the aPAD. The estimated concentrations of trichlorfon in groundwater are below the Agency's level of concern for all subpopulation including children 1-6 years. Based on available information, it appears that residues of trichlorfon in drinking water (when considered along with food) could result in an acute aggregate human health risk of concern for children 1-6 years when the source of drinking water is surface water. However, this modeled EEC is likely overly conservative as will be discussed in chapter 4 of this TRED, and therefore, does not indicate an aggregate risk concern.

b. Short/Intermediate Term Aggregate Risk

The aggregate short/intermediate-term risk assessment provides risk estimates resulting from residential exposure combined with average food and water. High end residential and recreational (golfing) exposure estimates are added to estimates of average food and water exposure. These are compared to an appropriate NOAEL from a toxicity study. The target MOE, including the FQPA safety factor of 10x, is 1,000 for combined dermal and inhalation exposure. Each of the following short/intermediate term residential exposure scenarios equaled or exceeded the target MOE (1000) when aggregated with the average food and water exposure. They are 1) dermal post-application residential handler exposure for adults loading/applying with a push type spreader to turf (8.2 lb ai/acre), 2) toddler post-application dermal, and 3) combined toddler post-application oral hand-to-mouth and dermal exposures.

A short term DWLOC of 182 ppb was calculated for dermal post-application risks to adults using a push type spreader, when aggregated with chronic food and water exposure. The GENEEC model estimated an EEC of 2.7 ppb. The EEC is less than the short/intermediate term DWLOC and therefore not of concern when aggregated with chronic food and water. Toddler post-application dermal exposure

associated with entering a lawn treated at 8.2 lb ai/acre (the maximum label rate) was assessed. When aggregated with chronic food and water exposure, it results in a short/intermediate term DWLOC of 90 ppb which when compared to the EECs of 2.7 ppb does not exceed the Agency's level of concern. Finally, toddler postapplication dermal exposure combined with hand-to-mouth exposure from entering trichlorfon lawns treated at the maximum label rate, when aggregated with chronic food and water exposures, do not exceed the Agency's level of concern. The short term DWLOC is 86 ppb while the EEC is 2.7 ppb. Further details can be seen in the memorandum dated April 24, 2001, *Trichlorfon: HED's Revised Drinking Water Levels of Concern and Aggregate Risk Assessment for Trichlorfon.*

Although the Agency acknowledges the contribution of trichlorfon residues to aggregate risks from drinking water from surface water sources for children 1-6 years old could be of concern, based on a comparison of the three scenarios mentioned above as compared to the chronic GENEEC model EECs, the Agency believes that the estimated aggregate risks for children 1-6 from surface water contributions are conservative and when coupled with appropriate mitigation measures will not exceed the Agency's level of concern.

c. Chronic (Non-Cancer) Aggregate Risk

A chronic aggregate assessment estimates risk from long term exposure to food and water, and also includes residential exposure if any long term scenarios are identified. No long term chronic residential and golfing use scenarios for trichlorfon were identified. The chronic DWLOC for Children 1-6 years is 1.5 ppb, while the surface water EEC is 2.7 ppb. The chronic EEC for surface water is only slightly greater than the chronic DWLOC. However, this modeled EEC is likely overly conservative as will be discussed in chapter 4 of this TRED, and therefore, does not indicate an aggregate risk concern.

6. Occupational Risk

The Agency usually only assesses the dietary risks when complying with the requirements to report on tolerance reassessment progress for pesticides reregistered prior to the enactment of FQPA, which amended FFDCA. For trichlorfon, the Agency received new data and applied revised methodologies and policies to more completely characterize the risks associated with occupational and residential uses. Therefore, the Agency has included an updated assessment for workers that can be exposed to a pesticide through mixing, loading, and/or application, or when reentering treated sites. Occupational handlers of trichlorfon include applicators who mix, load, and/or apply pesticides, including lawncare and turf management professionals. Occupational risks for lawncare operators were shown previously in Table 6. For occupational scenarios, MOEs greater than 100 do not exceed the Agency's level of concern. MOEs for the remaining nine occupational scenarios assessed by the Agency are presented in Table 10.

a. Toxicity

All risk calculations are based on the most current toxicity information available for trichlorfon. For occupational exposure and risk estimates, an uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability. The toxicological endpoints, and other factors used in the occupational risk assessment for trichlorfon are shown in Table 8.

Table 8. Endpoints for Assessing Occupational Risks for Trichlorfon

Endpoint	NOAEL mg/kg/day	Margin of Exposure and Uncertainty Factor	Study/Effect
Short and Intermediate-Term Dermal	100	100 UF = 100	21-day dermal (rabbit), RBC ChEI (MRIDs 0040369, 40306901)
Long-Term Dermal	A long-term exposure scenario is not expected based on the use patterns of trichlorfon.		
Inhalation Any time period	0.0127 mg/L[a] (3.45)	100 UF = 100	21-day inhalation (rats), RBC ChEI (MRID 00256446)

[a] 3.45 mg/kg/day = NOAEL (0.0127 mg/l) x respiration rate of a young adult Wistar rat (8.46 L/hr) x study daily exposure duration (6 hr/day) /body weight of a young adult Wistar rat (0.187 kg).

Acute toxicity values for trichlorfon in experimental animals and the corresponding Toxicity Categories are summarized in Table 9. Trichlorfon is relatively toxic given the category II rating for acute oral toxicity and acute eye irritation.

Table 9. Acute Toxicity Dose levels and Categories of Trichlorfon

Guideline Number and Study	MRID #	Result	Category
870.1100 Acute Oral Toxicity - Rat	00256446	LD_{50}=136 - 173 mg/kg	II
870.1200 Acute Dermal Toxicity - Rabbit	00090786	$LD_{50} \geq 2$ g/kg	III
870.1300 Acute Inhalation Toxicity - Rat 4 hour	00256446	LC_{50}=533 mg/m^3	III
870.2400 Acute Eye Irritation - Rabbit	44471301	moderately irritating	II
870.2500 Acute Dermal Irritation - Rabbit	40306901	non irritating	IV
870.2600 Skin Sensitization - Guinea Pig	00257599	moderate contact allergen	NA

b. Occupational Risk Assessment

No chemical-specific handler exposure data were submitted for trichlorfon. Therefore, an exposure assessment for each scenario was developed, using the *Pesticide Handlers Exposure Database (PHED)* Version 1.1., ORETF handler data, and standard assumptions about average body weight, work day, daily areas treated, volume of pesticide used, and other factors to estimate risks. The quality of the data and exposure factors represent the best sources of data currently available to the Agency for completing these

types of assessments. The PHED unit exposures from handling trichlorfon range from low to high quality. The scenario assessments are discussed in the *Reassessment of the Use of ORETF Granular push-type Spreader Studies (LCO and Homeowner -- MRID No. 449722-01) for the Trichlorfon Risk* Assessment, November 1, 2000, and the *Revised Preliminary Human Health Risk Assessment for Trichlorfon*, September 19, 2000.

Anticipated use patterns and application methods, range of application rates, and daily acres treated were used in the risk assessment. Application rates specified on trichlorfon labels range from 1.1 lb a.i./acre to 8.2 lb ai/acre. The Agency typically uses acres treated per day values that are thought to represent a typical work day (e.g., 8 hours) when using specific types of application equipment.

Occupational handler exposure assessments are conducted by the Agency assuming different levels of personal protection equipment (PPE). The Agency will evaluate all exposures with minimal protection and then add additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., increasing from minimal to maximum levels of PPE) that is not of concern to the Agency. The lowest level of PPE is baseline PPE. If MOEs are less than 100, increasing levels of PPE are applied. If MOEs are still less than 100, engineering controls are applied. However, for trichlorfon, the Agency did not consider this risk mitigation since engineering controls are not practicable for those scenarios with MOEs that exceed the Agency's level of concern. The current trichlorfon label requires handlers to wear long pants, a long-sleeved shirt, shoes, socks and chemical-resistant gloves. The levels of PPE that formed the basis for calculations of exposure from trichlorfon activities in this TRED include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Minimum PPE: Baseline + chemical resistant gloves and a respirator.
- Maximum PPE: Baseline + coveralls, chemical resistant gloves, and a respirator.

i. Occupational Handler Risk

The Agency evaluated ten occupational exposure scenarios for trichlorfon.(see the Revised Preliminary Risk Assessment, September 19, 2000). They are: (1) mixing/loading soluble powders for groundboom and chemigation applications; (2) applying with groundboom equipment; (3) mixing/loading/ applying with groundboom equipment for drench application; (4) mixing/loading/applying with high pressure handwand sprayer; (5) mixing/loading/applying with handgun sprayer; (6) mixing/loading/applying with low-pressure handwand sprayer; (7) mixing/loading/applying with backpack sprayer; (8) loading/applying with push-type drop spreader; (9) applying granulars by sprinkler can; and (10) applying granulars by hand around the house perimeter and to ant mounds. Table 10 shows MOEs for nine of the ten scenarios because the registrant has requested voluntarily cancellation of the residential house perimeter and ant mound use (scenario 10).

For both dermal and inhalation exposures, route specific studies were available and provided the NOAELs used to estimate risks. The same toxic effect or endpoint (i.e., ChEI) was selected to assess

dermal and inhalation risks. Therefore, the Agency combined the dermal and inhalation exposures to assess risks for various scenarios. The target MOE for occupational worker risks is 100. MOEs below this level represent a risk of concern.

Based on the occupational and residential exposure (ORE) assessment presented in Table 10, two scenarios posed potential risks of concern. Scenario 1, mixing/loading soluble powder for groundboom and chemigation application to golf courses and ornamentals has a total MOE of 51. Combined MOEs for scenario 6, mixing/loading/applying with a low pressure handwand for large (see ponds sizes and rate description below) ornamental fish and bait ponds range from 27 to 120 depending on the size of the pond and the application rate.

ii. Short/Intermediate-Term Risk

The Agency used various assumptions in performing the occupational assessment. The acres treated or amount of trichlorfon handled per day may vary depending on the target pest and application equipment. The Agency considered all scenarios to be of short/intermediate term in duration. The following is a list of the area treated per day assumptions used in the assessments:

- Golf course turfgrass and chemigation treatments: 40 acres;
- Turfgrass broadcast treatments: 5 acres;
- Turfgrass perimeter/spot treatments: 100 sq ft using a sprinkler can; and 1,000 ft^2 for hand-applied treatments;
- Narcissus drench treatment (groundboom):1,000 gallons;
- Ornamental treatments:1,000 gallons high-pressure handwand, 40 gallons for low-pressure handwand and backpack; and
- Pond/aquatic tank treatments: large pond (volume equals 15 acre-feet) and small pond (volume equals 7.5 acre-feet).

Table 10. Summary of Occupational Handler Short-term/Intermediate-term Risks for Trichlorfon at Baseline and PPE

Exposure Scenario (Scenario #)	Use	Short/Intermediate-term MOEs (Target MOE = 100)					
		Baseline			PPE		
		Dermal	Inhalation	Total	Dermal	Inhalation [3]	Total
MIXER/LOADER EXPOSURE							
Mixing/Loading Soluble Powder for Groundboom and Chemigation Application (1)	Turf (golf courses, ornamental lawns)	5.8	17	4.3	130[1]	86[a]	51[b]
APPLICATOR EXPOSURES							
Applying Spray with a Groundboom Sprayer (2)	Turf (golf courses, ornamental lawns)	1,500	990	600	NA	NA	NA
MIXER/LOADER/APPLICATOR EXPOSURES							
Mixing/Loading/Applying with a Groundboom as a Drench (3)	Narcissus	1,900	19,000	1,700	NA	NA	NA
Mixing/Loading/Applying with a High Pressure Handwand Sprayer (4)	Ornamentals	No Data	130	No Data	190[1]	670[1]	150[a]
Mixing/Loading/Applying with a Handgun Sprayer (5)	Turf	No Data	4,200	No Data	500[1]	NA	450
Mixing/Loading/Applying with a Low Pressure Handwand (soluble powder formulation) (6)	Turf (spot treat)	No Data	1,200	No Data	4,300[1]	NA	NA
	Ornamentals	No Data	370	No Data	1,400[1]	NA	NA
	Livestock areas	No Data	55	No Data	200[1]	270	120
	Pond - 1.4 lb ai/acre ft (5.0 acres surface area x 3 ft deep)	No Data	10	No Data	54[2]	52	27
	Pond - 0.64 lb ai/acre ft (5.0 acres surface area x 3 ft deep)	No data	23	No Data	120[2]	110	58
	Pond - 1.4 lb ai/acre ft (2.5 acres surface area x 3 ft deep)	No Data	21	No data	110[2]	100	53
	Pond - 0.64 lb ai/acre ft (2.5 acres surface area x 3 ft deep)	No data	46	No data	240[2]	230	120

Exposure Scenario (Scenario #)	Use	Short/Intermediate-term MOEs (Target MOE = 100)					
		Baseline			PPE		
		Dermal	Inhalation	Total	Dermal	Inhalation [3]	Total
Mixing/Loading/Applying with a Backpack Sprayer (7)	Turf (spot treat)	No Data	42,000	No data	15,000[1]	NA	11,000
	Ornamentals	No Data	13,000	No data	4,700[1]	NA	3,500
	Livestock areas	No Data	2,000	No data	700[1]	NA	520
Loading/Applying Granular with a Push Type Spreader (8)	Turf - maximum rate	550	830	330	130[1]	NA	120
Loading/Applying with a Sprinkling Can (9)	Turf (spot treat)	12,000	1.3E+6	12,000	NA	NA	NA

NA - indicates acceptable MOEs at baseline.
No data - indicates that there is no data for baseline attire

Footnotes:

a Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, and open cab tractor.
b The Agency expects this risk to increase two-fold if a more realistic breathing rate is applied.

[1] Long pants, long sleeved shirt, chemical resistant gloves.
[2] Double layer of clothing; chemical resistant gloves.
[3] PPE inhalation unit exposure represents use of dust mist respirator (80% protection factor applied to baseline unit exposure)

7. Post-application Exposure

Exposure to workers can occur upon entering trichlorfon treated sites after application. The Agency determined there are potential post-application exposures to workers performing tasks in treated golf courses and hand labor activities associated with treated ornamentals. Golf course activities of concern include mowing and maintenance of turfgrass. Potential exposure activities for nursery-grown ornamentals include pruning, harvesting, and thinning flowers.

Current labels for turf and ornamental use specify foliar spray application. The Agency relied on surrogate post-application exposure data to determine potential risks for these scenarios. The Agency determined that there is a post-application risk to nursery workers following foliar treatment of ornamentals up to 23 days after treatment. The registrant has agreed to voluntarily cancel this application method because of post-application risk concerns, and instead support only a direct soil application. Although the Agency did not perform a quantitative risk assessment for direct soil application to ornamentals, the Agency believes discontinuing foliar application and allowing soil application only at the base of the plant, combined with a 12 hour REI is appropriate to address postapplication exposure concerns. Details of the post-application exposure and risk assessment for occupational workers are presented in the *Revised Preliminary Human Health Risk Assessment for Trichlorfon*, September 19, 2000, and the August 30, 2000 addendum to the *Trichlorfon Risk Assessment: Residential Handler's and Post-application Ornamental Uses".*

The registrant submitted several turf transferable residue (TTR) studies for trichlorfon that the Agency used to assess the potential post-application exposure and risks to workers that mow and maintain treated golf courses. Estimated daily dermal post-application exposure to these workers resulted in MOEs greater than 100 on the day of application. Therefore, the risks are not of concern. Post-application risks are summarized in Table 11.

Although only trichlorfon residues were analyzed in the submitted study, potential exposure and risks from trichlorfon's degradate, DDVP, could pose a risk of concern.

Two estimates of DDVP TTR were developed for this risk assessment. Both estimates of DDVP began with the initial trichlorfon concentration of 0.0829 $\mu g/cm^2$ detected on the first sampling interval using the soluble powder formulation. The first DDVP estimate assumes the longest half-life from the FL site in the DDVP turf study (FL is 0.156 days; CA is 0.069 days; Ontario is 0.022 days) and the longest half-life of trichlorfon (2.5 days). The second estimate assumed the longest DDVP half-life from the FL site in the DDVP turf study and the shortest half-life of trichlorfon (0.93 days). The range of modeled residue levels of DDVP used in the risk assessment is 0.0028 to 0.0097 $\mu g/cm^2$. The highest value, 0.0097 $\mu g/cm^2$, is based on using the shortest half-life of trichlorfon. This value represents the estimate on turf 11 hours after treatment at the 8.2 lb ai/acre rate. It represents the highest value based on the trichlorfon TTR results and may overstate the levels at the time a child may be exposed because it occurs 11 hours after treatment (e.g., 8:00 am treatment and playing on turf at 7:00 pm). The Agency is including these data for completeness (only in Table 10) since the scope of this reregistration is limited to trichlorfon.

Table 11. Trichlorfon Occupational Post-Application Risk

Crop	Appl. Rate	DAT[a]	DFR (µg /cm²) [b]	TTR (µg/cm²) [c]	Golf Course: Mow/Maintain Tc=500 cm²/hr [d,e] Dermal Dose (mg/kg/day)	MOE	Dermal Dose (mg/kg/day)	Ornamentals: Pruning, harvesting, thinning flowers Tc = 7,00 0 cm²/-hr [d,e] Dermal Dose (mg/kg/day)	MOE
				(DDVP)	Trichlorfon		DDVP	Trichlorfon	
Golf Course Turf	8.2 lb ai/A	0	-	0.0138 (1) 0.0042 (2) 0.0097	0.00079	130,00 0	(1) 2.6E-5 (2) 6.1E-5	-	-
Ornamentals	3 lb ai/A (foliar) (0.015 lb ai/gal * 200 gal/A)	0	6.7	No data available to estimate potential DDVP residues	-	-	-	5.4	19
		9	2.6		-	-	-	2.1	48
		13	1.7		-	-	-	1.4	73
		16	1.2		-	-	-	1.0	100
Ornamentals	6 lb ai/A (foliar) (0.015 lb ai/gal * 400 gal/A)	0	13	No data available to estimate potential DDVP residues	-	-	-	11	9
		16	2.5		-	-	-	2.0	50
		20	1.6		-	-	-	1.3	76
		23	1.2		-	-	-	0.95	110

Footnotes:-

a DAT is "days after treatment."

b DFR = Application rate x Conversion factor (lb ai/-acre = 11.209µg/cm²) x fraction of initial ai retained on foliage (20% for ornamentals)* (1-daily dissipation rate)t, assuming a daily dissipation of 10%.

c Turf transferable residues (TTR) for trichlorfon from the GA site (granular formulation) at 12 hours after treatment (0.0138µg/cm²). The modeled DDVP residues are based on initial trichlorfon residue of 0.0829 µg/cm² and (1) the longest ½ life from FL site in the DDVP Turf study (FL is 0.156 days; CA is 0.069 days; Ont is 0.022 days) and the longest ½ life of trichlorfon (2.5 days); and (2) the longest ½ life from FL site in the DDVP Turf study (FL is 0.156 days; CA is 0.069 days; Ont is 0.022 days) and the shortest ½ life of trichlorfon (0.93 days).

d Daily Dermal Dose (mg/kg/day) = [TTR or DFR (µg/cm²) x Transfer Coefficient (/hr) x unit conversion (1 mg/1000 µg) x Exposure Duration (hrs/day) x absorption factor]/-Body Weight (kg). Trichlorfon is assessed using a dermal toxicological endpoint and therefore the dose is not adjusted for absorption. DDVP dermal absorption is estimated at 11 percent

e MOE = NOAEL (mg/kg/day) / Dermal Dose (mg/kg/day); where trichlorfon dermal NOAEL is 100 mg/kg/day with a target MOE of 100.

8. Incident Information

Relatively few incidents of illness have been reported due to trichlorfon based on the Incident Data System, Poison Control Center Data, or the California Pesticide Illness Surveillance Program. Because of uncertainty surrounding these limited data, those data were not factored into the risk assessment or risk mitigation decisions.

B. Environmental Risk Assessment

The scope of this review is limited to consideration of human health risks for trichlorfon as required by FQPA to complete the tolerance reassessment and reassessed the occupational risks based on new data. Ecological risks are not addressed in the TRED. However, the ecological assessment in the RED, which was issued in 1995, may be amended if warranted to account for new data or information that the Agency may receive or become aware of after this document has been issued.

IV. FQPA Tolerance Reassessment Progress & Interim Risk Management Decision

A. Tolerance Reassessment Progress & Interim Risk Management Decision

This document presents the Agency's assessment of the dietary and occupational risks of trichlorfon. Based on a review of generic data and public comments on the Agency's revised risk assessments for the active ingredient trichlorfon, the Agency has sufficient information on the human health effects of trichlorfon to make an interim decision as part of the tolerance reassessment process under FQPA.

Because the Agency has not yet completed its cumulative risk assessment for the OPs, this interim decision does not fully address tolerance reassessment as required by Section 408(q) of the FQPA; however, the Agency has completed its assessment of risk from dietary exposure to trichlorfon alone. When the cumulative assessment is considered, the FQPA tolerance reassessment requirement will be completed. Nothing in this report precludes the Agency from making further FQPA determinations and tolerance-related rulemaking that may be required on this pesticide or any other in the future. The Agency has also not considered risks associated with exposure to DDVP resulting from trichlorfon use. DDVP, although a trichlorfon degradate, is a registered OP pesticide that is currently undergoing reregistration. Once the DDVP IRED is complete, the Agency will determine whether the DDVP exposure resulting from trichlorfon use poses risk concerns. The Agency may determine that further action is necessary after assessing the cumulative risk of the organophosphate class. At that time, the Agency may also address any other risk concerns that may arise including risks associated with DDVP exposure.

Such an incremental approach to the tolerance reassessment process is consistent with the Agency's goal of improving the transparency of the implementation of FQPA. By evaluating each OP in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the OPs in as timely a manner as possible.

The Agency has determined that aggregate dietary risk from exposure to trichlorfon may exceed the Agency's level of concern for children 1-6 years when the source of drinking water is surface water. Therefore, mitigation measures are needed at this time to address this concern.

B. Phase 5 Comments

EPA released its revised risk assessment for trichlorfon to the public on April 25, 2000, and provided a 60-day comment period for interested parties to submit information, including risk mitigation suggestions or proposals. The public comment closed June 28, 2000. Chemical-specific comments were provided by the Golf Course Superintendents Association of America (GCSAA), and general comments by the Natural Resources Defense Council (NRDC).

GCSAA provided information on the benefits of trichlorfon in controlling pests on golf courses. Additionally, the GCSAA surveyed nearly 7,500 golf course superintendents to gather data on trichlorfon use. This information has been instrumental in helping the Agency understand exactly how trichlorfon is used in the golf course environment and provided a basis for refining use assumptions.

General comments concerning several OPs were received from the NRDC that were similar to those submitted regarding other OPs. The comments included remarks regarding the use of the FQPA 10x safety factor, aggregate exposure assessment and cumulative risk. EPA responses to these comments as well as the full text of the general comments document can be found in the public docket.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this individual OP. FQPA also requires the Agency to consider available information on cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the OPs through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of OPs once the methodology is developed. The tolerances to cover use on beef products into the U.S. remain in effect and unchanged until a full reassessment of the cumulative risk from all OPs is considered.

EPA has determined that risk from exposure to trichlorfon is within its own "risk cup." In other words, if trichlorfon did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the import tolerances for trichlorfon on beef and beef byproducts 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 chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, drinking water, and non-occupational uses (e.g., residential uses).

As noted in Chapter 3 of this TRED, the Agency's modeled acute surface water EEC exceeds the DWLOC by slightly more than a factor of two for the population subgroup, children 1-6 years old.

The modeled acute surface water EEC for trichlorfon is larger than the DWLOC and therefore trichlorfon does not appear to fit within its own "risk cup." However, the Agency does not believe the currently registered uses of trichlorfon actually pose an aggregate risk concern for the general population or any population subgroup for the following reasons and trichlorfon does fit within its own risk "cup." First, predicted trichlorfon concentrations for surface water are based on a moderately refined Tier I screening model. This level of analysis is intended to identify those situations where additional information, such as monitoring data, might be needed for risk assessment and/or risk mitigation purposes. In the case of trichlorfon, the Agency believes the assessment is conservative and the EECs sufficiently small, so as not to trigger monitoring or any other data requirement to address aggregate risks based on the current use pattern. Second, trichlorfon is not registered for use in the United States on any agricultural or other dietary commodity. There is a tolerance for beef intended to cover use on cattle outside the US. The Agency's dietary assessment conservatively assumes one, tolerance level residues for all imported beef, two that all imported beef has been treated with trichlorfon, and three, that 10% of consumed beef is imported. However, it is doubtful that the most highly exposed population subgroup, children 1- 6 years old, would consume solely imported beef consistent with the conservative assumptions in the risk assessment. Additionally, the predicted surface water drinking water concentrations are based on using trichlorfon on a golf course since the Agency does not have a model scenario to quantitatively predict drinking water exposure from the residential turf use. Even though the majority of trichlorfon use is on residential turf and runoff to surface water is likely, trichlorfon's short half-life together with the expectation that not every neighborhood lawn would be treated with trichlorfon on the same day together with the mitigation measures that will be implemented in accordance with this TRED are expected to adequately address potential surface water drinking water risks. Lastly, non-occupational and residential risks alone are not of concern for trichlorfon. Therefore, based on the conservative trichlorfon tolerance reassessment, the Agency does not believe aggregate risks are of concern nor is confirmatory data necessary based on the current limited use patterns.

b. Tolerance Summary

In this individual assessment, tolerances for residues of trichlorfon in/on livestock commodities are currently expressed in terms of residues of trichlorfon *per se* [40 CFR § 180.198]. These established tolerances may be reassessed upon the completion of the cumulative risk assessment of all OPs, and the additional data required to satisfy the metabolism in livestock guideline. The Agency is proposing the modifications to the existing tolerances shown in Table 12 but plans to defer modification of these tolerances pending the outcome of the cumulative assessment.

Table 12. Tolerance Summary for Trichlorfon

Commodity	Tolerance Listed Under 40 CFR § 180.198	Reassessed Tolerance[1]	Comment
Cattle, fat	0.1 (N)	0.5 ppm	The "(N)" designation (negligible residues) should be removed from all entries to conform to current Agency administrative practice.
Cattle, (mybp)	0.1 (N)	0.1 ppm	
Cattle, meat	0.1 (N)	0.2 ppm	

[1] The term "reassessed" here is not meant to imply that the tolerance has been reassessed as required by FFDCA as amended by FQPA, since tolerances may be reassessed only upon consideration of the cumulative risk assessment of all OPs, as required by this law. Rather, it provides a tolerance level for this single chemical.

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

3. Risk Mitigation

Summary

The Agency has determined most exposure scenarios for trichlorfon do not result in risks that are of concern. The ant mound and house perimeter uses have been voluntarily cancelled by the registrant to mitigate certain residential risk. Specific label changes are necessary in order for use on golf course turf and ornamentals and use in ornamental fish and bait ponds to be eligible for reregistration. Additionally workers will be required to use a dust/mist respirator when mixing and loading the soluble powder formulation to address inhalation exposure associated with handling large volumes of pesticide for groundboom and chemigation applications. Therefore, of the ten scenarios originally evaluated for trichlorfon, six did not raise risk concerns and are eligible for reregistration without any changes to the registration. Two uses have been voluntarily canceled to mitigate risk, and specific label changes are necessary for use on golf course turf (scenario 1) and use in ornamental fish and bait ponds (scenario 6) to be eligible for reregistration (see Table 10).

Ornamental Fish and Bait Pond Uses

Estimated MOEs did not exceed the target MOE of 100 for certain use rates for scenario 6 (mixing/loading/applying with a low pressure handwand for ornamental fish and bait pond uses). The worker MOEs range from 50 to120 when trichlorfon is applied by handwand sprayer depending on the application rate and size of the fish pond. Application of trichlorfon to small ponds at the lowest assessed application rate resulted in an MOE (120) that did not exceed the Agency's level of concern.

The Agency obtained detailed information from the California Aquaculture Association, the Missouri Aquaculture Association and the Arkansas Bait and Ornamental Pond Association to better characterize actual ornamental fish and bait pond use practices. These stakeholders indicated that for large ponds, trichlorfon is applied, in virtually all cases, by a truck drawn sprayer rig rather than with handheld equipment. Although the Agency does not have data specific to this use, PHED does contain data for enclosed cabs versus open cabs which have shown a significant decrease in the exposure and risks to applicators in such instances. Therefore, the Agency believes dermal and inhalation risks can be mitigated if the mixer/loader/applicator uses a truck drawn spray rig with a switch that is operated from inside the vehicle. A pair of chemical resistant gloves must be available in the truck for use in the event of an equipment problem.

With respect to small ponds, the Agency assessed the combined risks (dermal and inhalation) for a 2.5 acre, 3-foot deep pond with an application rate of 0.64 lb ai/acre foot assuming workers wear gloves and a double layer of clothing and using a low pressure handwand sprayer. Based on these assumptions, the MOE is 120, which is below the Agency's level of concern. Use at the maximum labeled application rate of 1.4 lb ai/acre for the same size pond (2.5 acres surface area by 3 feet deep) resulted in a MOE of 53 which exceeds the Agency's level of concern.

As a general rule, the Agency does not believe limitations on "acres treated" represents a preferred risk mitigation practice. However, given the unique nature of the ornamental fish and bait pond industry combined with the limited scope of the Section 24(c) labels, and the well defined pond areas, such an approach in this instance represents a sound, enforceable measure. Therefore, the Agency intends to allow use of hand-held equipment only for ponds with one acre of surface area and a maximum depth of three feet.

The combined MOE (51) for scenario 1, mixing/loading soluble powder for groundboom and chemigation to golf course turf and ornamental lawns exceeds the Agency's level of concern. However, the registrant has agreed to modify the golf course use pattern to address drinking water exposure. As discussed below, this modification will also result in a significant reduction in the amount of trichlorfon that can be applied to a golf course. Therefore, mixer/loader risks would not be of concern to the Agency.

To assess surface water vulnerability, the GENEEC model was run using the standard input parameters which include application rate, application interval, persistence, solubility, mobility, etc. Then, a series of refinements were applied to the EECs. These refinements included incorporating an 87% crop

area factor (default PCA) as well as the percentage of the golf course that actually receives pesticide treatment., bringing the resulting PCA factor down to 17%. It was assumed that tees and greens comprise 2.8% (5 acres) of the acreage of a golf course. When fairways are included, an additional 16.7% (30 acres) of the golf course is treated. In order to address concerns of runoff to surface water, the registrant has agreed to limit broadcast/chemigation use on golf courses to tees and greens and allow spot treatment of fairways only. The registrant has also agreed to establish a 7-day application interval and to limit application to three times per calendar year. These changes to the trichlorfon label will effectively mitigate occupational risk for groundboom and chemigation use on golf course turf and address surface water concerns. Below is a summary of risk mitigation measures for trichlorfon.

a. Ornamental Fish and Bait Pond

- Prohibit use of hand-held equipment for all ponds greater than one acre, three feet deep.
- Application to any pond equal to or greater than 1 acre, 3 feet deep must be done using a truck drawn sprayer rig where the spray is activated by a switch in the cab. A pair of chemical resistant gloves must be available in the truck.
- Handlers mixing/loading/applying to small ponds must wear double layer of clothing, gloves and a respirator.

b. Turf Uses: Occupational and Aggregate

For the golf course use:

- Limit applications to three per calendar year with 7-day retreatment interval. Broadcast/chemigation use is limited to tees and greens; use on fairways is limited to spot treatment.

c. Ornamentals: Re-entry Worker Risks

- Prohibit ornamental foliar use; allow only direct soil application at base of the plant.

d. Residential Use

- Voluntary cancellation of home perimeter and ant mound uses.

e. Summary of Worker Risks and Label Impacts

This TRED incorporates new information regarding the occupational and residential risks that resulted in some modifications to the original 1995 RED requirements. Also, the registrant requested voluntarily cancellation of the ant mound and house perimeter uses. Therefore, the requirements listed in the 1995 RED for these uses are no longer applicable. Table 13 summarizes changes to the 1995 RED resulting from this TRED. The list summarizes the original decision and any modifications that resulted from this assessment, as well as new requirements.

Table 13. Impact of 2001 TRED Decisions on the 1995 RED

Scenario	TRED Label Amendments	RED Label Amendment Decisions (1995)
Occupational: 1) Formulations: a) Soluble powder for groundboom and chemigation.	Recommends same PPE, but adds dust/mist respirator.	Long-sleeved shirt and long pants, socks and shoes, chemical resistant gloves.
b) Granular push-type spreader	Long-sleeved shirt and long , shoes and socks.[1]	Coveralls over long-sleeve shirt and long pants, chemical resistant gloves and chemical resistant footwear.[2]
Post-Application: 1)Worker Protection Standard. a)Ornamentals	Prohibit foliar application; only soil application.	Foliar application.
i) Reentry Intervals	12-hour REI.	24- hour REI.
ii) Early Entry.	Do not allow people or pets to come into contact with anything that has been treated.	Coveralls over long-sleeve shirt and long pants, chemical resistant gloves, shoes plus socks.
2) Non-Worker Protection Standards. a) Golf Courses i) Early Entry	Same restrictions as RED.	Liquid- Do not allow people or pets to enter until dry. Granular - Watering in required. Do not allow people or pets to enter (except people watering) and surface is dry.
Ornamental Ponds 1) Greater than 1 acre, 3 feet deep.	Use truck-drawn spray with operating switch inside rig. Chemical resistant gloves available inside truck.	Not considered. Special Local Need issued after 1995 RED.
2) Less than1 acre, 3 feet deep.	Handwand sprayer may be used. Long sleeve shirt and long pants, gloves, and shoes and socks.	Not considered. Special Local Need issued after 1995 RED.
Golf Course Treatment	Broadcast treatment permitted on tees and greens only. Only spot treatment to fairways is permitted.	Broadcast treatment allowed for entire golf course.

1 Agency considered new data and assumed 0.5 acre rather than 1.0 acre in original RED based on new information.
2 No push type spreader data is available.

4. Regulatory Rationale

Trichlorfon has three tolerances on beef and beef byproducts, which were used in the dietary risk assessment. The assessment for exposure from food alone is not of concern to the Agency. The acute dietary exposure for the general US population from food was estimated be 11% of the aPAD (17.6% of the PAD for the most highly exposed subgroup, children 1-6 years) and the chronic dietary exposure for the same population was estimated to be 12% of the cPAD (25% of the cPAD for children 1-6 years). Based on analyses of both acute and chronic dietary risk, the dietary risk estimates are below the Agency's level of concern when the source of drinking water is ground water, therefore, no mitigation measures are necessary for dietary risk. However, when the source of drinking water is surface water, there appears to be an aggregate risk concern for acute dietary risk to children 1-6 years.

The Agency believes the modeled estimates for exposure to trichlorfon residues in surface water sources of drinking water, which exceed the DWLOC by about two-fold, overestimate the dietary risk for several reasons. One, the exposure model used to generate the EEC values for surface water is a screening tool and is not well suited for estimating an EEC for a pesticide applied to turf. Two, the environmental fate properties for trichlorfon indicate that parent trichlorfon residues in surface waters are unlikely to reach consumers because of the rapid aerobic dissipation in the environment. Three, the GENEEC modeling is based on golf course use; however, most trichlorfon use is in the residential setting (78%) while only 18% is used on golf courses. Residential use is likely to be random, varying from residence-to-residence, but will likely cover less acres in a single day than the golf course use. Lastly, the target MOE is 1000, providing an additional safety factor for children which when combined with the conservatism in the modeled surface water and dietary assessments, provides high confidence that aggregate risks are not of concern nor is confirmatory data required.

The ornamental post-application worker risk is a concern to the Agency for the current application method. However, on December 20, 2000, the Bayer Corporation informed the Agency that they will revise the use pattern for its soluble powder products and prohibit foliar application. Only direct application to soil will be allowed for ornamentals. Prohibiting foliar application significantly impacts previous MOE estimates and restricted entry intervals (REBS). Although the Agency has not recalculated the MOEs, direct soil application to ornamentals is expected to effectively mitigate risk concerns. A statement must be placed on the label prohibiting foliar application and allowing only direct soil application at the base of the plant enabling the Agency to require a 12 hour REI.

The baseline inhalation MOE is 55 for treating livestock areas which is of concern. An MOE of 270 is attainable when considering the use of PPE (respirator). However, the Agency is in the process of revising its current inhalation exposure policy to reflect internationally accepted practices which would include matching the breathing rate to the handler's level of activity. If a breathing rate consistent with this policy where applied to the livestock use risk assessment, the MOE is expected to increase at least two-fold. Therefore, the Agency does not believe the risks during treatment of livestock areas will exceed the Agency's level of concern and risk mitigation is not warranted at this time.

For mixer/loaders handling soluble powder for groundboom and chemigation application, as mentioned earlier, the Agency expects the changes to the use practice for golf course turf will mitigate worker risk concerns. Limiting the broadcast treatment to tees and greens is expected to reduce the amount of trichlorfon handled. Again mitigation measures presented in this TRED address exposures and risk associated with use of trichlorfon alone. If it is determined that DDVP resulting from trichlorfon use presents potential risk concerns, the Agency will reconsider all applicable decisions.

5. Codex Harmonization

There are no Codex Maximum Residue Levels for residues of trichlorfon. Therefore, harmonization is not an issue at this time.

6. Spray Drift Management

Spray Drift Management

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

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

Registrants may elect to adopt the appropriate specified language in Chapter V or a version that is equally protective.

V. What Manufacturers Must Do

This section specifies the data requirements, responses and labeling changes necessary for the reregistration of trichlorfon manufacturing products. The label table includes requirements based on this TRED and incorporates amendments to requirements in the 1995 RED as appropriate.

A. Additional Data Requirements

The trichlorfon registrant has committed to conduct a developmental neurotoxicity study in rats in response to a data call-in notice issued to all registrants of OPs. The Agency is discussing the protocol for the conduct of the study. The following data gap exists; the Agency is issuing a DCI for this requirement.

Data Requirements:

Product chemistry:

98% T (EPA Reg.# 3125-9) - 830.7050 UV/Visible Absorption

1. Labeling Requirements for Manufacturing Use Products

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

All registrants must submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all required label amendments outlined in Table 13 of this document incorporated, and a description on the application, such as, "Responding to Report on Tolerance Progress and interim Management Decision" document. All amended labels must be submitted within 90 days of signature of this document. The Registration Division contact for trichlorfon is Akiva Abramovitch. His phone number is (703) 308-8328. Amended labels must be mailed to the Document Processing Desk, Office of Pesticide Program (7504C), U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington DC 20460-0001, Attn: Akiva Abramovitch.

2. End-Use Products

Additional Generic Data Requirements

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

study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining specific data requirements, accompanies this decision.

3. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this TRED. Persons other than the registrant may generally distribute or sell such products for 24 months from the date of the issuance of this TRED. 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.

B. Risk Mitigation Requirements

As discussed in this document, the Agency is concerned about several potential risks and is recommending risk management measures (see table below). The Agency may need to pursue further risk management measures for trichlorfon once the cumulative and DDVP assessments are finished.

C. Labeling Summary Table

See Table 13 below for the summary of label changes for trichlorfon.

Table 13: Summary of Labeling Changes for Trichlorfon		
Description	**Amended Labeling Language**	**Placement on Label**
	Manufacturing Use Products	
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"Only for formulation into an insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]." "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)."	Directions for Use
The use on Ant Mounds and home perimeters is not being supported by the registrant.	"Not for formulation into products labeled for ant mound and house perimeter use."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies .	**"Environmental Hazards"** "This chemical is toxic to aquatic species. 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 the 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 Statement Under Environmental Hazards.

Description	Amended Labeling Language	Placement on Label
	Occupational Uses (WPS and non-WPS)	
PPE Requirements Established by the tolerance reassessment progress report for soluble powder formulations and based on the a.i.[1]	"Personal Protective Equipment" (PPE) "Some materials that are chemical-resistant to this product are [registrant inserts correct material]. If you want more options, follow the instructions for category [registrant insert A, B, C, D, E, F, G, or H] on an EPA chemical-resistant category selection chart." "Mixers, loaders, applicators, and other handlers must wear: Long-sleeved shirt and long pants, shoes plus socks." In addition to the above, all mixers and loaders plus applicators using handheld equipment must wear chemical-resistant gloves. Applicators using handwand sprayers to treat ornamental fish and bait ponds must wear a respirator equipped with any N, R, or P series filter. In additional to the above, all mixers and loaders supporting groundboom and chemigation applications to golf courses and ornamental lawns must wear a non-powered air purifying respirator with any N, R, P, or HE filter."	Precautionary Statements: Immediately following the Hazards to Humans and Domestic Animals The respirator statement that applies to application to ornamental fish and bait ponds must be placed on the SLN label.
PPE Requirements Established by the tolerance reassessment progress report for granular formulations and based on the a.i.[1]	"Personal Protective Equipment" (PPE) "Some materials that are chemical-resistant to this product are [registrant inserts correct material]. If you want more options, follow the instructions for category [registrant insert A, B, C, D, E, F, G, or H] on an EPA chemical-resistant category selection chart." Mixers, loaders, applicators, and other handlers must wear: Long-sleeved shirt and long pants, shoes plus socks	Precautionary Statements: Immediately following the 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."	Precautionary Statements immediately following the PPE.

Description	Amended Labeling Language	Placement on Label
Engineering Controls for Water Soluble Powder Formulations	"Engineering Controls" "When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."	Precautionary Statements immediately following the User Safety Requirements.
Engineering Controls for 24(c) Label for ornamental fish and bait ponds	Engineering Controls: Applicators applying to ornamental ponds that are greater than 1 acre must use a truck-drawn spray rig equipped with an on/off operating switch located inside the truck cab.	Must appear on the SLN 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 immediately following the User Safety Requirements (Must be placed in a box..)
Environmental Hazards	For terrestrial uses, do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of waste."	Precautionary Statements immediately
Restricted-Entry Interval for products subject to WPS as required by Supplement Three PR Notice 93-7.	"Do not enter or allow others to enter the treated area until sprays have dried. worker entry into treated areas during the restricted entry interval (REI) of 12 hours." "Exception: if the product is applied by direct spray to base of plant, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated areas without restriction if there will be no contact with anything that has been treated."	Directions for Use
Entry Restrictions for Water Soluble formulations with non WPS occupational uses.	Do not enter or allow others to enter the treated area until sprays have dried.	Directions for Use

Description	Amended Labeling Language	Placement on Label
Entry Restrictions for Granular Formulations (non WPS occupational uses).	Do not enter or allow others to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete. If the incorporation is accomplished by watering-in, do not enter or allow others to enter the treated area until the surface is dry after the watering-in."	Directions for Use.
Early Entry Personal Protective Equipment for products subject to WPS as required by Supplement Three of PR Notice 93-7.	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is - coveralls - chemical resistant gloves made out of any waterproof material - socks and shoes	Directions for Use, in the Agricultural Use Box.
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions for all formulations	Got application to ornamental plants, foliar use is prohibited; allow only direct soil application at base of the plant. - For applications to turf, limit applications to 3 per calendar year with 7-day retreatment interval. - Broadcast/chemigation use on turf is limited to tees and greens; use on fairways is limited to spot treatment. - Limit applications to 24.51 lbs ai/A per year for grubs and mole crickets and 16.2 lbs ai/A per year for surface feeding insects.	Place in the Direction for Use in General Precautions and Restrictions section.
Other Application Restrictions for Granular Formulations Only.	Instructions for incorporation by watering in must be included in the directions for use.	Directions for Use.

Description	Amended Labeling Language	Placement on Label
Spray Drift Language	The following spray drift language, or equivalent language proposed by the registrant must be placed on the label. "Do not allow spray (or dust) to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreation areas, nontarget crops, aquatic and wetland areas, woodlands, pastures, rangelands, or animals." "For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use____(registrant to fill in blank with spray quality, e.g. fine or medium) or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles." "For overhead chemigation, apply only when wind speed is 10 mph or less." "The applicator also must use all other measures necessary to control drift."	Directions for Use
End Use Products Intended for Occupational Use (Non-WPS)		
Removal of Ant Hill and house perimeter Site	All references to use on Ant Hills and house perimeter must be removed from label as these uses are no longer supported	Directions for Use.

[1] PPE that is established on the basis of the 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 TRED for Trichorfon is supported by documents that are presently maintained in the OPP public 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 holidays from 8:30 to 4:00 pm.. All documents in hard copy form, may be viewed in the OPP docket room or viewed or downloaded or viewed via the Internet (**http://www.epa.gov/opppsrrd1/op/**).

The following documents are included in the public docket:

Revised HED Assessment;
Residential Post-application Exposure and Risks;
Revised Residential Handler's and Post-application Ornamental Uses;
Review of Determination of Transferable Turf Residues on Turf Treated with Trichlorfon;
Reassessment of the Use of ORETF Granular Push-Type Spreader Studies (LCO and Homeowner);
Refined Tier I Surface Water EECs;
Revised Drinking Water Levels of Concern and Aggregate Risk Assessment.

Appendix A: Trichlorfon (Case 0104): 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
Lawns/recreational turf (golf courses)				
Foliar Groundboom and chemigation	soluble powder granular 3125-9, 3125-184,3125-371,3125-449, 3125-507	8.2 lb ai/acre	3 times per calendar year	Spot treatment for fairways; broadcast treatment only to tees and greens. 7-day application interval. Curative treatment for white grubs and mole crickets.
Ornamentals				
Handwand sprayer	granular 3125-184; 3125-449	0.015 lb ai/gallon	NS	Apply to base of plant. 12 hour REI.
Commercial Ponds/Aquatic tank				
Foliar Handwand sprayer; truck-pulled spray rig.	AR98-003 CA98-0014 MO99-0005 (3125-184)	1.4 lb ai/acre foot	NS	Two or three applications per week may be necessary for trichlorfon treatment for commercial ponds according to special needs labels
Residential				
Spreader	Ready-to-Use Granules 3125-507	8.2 lb ai/acre	Apply when grubs are present	None

Appendix B: Data Supporting Guideline Requirements For Reregistration

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #0104, trichlorfon, covered by this TRED. It contains generic data requirements that apply to trichlorfon 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.

PRODUCT CHEMISTRY

New Guideline Number	Old Guideline Number	Study	Use Pattern	Citation
830.1550	61-1	Product Identity and Composition	All	00158290, 42835204
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	42835204
830.1670	61-2B	Formation of Impurities	All	42835204
830.1750	62-2	Certification of limits	All	00158290, 42835205
830.1800	62-3	Analytical Method	All	42835205
830.6302	63-2	Color	All	02835206
830.6303	63-3	Physical State	All	42835206
830.6304	63-4	Odor	All	42835206
830.7300	63-7	Density	All	42835206
830.7370	63-10	Dissociation Constant	All	42835206
830.7000	63-12	pH	All	42835206
830.6314	63-14	Oxidizing/Reducing Action	All	42835206
830.6316	63-16	Explodability	All	42835206
830.6317	63-17	Storage Stability	All	43139501
830.6320	63-20	Corrosion characteristics	All	43139501

TOXICOLOGY

870.1100	81-1	Acute Oral Toxicity-Rat	All	00152135, 00256446
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	All	00090786, 40306901
870.1300	81-3	Acute Inhalation Toxicity-Rat	All	00256446
870.2400	81-4	Primary Eye Irritation-Rabbit	All	41571302, 44471301
870.2500	81-5	Primary Skin Irritation	All	40306901
870.2600	81-6	Dermal Sensitization	All	00257599
870.3150	82-1	Subchronic Toxicity-Dog	All	HED #1668 & 1669
870.3200	82-2	21-Day Dermal Toxicity	All	00403069
870.3465	82-4	90-day Inhalation - Rat	All	00256446
870.3700	83-3	Prenatal developmental toxicity - Rat	All	40255601
870.3700	83-3	Prenatal developmental toxicity - Rabbit	All	41565201
870.3800	83-4	2-Generation Reproduction - Rat	All	42228301
870.4100	83-1	Chronic Toxicity	All	00090786
870.4200	83-2	Carcinogenicity - Mouse	All	40782401, 40844301
870.4300	83-5	Combined Chronic toxicity/carcinogenicity - Rat	All	41056201 41973001
870.5300	84-2	in vitro cytogenic study in mammalian cells	All	00022865

870.5550	84-2	Salmonella typhimurium gene mutation	All	00249535, 00256446, 00028625
870.5500	84-2	Bacterial DNA damage/repair	All	00256446
870.5575	84-2	Sacharomyces cerevisae gene mutation	All	00256446
870.5900	84-2	Sister chromatid exchange - Chinese hamster	All	40277201, 00028625
870.6100	81-7 82-5	Acute and 28-day delayed neurotoxicity	All	00152136, 00256446, 40351201, 40879301
870.6200	81-8	Neurotoxicity screening battery	All	44578001, 43871701
870.7485	85-1	Metabolism - Rat	All	40438101
Residue Chemistry				
860.1300	171-4(b)	Nature of Residue - livestock	All	44500701, 44500702
860.1340	171-4(d)	Residue Analytical Method - animals	All	44500704
860.1380	171-4(e)	Storage stability	All	44781401
860.1480	171-4(j)	Magnitude of Residue - Meat, Eggs, Poultry	All	44500703
Occupational and Residential Exposure				
875.2100	132-1	Transferable Turf Residues	All	45067201

Appendix C: Technical Support Documents

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

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

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

www.epa.gov/pesticides/op

Appendix D: Bibliography

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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00152135	Crawford, C.; Anderson, R (1973) the Acute Oral and Intraperitoneal Toxicity of five Trichlorfon Technical Samples of Rats: Report No. 37204. Unpublished study prepared by Mobay Chemical Corp. 7 p. (also numbered as 00256446).
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41056201	Hayes, R. (1989) Chronic Toxicity/Oncogenicity Study of Technical Grade Trichlorfon (Dylox) with Rats Study No. 86-271-02 Unpublished study prepared by Mobay Corp. 2893 p.
41535301	Sewekow. (1988) Vapor Pressure of Trichlorfon Pure Active Ingregdient: Lab Project Number: 100 128: 87267. Unpublished study prepared by Mobay Corp. 11 p.
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44308001	Manley, A. (1997) Metrifonate (MTF)/Dichlorvos (DDVP): Position Document on Long Term Administration in Humans: Lab Project Number: AM/001. Unpublished study prepared by Amvac Chemical Corp. 146 p.
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Appendix E: Generic Data Call-In

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

DRAFT COPY

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 0104 Trichlorfon Chemical # and Name 057901 Trichlorfon	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

DRAFT COPY

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. Company name and Address

2. Case # and Name
0104 Trichlorfon
Chemical # and Name 057901
Trichlorfon

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
830.7050	U/V Visible Absorption					CEFGIK		12 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

Appendix F: List Of Registrants Sent this Data Call-In

List of All Registrants Sent This Data Call-In Notice

Case # and Name
0104 Trichlorfon
Chemical # and Name
057901 Dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphona

Company Number	Company Name	Additional Name	Address	City & State	Zip
003125	BAYER CORP	AGRICULTURE DIVISION	8400 HAWTHORN RD BOX 4913	KANSAS CITY MO	64120
008660	PURSELL INDUSTRIES, INC.		BOX 540	SYLACAUGA AL	35150
009198	THE ANDERSONS LAWN FERTILIZER DIVI	DBA/ FREE FLOW FERTILIZER	BOX 119	MAUMEE OH	43537
019713	DREXEL CHEMICAL CO		1700 CHANNEL AVENUE BOX 13327	MEMPHIS TN	38113
032802	HOWARD JOHNSON'S ENTERPRISES INC		700 W. VIRGINIA ST STE 222	MILWAUKEE WI	53204
071649	ARKANSAS BAIT AND ORNANMENTAL FISH		1131 BROWNSVILL LOOP	LONOKE AR	72086
071857	CALIFORNIA AQUACULTURE ASSOCIATION		P.O. BOX 1004	NILAND CA	92257