# US Environmental Protection Agency
# Office of Pesticide Programs

# Reregistration Eligibility Decision for Chlorethoxyfos

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

Combined PDF document consists of the following:

- Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides (July 31, 2006)

- Chlorethoxyfos TRED

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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

# MEMORANDUM

**DATE:** July 31, 2006

**SUBJECT:** Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides

**FROM:** Debra Edwards, Director
Special Review and Reregistration Division
Office of Pesticide Programs

**TO:** Jim Jones, Director
Office of Pesticide Programs

As you know, EPA has completed its assessment of the cumulative risks from the organophosphate (OP) class of pesticides as required by the Food Quality Protection Act of 1996. In addition, the individual OPs have also been subject to review through the individual-chemical review process. The Agency's review of individual OPs has resulted in the issuance of Interim Reregistration Eligibility Decisions (IREDs) for 22 OPs, interim Tolerance Reassessment and Risk Management Decisions (TREDs) for 8 OPs, and a Reregistration Eligibility Decision (RED) for one OP, malathion.[1] These 31 OPs are listed in Appendix A.

EPA has concluded, after completing its assessment of the cumulative risks associated with exposures to all of the OPs, that:

(1) the pesticides covered by the IREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) are indeed eligible for reregistration; and

[1] Malathion is included in the OP cumulative assessment. However, the Agency has issued a RED for malathion, rather than an IRED, because the decision was signed on the same day as the completion of the OP cumulative assessment.

(2) the pesticide tolerances covered by the IREDs and TREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) meet the safety standard under Section 408(b)(2) of the FFDCA.

Thus, with regard to the OPs, EPA has fulfilled its obligations as to FFDCA tolerance reassessment and FIFRA reregistration, other than product-specific reregistration.

The Special Review and Reregistration Division will be issuing data call-in notices for confirmatory data on two OPs, methidathion and phorate, for the reasons described in detail in the OP cumulative assessment. The specific studies that will be required are:

- 28-day repeated-dose toxicity study with methidathion oxon; and
- Drinking water monitoring study for phorate, phorate sulfoxide, and phorate sulfone in both source water (at the intake) and treated water for five community water systems in Palm Beach County, Florida and two near Lake Okechobee, Florida.

The cumulative risk assessment and supporting documents are available on the Agency's website at www.epa.gov/pesticides/cumulative and in the docket (EPA-HQ-OPP-2006-0618).

**Attachment A:**

Organophosphates included in the OP Cumulative Assessment

| Chemical | Decision Document | Status |
|---|---|---|
| Acephate | IRED | IRED completed 9/2001 |
| Azinphos-methyl (AZM) | IRED | IRED completed 10/2001 |
| Bensulide | IRED | IRED completed 9/2000 |
| Cadusafos | TRED | TRED completed 9/2000 |
| Chlorethoxyphos | TRED | TRED completed 9/2000 |
| Chlorpyrifos | IRED | IRED completed 9/2001 |
| Coumaphos | TRED | TRED completed 2/2000 |
| DDVP (Dichlorvos) | IRED | IRED completed 6/2006 |
| Diazinon | IRED | IRED completed 7/2002 |
| Dicrotophos | IRED | IRED completed 4/2002 |
| Dimethoate | IRED | IRED completed 6/2006 |
| Disulfoton | IRED | IRED completed 3/2002 |
| Ethoprop | IRED | IRED completed 9/2001<br>IRED addendum completed 2/2006 |
| Fenitrothion | TRED | TRED completed 10/2000 |
| Malathion | RED | RED completed 8/2006 |
| Methamidophos | IRED | IRED completed 4/2002 |
| Methidathion | IRED | IRED completed 4/2002 |
| Methyl Parathion | IRED | IRED completed 5/2003 |
| Naled | IRED | IRED completed 1/2002 |
| Oxydemeton-methyl | IRED | IRED completed 8/2002 |
| Phorate | IRED | IRED completed 3/2001 |
| Phosalone | TRED | TRED completed 1/2001 |
| Phosmet | IRED | IRED completed 10/2001 |
| Phostebupirim | TRED | TRED completed 12/2000 |
| Pirimiphos-methyl | IRED | IRED completed 6/2001 |
| Profenofos | IRED | IRED completed 9/2000 |
| Propetamphos | IRED | IRED completed 12/2000 |
| Terbufos | IRED | IRED completed 9/2001 |
| Tetrachlorvinphos | TRED | TRED completed 12/2002 |
| Tribufos | IRED | IRED completed 12/2000 |
| Trichlorfon | TRED | TRED completed 9/2001 |

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-00-003
June 2000

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

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency has completed its review of the available data and public comments related to the revised human health risk assessment for the organophosphate pesticide chlorethoxyfos. The attached document entitled, "Report on FQPA Tolerance Reassessment and Interim Risk Management Decision for Chlorethoxyfos" summarizes the Agency's assessment of the dietary and occupational risk from chlorethoxyfos. Based on its review, EPA has identified risk mitigation measures believed necessary to address the human health risks associated with the current use of chlorethoxyfos. These risk mitigation measures can be found in the attached document.

The major means by which the Agency reassesses tolerances is through its reregistration process. Each pesticide registered prior to 1984 is subject to a comprehensive evaluation of its effects on human health and the environment. Such an evaluation includes a determination of whether the tolerances are safe. Since chlorethoxyfos was registered after 1984, it is not subject to reregistration. However, chlorethoxyfos tolerances are subject to reassessment in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (FQPA). FQPA requires EPA to re-evaluate existing tolerances to ensure that children and other sensitive subpopulations are protected from pesticide risk.

At the time chlorethoxyfos was registered, it was granted a conditional registration contingent on the submission of dermal and inhalation toxicity studies and handler exposure studies. The Agency decided, in addition to reassessing chlorethoxyfos tolerances, to conduct an occupational risk assessment incorporating the results of the data submitted as a condition of registration. These data have been reviewed and considered in the updated occupational risk assessment.

The Agency has not conducted a new risk assessment for the effects of chlorethoxyfos on

non-target species (e.g., fish and birds) since it believes that the conclusions reached at the time of the initial decision to register chlorethoxyfos in 1995 remain unchanged.

The "Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for chlorethoxyfos" is based on the revised human health assessment, updated technical information, and public comments received by the Agency, all of which are available in the chlorethoxyfos public docket. The docket includes both the preliminary and revised risk assessment for chlorethoxyfos as well as comments on the risk assessments submitted by the general public and stakeholders. The Agency did not receive comments on the revised risk assessment or risk mitigation proposals during the Phase 5 Risk Management comment period which ended October 18, 1999. The risk assessment and the 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/.

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

Please note that the chlorethoxyfos risk assessment concerns only this particular organophosphate. It does not address the cumulative effects of other organophosphates as a class. Because FQPA directs the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with cholinesterase, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after completing risk assessments for individual organophosphates. While working to complete a methodology to assess cumulative risk, the Agency has decided to move forward with individual assessments and identify mitigation measures which the Agency believes are necessary. The Agency will issue its final decision on chlorethoxyfos when the cumulative assessment for all organophosphates has been completed.

End-use product labels must be revised by the manufacturer to adopt the changes set forth in Section IV of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in section V of this document.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Deanna Scher at (703) 308-7043.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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## CHLORETHOXYFOS TEAM

**Office of Pesticide Programs:**

Health Effects Risk Assessment

| | |
|---|---|
| Gary Bangs | Reregistration Branch III |
| Steven Knizner | Reregistration Branch III |
| Jess Rowland | Reregistration Branch III |

Environmental Fate (Drinking Water) Risk Assessment

| | |
|---|---|
| Robert Matzner | Fate and Monitoring Branch |

Risk Management

| | |
|---|---|
| Deanna Scher | Reregistration Branch I |
| Stephanie Willett | Reregistration Branch I |

# GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| ADI | Acceptable Daily Intake. A now defunct term for reference dose (RfD). |
| AE | Acid Equivalent |
| a.i. | Active Ingredient |
| aPAD | Acute Population Adjusted Dose |
| ARC | Anticipated Residue Contribution |
| CAS | Chemical Abstracts Service |
| ChE | Cholinesterase |
| CI | Cation |
| CNS | Central Nervous System |
| cPAD | Chronic Popoulation Adjusted Dose |
| CSF | Confidential Statement of Formula |
| 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, non carcinogenic health effects are not anticipated to occur. |
| 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 |
| FDA | Food and Drug Administration |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FQPA | Food Quality Protection Act |
| FOB | Functional Observation Battery |
| GLC | Gas Liquid Chromatography |
| 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. |
| HDT | Highest Dose Tested |
| $LC_{50}$ | 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. |
| $LD_{lo}$ | Lethal Dose-low. Lowest Dose at which lethality occurs. |
| LEL | Lowest Effect Level |
| LOC | Level of Concern |
| LOD | Limit of Detection |
| LOEL | Lowest Observed Effect Level |
| 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. |
| µg/g | Micrograms Per Gram |
| $\mu$g/L | Micrograms per liter |
| 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. |
| N/A | Not Applicable |
| NOEC | No Observable Effect Concentration |
| NPDES | National Pollutant Discharge Elimination System |
| NOEL | No Observed Effect Level |
| NOAEL | No Observed Adverse Effect Level |
| OP | Organophosphate |
| OPP | Office of Pesticide Programs |
| Pa | pascal, the pressure exerted by a force of one newton acting on an area of one square meter. |
| PADI | Provisional Acceptable Daily Intake |
| PAG | Pesticide Assessment Guideline |
| PAM | Pesticide Analytical Method |
| PHED | Pesticide Handler's Exposure Data |
| PHI | Preharvest Interval |
| ppb | Parts Per Billion |
| PPE | Personal Protective Equipment |
| ppm | Parts Per Million |
| PRN | Pesticide Registration Notice |
| $Q^*_1$ | The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model |
| RBC | Red Blood Cell |
| RED | Reregistration Eligibility Decision |
| REI | Restricted Entry Interval |
| RfD | Reference Dose |
| RS | Registration Standard |
| RUP | Restricted Use Pesticide |
| SLN | Special Local Need (Registrations Under Section 24(c) of FIFRA) |
| TC | Toxic Concentration. The concentration at which a substance produces a toxic effect. |
| TD | Toxic Dose. The dose at which a substance produces a toxic effect. |
| TEP | Typical End-Use Product |
| TGAI | Technical Grade Active Ingredient |
| TLC | Thin Layer Chromatography |
| TMRC | Theoretical Maximum Residue Contribution |
| torr | A unit of pressure needed to support a column of mercury 1 mm high under standard conditions. |
| WP | Wettable Powder |
| WPS | Worker Protection Standard |

## Executive Summary

EPA has completed its review of available data and public comments, revised the preliminary human health assessment, and developed the risk management measures set forth in this report. The Agency invited stakeholders to provide proposals and suggestions on appropriate mitigation measures before issuing its risk management decision on chlorethoxyfos, however, no risk mitigation proposals were received. This "Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision" will not be considered final until the cumulative risk assessment of all organophosphate pesticides is complete. The cumulative assessment may result in further risk mitigation measures for chlorethoxyfos.

Chlorethoxyfos is a restricted use, organophosphate insecticide registered for use on field corn, seed corn, sweet corn, and popcorn for the control of corn rootworms, wireworms, cutworms, seed corn maggots, white grubs and symphylans. It was first registered in the United States in 1995 and is formulated into 2.5% and 5% granular end-use products (Fortress® 2.5G and 5G). Use is limited to one application per year at planting, at a maximum rate of 0.1625 lb ai/acre. Annual domestic usage of chlorethoxyfos is estimated to range from 8,500 to 17,800 pounds active ingredient for approximately 37,000 to 122,000 acres treated. Approximately 1% of all corn acreage is treated.

### Overall Risk Summary

EPA's dietary (food) risk assessment for chlorethoxyfos indicates that neither the acute or chronic risks exceed the Agency's level of concern, i.e., less than 100% of the acute or chronic PAD is utilized for the general U.S. population and all population subgroups, including infants and children at the 99.9th percentile of exposure.

Acute and chronic dietary risks from drinking water are also below the Agency's level of concern. Surface water and ground water estimated environmental concentrations (EECs) do not exceed the Agency's drinking water levels of comparison (DWLOC) for acute and chronic aggregate dietary exposure. Aggregate risk, based on food and water exposure, does not exceed the Agency's level of concern, therefore, no risk mitigation based on dietary risk estimates is necessary at this time.

The Agency has determined that there is potential exposure to handlers for use-patterns associated with chlorethoxyfos. Occupational handler risk estimates are based on chemical-specific dermal and inhalation exposure studies. The risks in all exposure scenarios do not exceed the Agency's level of concern when the appropriate PPE and engineering controls are utilized during the loading and application processes.

EPA did not quantitatively assess the risks to post application workers. Minimal post-application exposure is anticipated since chlorethoxyfos is typically incorporated into the soil, is applied at planting, is not systemic in the plant and degrades readily.

The Agency is requiring the following label changes which are intended to mitigate potential occupational risk and/or better characterize risk from occupational exposure to chlorethoxyfos products:

- Labels must state that in addition to the PPE which loaders of the Fortress® 5G in the SmartBox™ must wear (long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves), loaders must also have immediately available for use in case of an emergency: a respirator with an organic-vapor removing cartridge or canister, a chemical-resistant apron, and chemical-resistant footwear.
- "Other handlers" must be specified on labels and must wear long-sleeved shirts, long pants, shoes plus socks and chemical-resistant gloves.
- A "double notification" statement must be added to end-use labels. Double notification requires that workers be advised about the application both orally and by posting warning signs at entrances to treated areas during the REI.
- The PPE requirement for loaders of Fortress® 2.5G (coveralls over a long-sleeved shirt and long pants) must be reduced to a long-sleeved shirt and long pants.
- The use of eye protection while loading Fortress products is not required by the WPS based on current toxicity values for the products. Registrants may continue to list eyewear as a user recommendation at their option.

## I. Introduction

This report on the progress toward tolerance reassessment for chlorethoxyfos is the result of the pilot process developed through the Tolerance Reassessment Advisory Committee (TRAC) to facilitate greater public involvement in the ongoing FIFRA reregistration and/or FQPA tolerance reassessment initiatives on pesticides. Since chlorethoxyfos was first registered in 1995, it is currently not subject to the reregistration process, only to the requirements of FQPA. However, some history and background on reregistration and FIFRA is included here for informational purposes and to provide a discussion of the existing laws requiring action on pesticides.

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment during reregistration. It also requires that EPA review all tolerances in effect on the day before the date of the enactment of the FQPA by August 2006. FQPA amends both FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA), but 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 is also continuing its progress toward tolerance reassessment as required by FQPA for all of the organophosphate chemicals, whether or not they are subject to the reregistration process. While the methodology for completion of the cumulative assessment for all of the organophosphates is being developed, individual risk assessments and risk mitigation measures, where appropriate, are being conducted. Although not subject to the reregistration process, the individual dietary assessment for the organophosphate chlorethoxyfos has been completed, and will be used in the cumulative assessment of all of the organophosphate chemicals to satisfy the requirements of FQPA. This document presents the Agency's dietary risk assessment for chlorethoxyfos, as part of the tolerance reassessment process.

The Agency has also revised occupational risk estimates for chlorethoxyfos. Chlorethoxyfos end-use products were conditionally registered in 1995 pending the submission of additional studies including dermal and inhalation toxicity studies and handler exposure studies. These data have been reviewed and considered in the updated occupational risk assessment.

As part of the EPA's effort to involve the public in the implementation of FQPA, the Agency is undertaking a special effort to maintain open public dockets on the organophosphate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. The public process was discussed by TRAC, a large multi-stakeholder advisory body which advised

the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the organophosphates are following this new process.

Phases 1 through 4 of the pilot process address the development and refinement of the risk assessments. Phases 5 and 6 are concerned with the development and implementation of risk management plans and provide opportunity for the registrants, user community, and general public to propose risk mitigation based on the revised risk assessments. During phase 6 of the process, the Agency prepares an interim Reregistration Eligibility Decision (RED) Document or a Report on FQPA Tolerance Reassessment and Interim Risk Management Decision Document, from which risk management will be implemented. Prior to finalizing a risk management decision, the Agency typically arranges a conference call with USDA, growers, registrants, and other interested parties to assess the feasibility of proposed mitigation measures.

Note that there is no comment period for this document. As part of the process developed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessment for chlorethoxyfos has already been subject to numerous public comment periods and a further comment period was deemed unnecessary. A Notice of Availability for this document, however, is being published in the *Federal Register*.

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

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

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

In addition to the policy issues that resulted from the TRAC process, the Agency published in the *Federal Register* on August 2, 1999 a draft Pesticide Registration Notice that presents EPA's proposed approach for managing risks to occupational users from organophosphate pesticides (www.epa.gov/pesticides/op/pr/pdf). This notice describes the Agency's approach to managing risks to handlers and workers of organophosphate pesticides. Generally, protective measures such as protective clothing, closed mixing and loading systems or enclosed cab equipment as well as increased reentry intervals will be required for most uses where current risk assessments indicate a risk and such protective measures are feasible. The draft guidance policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this interim document are consistent with the draft Pesticide Registration Notice.

This document consists of six sections. Section I introduces the regulatory framework for reregistration and tolerance reassessment reviews for the organophosphate pesticides. Section II provides a profile of chlorethoxyfos use patterns and usage. Section III summarizes the human health assessment. Section IV presents the Agency's regulatory position on this chemical. Section V summarizes the label changes necessary to implement the measures outlined in Section V and the procedure for label amendment. Finally, Section VI provides information on how to access all related documents.

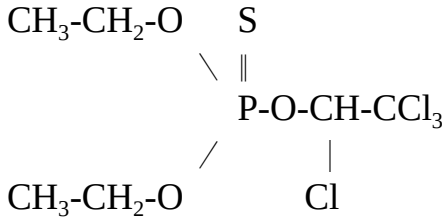
## II. Chemical Overview

### A. Regulatory History

Chlorethoxyfos was first registered in the United States in 1995 for use as an insecticide. This interim tolerance reassessment review is the Agency's first reevaluation of chlorethoxyfos since its initial registration in 1995.

### B. Chemical Identification

Chlorethoxyfos:



- **Common Name:** Chlorethoxyfos
- **Chemical Name:** O,O-Diethyl O- (1,2,2,2-tetrachloroethyl) phosphorothioate

- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 54593-83-8
- **OPP Chemical Code:** 129006
- **Empirical Formula:** $C_6H_{11}Cl_4O_3PS$
- **Trade and Other Names:** Fortress®
- **Basic Manufacturer:** E.I. du Pont de Nemours & Company

A detailed discussion on the physical properties of chlorethoxyfos can be found in the Chlorethoxyfos human health revised risk assessment: "Human Health Risk Assessment, Chlorethoxyfos (August 6, 1999)".

**C. Use Profile**

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

**Type of Pesticide:** Insecticide

**Summary of Use Sites:** Terrestrial food and feed crop - corn

Food: Seed corn, field corn, sweet corn, and popcorn

Nonfood: None

Residential: No residential uses

**Target Pests:** Chlorethoxyfos is used to control corn rootworms, wireworms, cutworms, seed corn maggots, white grubs and symphylans.

**Formulation Types Registered:** A technical grade, 88% a.i, (352-553) and two granular end-use products, Fortress® 2.5G (352-579) and 5G (352-552), 2.5% and 5% a.i. respectively.

**Method and Rates of Application**:

Equipment - Applied with ground equipment (tractor-drawn planter). The 5% formulation is only available in a SmartBox™ , which is a completely enclosed, tamper-proof delivery system. The 2.5% formulation is

supplied in 50 lb. bags for open loading.

Method and Rate - Applications are made in a T-band over the row or in the furrow. Use is limited to one application per year, at a maximum rate of 0.1625 lb ai/acre.

Timing - One application per year (maximum) at planting.

**Use Classification:** Chlorethoxyfos is a "restricted use" chemical due to acute human, avian, and aquatic invertebrate toxicity.

### D. Estimated Usage of Pesticide

Annual domestic usage of chlorethoxyfos is estimated to range from 8,500 to 17,800 pounds active ingredient for approximately 37,000 to 122,000 acres treated. Less than 1% of all corn acreage is treated. 90% of all use occurs in Illinois, Indiana and Ohio.

## III. Overview of Chlorethoxyfos Human Health Risk Assessment

Following is a summary of EPA's human health risk findings for the organophosphate pesticide chlorethoxyfos, as fully presented in the document, "Human Health Risk Assessment: Chlorethoxyfos," dated August 6, 1999. The risk assessment presented here forms the basis of the Agency's risk management decision for chlorethoxyfos.

Using relevant data, published scientific literature, and available surrogate data, the Agency assessed the human health risks associated with using chlorethoxyfos on corn. The residue of concern is parent chlorethoxyfos only. Although other minor metabolites were identified, these compounds were not included in the tolerance expression or the risk assessment based on the current use pattern. The Agency calculated human health risks from food, water, and occupational exposures. Potential dietary exposure to chlorethoxyfos residues may occur through the consumption of corn and through drinking water. There are no residential or other non-occupational use sites, therefore, in quantifying aggregate risks, the Agency only considered exposures from food and drinking water. The results of the food and drinking water analysis indicate that acute and chronic aggregate risk is below the Agency's level of concern.

The occupational assessment for chlorethoxyfos considered exposures that could result from handler and post-application tasks. The risks for each handler exposure scenario do not exceed the Agency's level of concern if PPE and engineering controls are utilized during the loading and application processes. EPA believes that there is low potential for significant post-application exposure because chlorethoxyfos is mainly incorporated into the soil, is applied once at planting, is not systemic in the plant, and degrades readily. The following section outlines the results of all risk assessments for chlorethoxyfos.

## A. Dietary Risk from Food

### 1. Toxicity

The Agency has reviewed all toxicity studies submitted and determined that the toxicity database is adequate to support an interim tolerance reassessment determination for all currently registered uses. This interim determination pertains only to chlorethoxyfos alone and does not consider the cumulative risk from all other organophosphates.

The acute toxicity profile for the active ingredient (technical) as well as the 5% a.i. granular end-use product (Fortress® 5G) is presented in Table I.

**Table I: Acute Toxicity Profile of Chlorethoxyfos**

| Study Type | Toxicity Category (Technical) | 5% a.i. end-use product (Fortress® 5G)* |
|---|---|---|
| Acute Oral | I | I** |
| Acute Dermal | I | III |
| Acute Inhalation | I | II |
| Primary Eye Irritation | I | III |
| Primary Skin Irritation | I | IV |
| Dermal Sensitization | NA (non-sensitizing) | NA (non-sensitizing) |

* DuPont cited most of the acute toxicity studies on the 5% granular formulation for the registration of Fortress® 2.5G. According to the registrant, the major difference between these two formulations is the reduction of active ingredient from 5.0% to 2.5%. Therefore, the toxicity of the 2.5% formulation would probably be equal or less than the 5.0% formulation.

**An acute oral toxicity study was conducted with Fortress® 2.5G. The results of this study placed Fortress® 2.5G in toxicity category II for acute oral toxicity.

Chlorethoxyfos has been classified as a group D chemical, not classifiable as to human carcinogenicity based on lack of evidence of carcinogenic potential in mice and rats. Chlorethoxyfos was non-mutagenic both *in vivo* and *in vitro*. Further details on the toxicity of chlorethoxyfos can be found in the August 6, 1999 Human Health Risk Assessment. The toxicology endpoints selected for the dietary risk assessment are presented in Table II.

**Table II: Summary of Toxicological Endpoints for Human Dietary Risk Assessment of Chlorethoxyfos**

| Assessment | Dose | Endpoint | Study | UF | FQPA Safety Factor | aPAD/cPAD* |
|---|---|---|---|---|---|---|
| Acute Dietary | NOAEL = 0.06 mg/kg/day | Plasma cholinesterase inhibition | Based on day 3 of a 6-month oral study in dogs | 100 | 1X | 0.0006 mg/kg/day |
| Chronic Dietary | NOAEL = 0.06 mg/kg/day | Overall (plasma, red blood cell and/or brain) cholinesterase inhibition following subchronic and chronic exposures | Based on the combined results of the 90-day, 6-month and 1-year feeding studies in dogs | 100 | 1X | 0.0006 mg/kg/day |

*The population adjusted dose (PAD) is a term that reflects the Reference Dose (RfD), either acute or chronic, adjusted to account for the FQPA safety factor.

Typically, a rat study rather than a dog study is used to determine the acute dietary endpoint. In the acute neurotoxicity study in rats, a NOAEL could not be established for the principal effect because cholinesterase inhibition was seen in both sexes at the lowest dose tested at the 1-day measurement. Inhibition at the lowest dose is a concern since chlorethoxyfos is a potent cholinesterase inhibitor with a steep dose response curve. If the LOAEL (0.25 mg/kg/day) from the rat study is used to derive the aPAD, then an additional uncertainty factor of 3 must be applied due to the lack of a NOAEL, which would result in a total uncertainty factor of 300 (i.e., 10x for inter species extrapolation, 10x for intra-species variation, and 3x for the use of LOAEL). The resulting aPAD would be: 0.25 mg/kg/day (LOAEL)÷300 (UF) = 0.0008 mg/kg/day. The aPAD calculated using the NOAEL from the dog study was calculated to be 0.0006 mg/kg/day. Since there is essentially no difference between the two aPADs, it is better to use a study with a NOAEL rather than a study with a LOAEL and additional factors. In addition, a species sensitivity difference with rats and dogs was not demonstrated for chlorethoxyfos in acute, subchronic or chronic studies. These are the reasons why EPA selected the dog study over the rat acute neurotoxicity study.

### 2. FQPA Safety Factor

An uncertainty factor of 100 (the standard uncertainty factor) to account for both interspecies extrapolation and intraspecies variability was applied to both acute and chronic dietary risk assessments. The 10X FQPA Safety Factor was reduced to 1X because; 1) there was no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in prenatal developmental toxicity studies, 2) no offspring toxicity was seen at the highest dose tested in the two-generation reproduction toxicity study and there was no evidence of abnormalities in the development of the fetal nervous system in these studies and, 3) adequate data and modeling outputs are available to satisfactorily assess dietary exposure and to provide a screening level drinking water exposure assessment. The Agency believes that the assumptions and models used in the assessments do not underestimate the potential risk for infants and children.

### 3. Dietary Exposure Assumptions

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

The acute dietary risk analysis was conducted with anticipated residues set at ½ the limit of detection (0.005 ppm) and 1% crop treated. This Tier 3 probabilistic analysis reports risk at the 99.9$^{th}$ percentile of exposure. One-half the limit of detection was used for chlorethoxyfos because field trials showed no residues (<0.01 ppm) of parent in any of the corn raw agricultural commodities analyzed, even after treatment at a 10x rate. Due to the lack of significant residues in the corn field trials and animal metabolism studies, tolerances are not required at this time for residues in milk and livestock tissues[1].

For the chronic dietary risk assessment, the three-day average of consumption for each sub-population was combined with the tolerance-level residue value (0.01 ppm) to determine average exposure. A Tier 2 chronic risk assessment was conducted using 1% percent crop treated.

### 4. Food Risk Characterization

The acute and chronic PAD for chlorethoxyfos is 0.0006 mg/kg. The chlorethoxyfos **acute dietary risk** from food is well below the Agency's level of concern. For the most exposed subgroup, children (1-6 years), the % aPAD value is 2% at the 99.9$^{th}$ percentile of exposure. Similarly, the **chronic dietary risk** from food is well below the Agency's level of concern. For the most exposed subgroups, (children 1-6 years and < 1 year), the % cPAD value is 0.1%. In summary, both acute and chronic dietary exposure and risk associated with chlorethoxyfos-treated foods are considered to be negligible (see Table III). Therefore, further refinements to the dietary analyses are not warranted at this time.

**Table III. Risk Estimates as a Percentage of the Acute and Chronic PAD (% PAD)**

| Subgroups | Acute Tier 3 Probabilistic Assessment* | Chronic Tier 2 Assessment |
|---|---|---|
| U.S. Population | 0.5% | < 0.1% |
| Non-nursing Infants (less than 1 year old) | 0.2% | 0.1% |
| Children, 1-6 years old | 2.0% | 0.1% |

* 99.9$^{th}$ percentile of exposure

### B. Dietary Risk from Drinking Water

Exposure to pesticides through drinking water can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks

[1] For a complete listing of chlorethoxyfos tolerances, see Section IV of this document.

and uses either modeling or actual monitoring data, if available, to estimate those risks. The residue of concern in drinking water is the parent only. Based on environmental fate data, chlorethoxyfos is moderately persistent in water and soil and is not expected to be mobile in soil.

To determine the maximum allowable contribution of treated water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food, then determines a "drinking water level of comparison" (DWLOC). The DWLOC is the maximum concentration of chlorethoxyfos in drinking water which does not exceed a level of concern when considered together with dietary exposure from food alone. Since there are no residential risks associated with chlorethoxyfos use, only the dietary risk from food is considered for purposes of calculating the DWLOC.

No water monitoring data are available for chlorethoxyfos. Therefore, the surface and ground water assessments are based on modeling predictions. Modeling is considered to be an unrefined assessment and provides a high end estimate of risk. Ground water modeling with SCI-GROW and surface water modeling with PRZM-EXAMS were used to calculate drinking water estimated concentrations which were then compared to the DWLOC.

### 1. Surface Water

Upper-bound drinking water concentrations from surface water were estimated with PRZM-EXAMS, a Tier 2 model. This model, although considered screening level, is based on more refined assumptions than the Tier I GENEEC model. Table IV lists the modeling results for chlorethoxyfos in surface water based on the two current application methods.

**TABLE IV. PRZM-EXAMS Modeling Results for Chlorethoxyfos in Surface Water**

| Application Method | Acute (High) Concentration (ppb) | Chronic (60-day) Concentration (ppb) |
|---|---|---|
| In-Furrow | 0.064 | 0.012 |
| T-Band | 0.427 | 0.080 |

### 2. Ground Water

Drinking water concentrations from ground water were estimated with SCI-GROW, a Tier 1 assessment tool. For ground water, the maximum acute and chronic estimated concentration of chlorethoxyfos is 0.002 ppb. This screening level model does not provide different values for acute and chronic estimated residue levels.

### 3. Drinking Water Levels of Comparison (DWLOCs)

The acute and chronic DWLOC is 21 ppb for the US population and 6 ppb for children 1-6, the most sensitive population. The acute and chronic estimated concentrations in surface and ground water result in potential exposures that are below the Agency's level of concern.

## C. Aggregate Risk

Aggregate risk consists of the combined risk from exposure through food, drinking water, residential, and non-occupational uses of a pesticide. For chlorethoxyfos, acute and chronic aggregate risk is limited to food and water exposure because chlorethoxyfos is not used in residential settings or other areas that are frequented by the general public. Generally, the combined risks from these different exposures must be less than 100% of the acute or chronic PAD, respectively. Since the ground and surface water estimated concentrations are substantially below the DWLOCs based on screening models, acute and chronic aggregate (food and water) exposure to chlorethoxyfos is not of concern for any population sub-group.

## D. Occupational Risk

Occupational workers may be exposed to a pesticide through tasks such as mixing, loading, applying a pesticide, or re-entering a treated site. EPA estimates handler risk by evaluating occupational exposure levels, including both dermal and inhalation exposures, against the NOAEL demonstrated in animal studies. The ratio of the estimated exposure to the NOAEL is referred to as the Margin of Exposure (MOE). For chlorethoxyfos, MOEs greater than 100 do not exceed the Agency's level of concern.

### 1. Toxicity

With the exception of the intermediate-term inhalation assessment, route-specific toxicity studies were available and used to select the endpoints. The toxicology endpoints selected for the occupational risk assessment are presented in Table V.

**Table V: Toxicology Endpoints Selected for Occupational Risk Assessment**

| Assessment | Exposure Route | Dose | Endpoint | Study |
|---|---|---|---|---|
| Short Term (1-7 days) | Dermal | Dermal NOAEL = 1.25 mg/kg/day | RBC cholinesterase inhibition (ChEI) | 21-day dermal toxicity study in rats |
| Intermediate Term (7 days - several months) | Dermal | Dermal NOAEL = 1.25 mg/kg/day | RBC ChEI | 21-day dermal toxicity study in rats |
| Short Term (1-7 day) | Inhalation | Inhalation NOAEL = 0.00058 mg/L (0.13 mg/kg/day) | Plasma, RBC, and brain ChEI | 7-day inhalation study in rats* |
| Intermediate Term (7 days - several months) | Inhalation | Oral NOAEL = 0.06 mg/kg/day | Plasma ChEI | 6-month oral study in dogs** |

*The inhalation study duration is only 7 days and is therefore not appropriate for use as an endpoint in the intermediate term inhalation assessment.

**Since an oral NOAEL was selected, the use of a 100% (default) inhalation absorption rate is required.

## 2. Exposure

Chlorethoxyfos is not expected to be used on a continuous long-term basis (greater than 6 months a year) resulting in chronic exposure. Therefore, the risk assessments were conducted for short- (1-7 days) and intermediate- (one week-several months) term occupational exposure scenarios. EPA has determined that there are potential exposures to loaders, applicators, and other handlers for use-patterns associated with chlorethoxyfos. The major exposure scenarios identified for chlorethoxyfos are:

1) loading the granular formulation for ground equipment application
2) applying the granular formulation with ground equipment (tractor drawn planter)

Chemical-specific exposure studies were available for chlorethoxyfos. Anticipated use patterns and application methods were derived from current labeling. The maximum label rate of 0.1625 lb ai/acre and the maximum corn-planting rate estimate of 180 acres/day were assumed. This planting estimate is based on the use of a 12- to 15-row planter set for 30-inch wide rows. The Agency also applied standard assumptions (average body weight, hours in a work day, etc.).

Handler exposure estimates were derived from the chemical-specific studies only, which included the use of PPE and engineering controls. Loader exposure to Fortress® 5G in the SmartBox™ is based on the use of a long-sleeved shirt, long pants, shoes plus socks and chemical resistant gloves. Loader exposure to Fortress® 2.5G is based on wearing coveralls over long-sleeved shirt, long pants, shoes plus socks and chemical resistant gloves, plus an organic vapor removing respirator with pesticide prefilter or pesticide canister. Loader exposure to Fortress® 2.5G without coveralls was also calculated. Applicator risk from Fortress® 2.5G and Fortress® 5G is based on the use of a closed-cab tractor while wearing baseline PPE (long-sleeved shirt, long pants, shoes plus socks).

The level of protection employed in the handler exposure assessment is comparable to what is currently on chlorethoxyfos end-use labels. A summary of the PPE and engineering control requirements on current labels is provided in Table VI.

**Table VI: PPE and Engineering Controls on Current Chlorethoxyfos Labels**

| Formulation | Loaders | Applicators |
|---|---|---|
| Fortress® 5G in the SmartBox™ | Long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, protective eyewear. | Closed cab. Long-sleeved shirt and long pants, shoes plus socks.* |
| Fortress® 2.5G in 50 lb. bags | Coveralls, long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, protective eyewear, an organic vapor equipped with either an organic vapor-removing cartridge or canister. | Closed cab. Long-sleeved shirt and long pants, shoes plus socks.* |

* More protective PPE is required on labels for applicators who must exit the cab to repair or adjust the planter.

## 3. Handler Exposure Estimates

A summary of exposure estimates for occupational handlers is included in Tables VII, VIII and IX. For chlorethoxyfos, MOEs greater than 100 do not exceed the Agency's level of concern.

### Table VII. Occupational Handler Exposure Estimates and Risk Assessment Summary: Fortress 5G in the SmartBox™

| Scenario/Rate | | Dermal | | | Inhalation | | | | Combined MOE |
|---|---|---|---|---|---|---|---|---|---|
| Application Scenario | (lb ai/day) | UE[b] mg/lb a.i. | ADD[c] (mg/kg/day) | Short-& interm.-term MOE[d] | UE[e] mg/day | ADD[f] (mg/kg/day) | Short-term MOE[d] | Interm.-term MOE[d] | **MOE Total[g]** |
| Loader[a]- using a SmartBox™ | 29.25 | 0.0002 | 0.000084 | 15,000 | $9.6X10^{-5}$ | $1.4 X10^{-6}$ | 93,000 | 43,000 | **Short-term 13,000 Interm.-term 11,000** |
| Applicator -closed-cab tractor | 29.25 | 0.00081 | 0.00034 | 3,700 | 0.0019 | $2.7 X10^{-5}$ | 4800 | 2200 | **Short-term 2100 Interm-term 1400** |
| Combined[h] | 29.25 | 0.0010 | 0.00042 | 3,000 | 0.0020 | $2.8 X10^{-5}$ | 4600 | 2100 | **Short-term 1800 Interm.-term 1200** |

[a] Loader exposure reflects closed system (SmartBox™), long sleeve shirt and long pants, shoes, socks, and chemical resistant gloves. Applicator exposure reflects long sleeve shirt, long pants, and shoes with socks.
[b] UE = Dermal Unit Exposure is the amount of exposure measured in terms of mg a.i./lb a.i handled
[c] ADD(mg/kg/day) [dermal]: = unit exposure (UE) from studies in mg/lb a.i. handled * 29.25 lb a.i./day / 70 kg wt;
[d]MOE = NOAEL/ADD; For Dermal (short-,& intermediate-term time periods)-NOAEL= 1.25mg/kg/day; For short-term inhalation-NOAEL=0.13 mg/kg/day(Based on 7-day inhalation study); For intermediate-term inhalation-NOAEL =0.06 mg/kg/day (based on an oral study, assume 100% absorption). Inhalation NOAEL= 0.13 mg/kg/day =0.000508 mg/l X (10.3 l/hr sprague-Dawley inhalation rate) X ( rat exposed 6hrs/day) divided by 0.236 kg (Sprague-Dawley rat body weight).
[e] UE = The Inhalation Unit Exposure factor is based on the respiratory rate of 29 liters/minute. Loader exposure was 0.25 hours/day (=435 liters); applicator 7.75 hours/day (=13,485 liters). UE (loader) =(0.22 nanograms ai /liter) X ($1 X10^{-6}$mg/nanogram) X 435liters/day = $\underline{9.6X10^{-5}\ mg/day}$; UE (applicator) =(0.14 nanograms ai/liter) X ($1 X10^{-6}$ mg/nanogram) X 13,485 liters/day= $\underline{0.0019\ mg/day.}$
[f] ADD(mg/kg/day) [inhalation] = UE is divided by avg body weight for ADD: mg/day / 70kg = mg/kg/day (The total dose).
[g] MOE Total is based upon the following formula: the inverse of the sum of the inverses of the dermal and inhalation MOEs: $1 / (1/MOE_{dermal} + 1/MOE_{inhalation})$; these MOEs have a common endpoint. [1] = Short-term, and [2] = intermediate-term
[h] Loader/Applicator = 1 person performing both loading and application of the pesticide to the crop/commodity.
These estimates are based on data from a study (MRID#443998-02) which used 3.25 lb. product/acre (equivalent to 0.1625 lb a.i./acre)

### Table VIII. Occupational Handler Exposure Estimates and Risk Assessment Summary: Fortress 2.5G Granules with Single Layer Body Protection

| Scenario/Rate | | Dermal (With baseline PPE plus gloves)[a] | | | Inhalation (With OV respirator for loader) | | | | Combined MOE |
|---|---|---|---|---|---|---|---|---|---|
| Application Scenario | (lb ai/day) | UE[b] (mg/lb a.i.) | ADD[c] (mg/kg/day) | MOE[d] | UE[e] (mg/day) | ADD[f] (mg/kg/day) | Short-term MOE[d] | Interm.-term MOE | **MOE Total[g]** |
| Loader[a] (without coveralls) | 29.25 | 0.0023 | 0.00096 | 1300 | 0.001 | 1.4 E-05 | 9300 | 4300 | **Short-term 1100 Interm.-term 1000** |
| Applicator in a closed-cab tractor | 29.25 | 0.0025 | 0.00 10 | 1200 | 0.0047 | 6.7 E-05 | 1900 | 900 | **Short-term 740 Interm.-term 510** |
| Combined | 29.25 | 0.0048 | 0.0020 | 620 | 0.0057 | 8.1 E-05 | 1600 | 740 | **Short-term 450 Interm.-term 340** |

[a] The PPE for loaders is calculated with organic vapor removing respirator, long sleeve shirt, long pants, shoes, socks, and chemical resistant gloves The minimum PPE for applicators in the cab is long sleeve shirt, long pants, and shoes with socks.
[b] UE = Unit Exposure is the amount of exposure measured in terms of mg a.i./lb a.i handled
[c]ADD(mg/kg/day): = unit exposure (UE) from studies in mg/lb a.i. handled * 29.25 lb a.i./day / 70 kg wt;
[d]MOE = NOAEL/ADD
[e] UE = Unit Exposure for inhalation is based upon air sampling data and is expressed in terms of nanograms (mg x 10-6) of ai per liter of air respired.
[f] ADD(mg/kg/day) [inhalation] = The UE factor is multiplied by the respiratory rate of 29 liters/minute. Loader exposure was 0.3 hours/day; applicator 7.7 hours. The total dose is divided by avg body weight for ADD: [(nanogram/liter * liter/min * minutes) / 70kg]
[g] MOE Total is based upon the following formula: the inverse of the sum of the inverses of the dermal and inhalation MOEs:
$1 / (1/MOE_{dermal} + 1/MOE_{inhalation})$; these MOE have a common endpoint

The study data this is based on used 5.5 lb of product with 5% ai, equal to 0.275 lb ai/acre ; data were adjusted to current label application rate of 6.5 lb. product/acre (equivalent to 0.1625 lb a.i./acre).

**Table IX. Occupational Handler Exposure Estimates and Risk Assessment Summary: Fortress 2.5G Granules with Double Layer Body Protection**

| Scenario/Rate | | Dermal (With Coveralls)[a] | | | Inhalation (With OV respirator for loader) | | | | Combined MOE |
|---|---|---|---|---|---|---|---|---|---|
| Application Scenario | lb ai/day | UE[b] (mg/lb a.i.) | ADD[c] (mg/kg/day) | MOE[d] | UE[e] (mg/day) | ADD[f] (mg/kg/day) | Short-term MOE[d] | Interm.-term MOE | **MOE Total[g]** |
| Loader[a] (with coveralls) | 29.25 | 0.0016 | 0.00066 | 1900 | 0.001 | 1.4 E-05 | 9300 | 4300 | **Short-term 1600 Interm.-term 1300** |
| Applicator using a closed-cab tractor | 29.25 | 0.0017 | 0.00071 | 1800 | 0.0047 | 6.7 E-05 | 1900 | 900 | **Short-term 920 Interm.-term 600** |
| Combined | 29.25 | 0.0033 | 0.0014 | 910 | 0.0057 | 8.1 E-05 | 1600 | 740 | **Short-term 580 Interm.-term 410** |

[a] The PPE for loaders is calculated with organic vapor removing respirator, coveralls over long sleeve shirt, long pants, shoes, socks, eye protection, and chemical resistant gloves
The PPE for applicators is calculated here with coveralls over long sleeve shirt, long pants, and shoes with socks.
[b] UE = Unit Exposure is the amount of exposure measured in terms of mg a.i./lb a.i handled.
[c] ADD(mg/kg/day): = unit exposure (UE) from studies in mg/lb a.i. handled * 29.25 lb a.i./day / 70 kg wt;
[d] MOE = NOAEL/ADD
[e] UE = Unit Exposure for inhalation is based upon air sampling data and is expressed in terms of nanograms (mg x 10-6) of ai per liter of air respired. [f] ADD(mg/kg/day) [inhalation] = The UE factor is multiplied by the respiratory rate of 29 liters/minute. Loader exposure was 0.3 hours/day; applicator 7.7 hours. The total dose is divided by avg body weight for ADD: [(nanogram/liter * liter/min * minutes) / 70kg].
[g] MOE Total is based upon the following formula: the inverse of the sum of the inverses of the dermal and inhalation MOEs: $1 / (1/MOE_{dermal} + 1/MOE_{inhalation})$; these MOEs have a common endpoint.
The study data this is based on used 5.5 lb of product with 5% ai, equal to 0.275 lb ai/acre ; data were adjusted to current label application rate of 6.5 lb. product/acre (equivalent to 0.1625 lb a.i./acre).

### 4. Post Application Risk

The Agency did not quantitatively assess the risks to postapplication workers. EPA believes that there is low potential for significant post-application exposure since chlorethoxyfos is mainly incorporated into the soil, is applied once at planting, degrades readily, and is not systemic in the plant.

The restricted-entry interval (REI) is the time immediately after a pesticide application when entry into the treated area is limited. The REI on chlorethoxyfos end-use products is 48 hours (or 72 hours where average rainfall is less than 25 inches per year).

## IV. FQPA Tolerance Reassessment Progress & Interim Risk Management Decision

### A. Tolerance Reassessment Progress & Interim Risk Management Decision

This interim evaluation presents the Agency's current position on products containing the active ingredient chlorethoxyfos. The Agency has sufficient information on the human health effects of chlorethoxyfos to make interim decisions as part of the tolerance reassessment process under FQPA. Based on its current evaluation of chlorethoxyfos alone, the Agency has determined that chlorethoxyfos products, labeled and used as specified in this document, will not present unreasonable dietary and occupational adverse effects.

The Agency will finalize the decision for chlorethoxyfos after evaluating the cumulative risk of the organophosphate class. Because the Agency has not yet completed the cumulative risk assessment for the organophosphates, this interim decision does not fully address the reassessment of the existing chlorethoxyfos food residue tolerances as required by section 408(q) of the Food Quality Protection Act. When the Agency has completed the cumulative assessment, chlorethoxyfos' tolerances will be reassessed along with the other organophosphate pesticides and a final determination will be made. 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 organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

This interim evaluation does not limit the Agency from making further Food Quality Protection Act determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future. If the Agency determines, as a result of this later implementation process, that any of the determinations described in this Report on FQPA Tolerance Reassessment Progress and risk management document are no longer appropriate, the Agency will pursue appropriate action, including but not limited to, reconsideration of any portion of this interim document.

## B. Summary of Phase 5 Comments and Revisions to the Risk Assessment

The availability of the revised risk assessment and supporting documents was announced on August 18, 1999 in Federal Register Notice 64 FR 44921. Interested parties were provided a 60 day period to submit comments, including risk mitigation proposals. No submissions were received during this public comment period.

After the revised risk assessment was made available, calculation errors in the handler exposure estimates with the Fortress® 2.5G product were corrected by adjusting the actual study rate of application (5.5 lb product at 5% ai/A=0.275 lb ai/A) to that on the current label (6.5 lb at 2.5% ai/A = 0.1625 lb ai/A). The study rate was reduced by 1.8x. MOEs are not significantly different from prior estimates of exposure. Loader exposure to Fortress® 2.5G without the addition of coveralls (a 50% protection factor) was also calculated after the revised assessment was made available. The new calculations are included in Section III of this document.

## 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 organophosphate. 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 organophosphates through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of organophosphates once the methodology is developed and the policy concerning cumulative assessments is resolved.

EPA has determined that risk from exposure to chlorethoxyfos is within its own “risk cup.” In other words, if chlorethoxyfos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for chlorethoxyfos on corn 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 and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to chlorethoxyfos "fit" within the individual risk cup. Therefore, the chlorethoxyfos tolerances remain in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is completed.

### b. Tolerance Summary

Established tolerances for residues of chlorethoxyfos in/on plant commodities are currently expressed in terms of residues of chlorethoxyfos *per se.* Based upon the lack of chlorethoxyfos residues measured in field corn, popcorn, and sweet corn commodities (<0.01 ppm) and the results of the goat metabolism study, finite transfer of chlorethoxyfos residues is not expected to meat, fat, meat byproducts, milk, or eggs. Therefore, no tolerances on meat, fat, meat byproducts, milk, or eggs are necessary. Residues of chlorethoxyfos are not expected to be detectable (<0.01 ppm, limit of quantitation for each) in corn grain, corn forage and stover as a result of soil application. There are no CODEX, Canadian, or Mexican limits established for chlorethoxyfos, therefore, no compatibility problem exists.

This summary provides the tolerance levels for chlorethoxyfos [O,O-diethyl (1,2,2,2-tetrachloroetyl) ester], as supported by submitted residue data. Sufficient data are available to ascertain the adequacy of the established tolerances for the following commodities, as defined in 40 CFR §180.486. Based upon these data, the established tolerances do not need to be amended at this time. Note that these tolerances cannot be considered "reassessed", as required by FQPA, until the cumulative risk assessment of all organophosphates is completed.

**Table X: Tolerance Summary for Chlorethoxyfos**

| Commodity | Parts per million |
|---|---|
| Corn, field, forage | 0.01 |
| Corn, field, grain | 0.01 |
| Corn, field, stover (fodder) | 0.01 |
| Corn, pop, grain | 0.01 |
| Corn, pop, stover (fodder) | 0.01 |
| Corn, sweet (K + CWHR) | 0.01 |
| Corn, sweet, forage | 0.01 |
| Corn, sweet, stover (fodder) | 0.01 |

### 2. Endocrine Disruptor Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "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 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 EPA include evaluations of potential effects in wildlife. For pesticides, 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 EDSP have been developed, chlorethoxyfos may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

### 3. Required Label Modifications

The regulatory rationale for each risk management measure outlined below is discussed immediately after this section.

The following measures, in addition to the existing label requirements, are intended to clarify and strengthen the existing label language to help ensure that no risk will occur from proper use.

- Labels must state that in addition to the PPE that loaders of the Fortress® 5G in the SmartBox™ must wear (long-sleeved shirt, long pants, shoes plus socks, chemical resistant gloves), loaders must also have immediately available for use in case of an emergency: a respirator with an organic-vapor removing cartridge or canister, a chemical resistant apron, and chemical resistant footwear.

- "Other handlers" must be specified on labels and must wear long-sleeved shirts, long pants, shoes plus socks and chemical-resistant gloves.
- A "double notification" statement must be added to end-use labels. Double notification requires that workers are advised about the application both orally and by posting warning signs at entrances to treated areas during the REI.

The following label changes are intended to better characterize risk from occupational exposure to chlorethoxyfos products:

- The PPE requirement for loaders of Fortress® 2.5G (coveralls over a long-sleeved shirt and long pants) must be reduced to a long-sleeved shirt and long pants.
- The use of eye protection while loading Fortress products is not required by the WPS based on current toxicity values for the products. Registrants may continue to list eyewear as a user recommendation at their option.

## D. Regulatory Rationale

Dietary (Food) Risk Mitigation

The Agency is not proposing mitigation for acute or chronic dietary food risks. The current risks are not of concern based on the acute and chronic DEEM models.

Dietary (Water) Risk Mitigation

The Agency is not proposing mitigation for acute or chronic drinking water risks. Current risks are not of concern based on the comparison of the DWLOC against the estimated concentrations from surface and ground water modeling.

Aggregate (Food + Water) Risk Mitigation

For chlorethoxyfos, the aggregate risk is limited to food and water. No risk mitigation for aggregate risk is necessary at this time because food and drinking water estimates indicate that the Agency's level of concern is not exceeded for any subgroup.

Handler Risk Mitigation

Chlorethoxyfos end-use products were conditionally registered in 1995 pending the submission of additional studies needed to refine the Agency's risk assessments. The Agency is now requiring changes, less stringent measures in some cases, to the labeling than was required in 1995.

- Loaders using a closed system (i.e. the SmartBox™ system) must have personal protective equipment immediately available for use in case the system fails in accordance with the Worker Protection Standard. Current chlorethoxyfos labels do not state this requirement.

The Agency recognizes that no system is fail-safe, therefore, in addition to the PPE that loaders of the Fortress® 5G in the SmartBox™ must wear (long-sleeved shirt, long pants, shoes plus socks, chemical resistant gloves), loaders must also have immediately available for use in case of an emergency: a respirator with an organic-vapor removing cartridge, a chemical-resistant apron, and chemical resistant footwear.

- On current chlorethoxyfos labels, PPE and engineering controls are only specified for loaders and applicators. However, there are other handler tasks which involve direct contact with the material, for example, cleaning, adjusting or repairing parts of the loading or application equipment, disposing of pesticide containers, performing tasks as a crop advisor, or assisting loaders and applicators in their tasks. Handlers may also have contact with residues on application equipment during corn seed loading. Therefore, the Agency is requiring that "other handlers" must wear a long-sleeve shirt, long pants, shoes plus socks and chemical-resistant gloves.

- Loaders of Fortress® 2.5G must currently wear coveralls over a long-sleeved shirt and long pants. However, the MOEs in the handler exposure assessment indicate that the risk to loaders of the Fortress® 2.5G wearing baseline PPE (long-sleeved shirt and long pants) is still well below the Agency's level of concern. In addition, double layers are typically required when the end-use product is in toxicity category I for acute dermal toxicity or skin irritation potential. Fortress® 5G is in toxicity category III for acute dermal toxicity and toxicity category IV for dermal irritation. Based on the results of the exposure assessment, the toxicity categories of the end-use products and the fact that coveralls worn over a long-sleeved shirt and long pants may result in heat stress, the Agency recommends that the double layer body protection requirement for loaders of Fortress® 2.5G be reduced to single layer body protection.

- The use of eye protection while handling Fortress products is not required by the WPS based on current toxicity values for the products (tox. cat. III for eye irritation). Registrants may continue to list eyewear as a user recommendation at their option.

Post Application Risk Mitigation

The Agency is requiring post-application risk mitigation that varies from what is currently on the labels:

- The active ingredient chlorethoxyfos is classified as toxicity category I for both acute dermal and primary skin irritation. Either of these classifications triggers the requirement to notify workers about the application both orally and by posting warning signs at the entrances to treated areas. Therefore, each product label must bear the statement, "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas".

Other Considerations

- Although the inhalation MOEs for loaders of Fortress® 2.5G are relatively high with the use of an organic-vapor removing respirator (short-term MOE = 9,300, intermediate term MOE = 4,300), the requirement for an organic-vapor removing respirator remains necessary. The product essentially behaves as a fumigant (vapor pressure = $1.7 \times 10^{-3}$) during the loading process, probably due to vapor trapped in the head-space of the bag. Significant volatilization of the formulation was apparent during loading in the registrant-submitted study (MRID 42559222) and constituted 50% of total exposure to the loader. Consequently, the Agency believes it is imperative that a loader wear an approved organic vapor removing respirator, rather than a dust/mist respirator during the loading process.

- Post application risk estimates were not quantitatively calculated. EPA believes that there is low potential for significant post-application exposure because chlorethoxyfos is mainly incorporated into the soil, is applied once at planting, is not systemic in the plant, and degrades readily. The restricted-entry interval (REI) is the time immediately after a pesticide application when entry into the treated area is limited. The current WPS-established REI on chlorethoxyfos end-use products of 48 hours or 72 hours where average rainfall is less than 25 inches per year will be retained.

## V. What Registrants Must Do

### A. Manufacturing Use Products

The generic data base supporting the registration of chlorethoxyfos for use on corn has been reviewed and determined to be substantially complete.

### B. End-Use Products

#### 1. Labeling Modifications for End-Use Products

Label changes are necessary to implement the measures outlined in Section IV above. Specific language to implement these changes is detailed in Table XI.

**Table XI: Summary of Labeling Changes for Chlorethoxyfos**

| Description | Required Labeling | Placement on Label |
|---|---|---|
| End Use Products Intended for Use on Corn | | |
| PPE Requirements* for the granular product in a SmartBox™ system | "Personal Protective Equipment (PPE)<br>Some materials that are chemical-resistant to this product are (*registrant insert correct material*). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart.<br><br>Loaders, applicators and other handlers must wear:<br>-- Long-sleeved shirt and long pants<br>-- Shoes plus socks<br>-- Chemical resistant gloves (except for applicators)"<br><br>See Engineering Controls for additional requirements. | Precautionary Statements: Hazards to Humans and Domestic Animals |
| PPE Requirements* for the granular product (not in a SmartBox™ system) | "Personal Protective Equipment (PPE)<br>Some materials that are chemical-resistant to this product are *(registrant insert correct materials*). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart.<br><br>Loaders, applicators and other handlers must wear:<br>-- Long-sleeved shirt and long pants<br>-- Shoes plus socks<br>-- Chemical resistant gloves (except for applicators)<br>-- Loaders must also wear a respirator with:<br>- an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or<br>- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an (OV) cartridge, or<br>- a canister with any *N,R,P or HE prefilter"<br><br>See Engineering Controls for additional requirements. | Precautionary Statements: Hazards to Humans and Domestic Animals |

**Table XI: Summary of Labeling Changes for Chlorethoxyfos**

| Description | Required Labeling | Placement on Label |
|---|---|---|
| User Safety Requirements | "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." | Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following the PPE requirements) |
| Engineering Controls | "IMPORTANT: the SmartBox™ system when used correctly qualifies as a closed loading system under the WPS.<br><br>Loaders using the SmartBox™ system must:<br>--wear the PPE specified above for loaders<br>-- in addition to wearing the required PPE, have immediately available for use in case of an emergency: chemical-resistant apron, chemical-resistant footwear, and a NIOSH-approved respirator with 1) an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or 2) a canister approved for pesticides (MSHA/NIOSH approval prefix TC-14G), or 3) an organic vapor (OV) cartridge or canister with any N*, R, P, or HE prefilter.<br><br>Applicators must be in enclosed cabs and must:<br>--wear the PPE specified above for applicators,<br>–in addition to wearing the required PPE, have available for use: coveralls, chemical-resistant gloves, and protective eyewear if it is necessary to exit the cab and contact pesticide-treated surfaces in the treated area,<br>--remove PPE that was worn in the treated area before reentering the cab, and<br>--store all PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab. " | Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following PPE and User Safety Requirements.) |
| User Safety Recommendations | "User Safety Recommendations"<br><br>"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."<br><br>"Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."<br><br>"Users should remove PPE immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing." | Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls |
| Restricted-Entry Interval | "Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. The REI is 72 hours where average rainfall is less than 25 inches per year." | |

**Table XI: Summary of Labeling Changes for Chlorethoxyfos**

| Description | Required Labeling | Placement on Label |
|---|---|---|
| Early Entry Personal Protective Equipment | "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:<br><br>-- coveralls<br>-- chemical resistant gloves<br>-- shoes plus socks" | Directions for Use, Agricultural Use Requirements Box |
| Double Notification Statement | "Double Notification: Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas." | Directions for Use, Agricultural Use Requirements Box |
| General Application Restrictions | "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." | Directions for Use directly above the Agricultural Use Box. |

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

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

Instructions in the Labeling Required section not in quotes represent actions that the registrant must take to amend their labels or product registrations.

### 2. Procedure and Timing for Label Amendment

Registrants must submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of each revised label, and a description on the application, such as, "Responding to Interim Tolerance Reassessment Evaluation and Risk Management Document." Registrants should send applications for amendment to the appropriate following address within 90 days after receipt of this document.

Document Processing Desk (APPL)
Office of Pesticide Programs
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Dr. William Sproat
Insecticide Branch (7505C)

### C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this Report on FQPA Tolerance Reassessment and Interim Risk Management Decision. Persons other than the registrant may generally distribute or sell such products for 24 months from the date of the issuance of this Report on FQPA Tolerance Reassessment Progress and risk management decision. 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.

## VI. Related Documents and How to Access Them

This report is supported by documents that are presently maintained in the OPP docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays from 8:30 AM to 4:00 PM.

The docket initially contained the preliminary risk assessment and related documents as of January 15, 1999. On March 15, the first public comment period closed. EPA then considered comments, revised the risk assessment, and placed the revised risk assessment in the docket on August 18, 1999. All documents, in hard copy form, may be viewed in the OPP docket room or viewed or downloaded via the Internet (http://www.epa.gov/pesticides/).

## Appendix I. Bibliography

## GUIDE TO 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 (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

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**Appendix II: Pesticide Registration Kit** www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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

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

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

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

   a. Registration Division Personnel Contact List
   II Biopesticides and Pollution Prevention Division (BPPD) Contacts

C. Antimicrobials Division Organizational Structure/Contact List

d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' Web Site

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

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

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

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

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

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the

applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

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

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