**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL (Document # EPA-R-01-003)

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 chlorpyrifos methyl. The attached document entitled, "Report on FQPA Tolerance Reassessment and Risk Management Decision for Chlorpyrifos methyl" which was approved on December 30, 2000, summarizes the Agency's assessment of the dietary and occupational risk from chlorpyrifos methyl. Based on its review, EPA has identified risk mitigation measures believed necessary to address the human health risks associated with the current use of chlorpyrifos methyl. 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 chlorpyrifos methyl was registered after 1984, it is not subject to reregistration. However, chlorpyrifos methyl 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 required EPA to re-evaluate tolerances existing at the time it was passed to ensure that children and other sensitive subpopulations are protected from pesticide risk.

The "Report on FQPA Tolerance Reassessment Progress and Risk Management Decision for Chlorpyrifos methyl" 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 chlorpyrifos methyl public docket. The docket includes both the preliminary and revised risk assessment for chlorpyrifos methyl as well as comments on the risk assessments submitted by the general public and stakeholders. During the Phase 5 Risk Management comment period which ended June 27, 2000, the Agency received five comments. Subsequent to the close of the comment period, the Agency received several hundred letters from the grain industry advising the Agency that no alternative to chlorpyrifos methyl is currently available and asking that the Agency allow enough time for continued use to provide for an orderly transition away from chlorpyrifos methyl. 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/op.

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 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 which has been expanded to include decisions and other classes of chemicals, as well.

Please note that the chlorpyrifos methyl 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. This document represents the Agency's final decision on the registration of chlorpyrifos methyl and an interim decision regarding tolerances. The Agency will issue its final decision regarding the tolerances for chlorpyrifos methyl when the cumulative assessment for all organophosphates has been completed.

This document contains labeling needed for chlorpyrifos methyl products. End-use product labels should be revised by the manufacturer in order to adopt changes set forth in Section IV of this document. Instructions for registrants on submitting revised labeling and the time frame needed are in Section V of this document.

If you have questions on this document, please contact the Special Review and Reregistration Division representative, Stephanie Nguyen at (703) 605-0702.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

# Report on FQPA Tolerance Reassessment Progress and Risk Management Decision for Chlorpyrifos methyl

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## Chlorpyrifos methyl TEAM

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## GLOSSARY OF TERMS AND ABBREVIATIONS

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

| | |
|---|---|
| HA | Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur. |
| HAFT | Highest Average Field Trial |
| HDT | Highest Dose Tested |
| IR | Index Reservoir |
| $LC_{50}$ | Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm. |
| $LD_{50}$ | Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg. |
| LEL | Lowest Effect Level |
| LOC | Level of Concern |
| LOD | Limit of Detection |
| LOAEL | Lowest Observed Adverse Effect Level |
| MATC | Maximum Acceptable Toxicant Concentration |
| MCLG | Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act. |
| mg/kg/day | Milligram Per Kilogram Per Day |
| mg/L | Milligrams Per Liter |
| MOE | Margin of Exposure |
| MP | Manufacturing-Use Product |
| MPI | Maximum Permissible Intake |
| MRID | Master Record Identification (number). EPA's system of recording and tracking studies submitted. |
| NA | Not Applicable |
| N/A | Not Applicable |
| NAWQA | USGS National Water Quality Assessment |
| NOEC | No Observable Effect Concentration |
| NOEL | No Observed Effect Level |
| NOAEL | No Observed Adverse Effect Level |
| NPDES | National Pollutant Discharge Elimination System |
| NR | Not Required |
| OP | Organophosphate |
| OPP | EPA Office of Pesticide Programs |
| OPPTS | EPA Office of Prevention, Pesticides and Toxic Substances |
| Pa | pascal, the pressure exerted by a force of one newton acting on an area of one square meter. |
| PAD | Population Adjusted Dose |
| PADI | Provisional Acceptable Daily Intake |
| PAG | Pesticide Assessment Guideline |
| PAM | Pesticide Analytical Method |

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

## Executive Summary

EPA has completed its review of 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 chlorpyrifos methyl, however, no risk mitigation proposals were received. This "Report on FQPA Tolerance Reassessment Progress and Risk Management Decision" includes the Agency's final decision regarding the registration of chlorpyrifos methyl and an interim decision regarding tolerances. A tolerance reassessment decision on remaining import tolerances will not be considered final until the cumulative risk assessment of all organophosphate pesticides is complete. The cumulative assessment may result in further revisions to tolerances for chlorpyrifos methyl.

Chlorpyrifos methyl is an organophosphate insecticide, registered for use on stored grain, including wheat, barley, oats, rice, and sorghum. It was first registered in the United States in 1985 and is formulated as 2% and 3% dust and 43% liquid (emulsifiable concentrate) end-use products. Reldan ® 2% dust is applied at a rate of 15 lbs of product (0.3 lbs a.i) per 1000 bushels, and Reldan ® 3% dust at 10 lbs product (0.3 lbs a.i) per 1000 bushels. The liquid Reldan 4E® is diluted by mixing a label-specified quantity (depending on the type of grain) of pesticide with 5 gallons of water for each 1000 bushels of grain; application rates range from 3.1 to 11.5 fluid oz of product (0.097 to 0.36 lbs a.i).

Annual domestic usage of chlorpyrifos methyl is an estimated 80,000 pounds active ingredient for approximately 267,497,000 bushels of grain. Approximately 8% of all stored wheat, 5% of sorghum and 5% of barley are treated with chlorpyrifos methyl annually.

### Overall Risk Summary

EPA's dietary (food) risk assessment for chlorpyrifos methyl indicates that neither the acute nor chronic risks exceed the Agency's level of concern; i.e., less than 100% of the acute or chronic Population Adjusted Dose (PAD) is utilized for the general U.S. population and all population subgroups.

Because of the use pattern for chlorpyrifos methyl (on stored grains and inside grain storage facilities, with no residential uses), residues in water are not anticipated and an aggregate assessment is not required. Therefore, a drinking water exposure analysis was not conducted. No risk mitigation, based on dietary risk estimates is necessary at this time.

There were no chemical-specific occupational exposure data available for chlorpyrifos methyl. Therefore, the risk assessment has been performed using surrogate data from the Pesticide Handler's Exposure Database (PHED) where available. No data, surrogate or otherwise, were available for some pesticide handler scenarios. All but one exposure scenario has risks of concern even when the appropriate PPE and engineering controls are utilized during the mixing, loading and application processes.

Postapplication risks include bystander exposure to dusts generated by grain being conveyed into, out of, or within storage containers, and dermal exposure when sampling treated grain. Personnel rarely have direct contact with the stored grain and therefore skin exposure is only a concern during short exposures such as testing of grain or maintenance work. The employees of a grain elevator or the farmer/operator who operates a portable auger to load treated grain into a bin may be exposed to treated grain dust, but inadequate data are available to quantify such exposures. Therefore, chemical-specific data for handler and postapplication exposure to insecticidal dust are required to complete the risk assessment.

Summary of Risk Mitigation

In response to a data call-in notice requiring acute, subchronic, and developmental neurotoxicity studies, the registrants requested voluntary cancellation of all chlorpyrifos methyl registrations. All dust formulations have been canceled, and sales and distribution is allowed through March 30, 2001. The use of existing stocks will be allowed through December 31, 2001, and at the end of this period, the use of the dust formulation will be canceled. Because chlorpyrifos methyl fills an important role in pest management for certain stored grains and no adequate alternative is currently available, cancellation of liquid formulations will not occur until December 31, 2003, and use of all existing stocks will be permitted until December 31 , 2004, provided certain changes are made to all product labels. The changes include deletion of all but two uses from all product labels. Only direct treatment of grain with automated admixture systems and empty bin treatment from outside the bin will be allowed.

Also, the Agency has requested additional data from the registrants in order to better characterize the risk associated with this chemical. During the phase out of this chemical, the Agency will receive from the registrants the following studies to address some of the data gaps associated with chlorpyrifos methyl (The Agency will, if necessary, make any changes to the registration as indicated by these data):

- Acute delayed neurotoxity study in hens;
- Two generation rat reproduction study;
- Acute oral toxicity -Rat;
- Acute dermal toxicity - Rabbit;
- Acute inhalation study -Rat;
- Primary ocular irritation -Rabbit;
- Primary dermal irritation- Rabbit; and
- Dermal sensitization study- Guinea pigs.

## I. Introduction

This report on the progress toward tolerance reassessment for chlorpyrifos methyl 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 chlorpyrifos methyl was first

registered in 1985, it is 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 related to pesticide registration and use.

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 reassessment of all existing tolerances in effect at the time of passage by 2006. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. 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. Until a final methodology for completion of the cumulative assessment for all of the organophosphates is established, 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 chlorpyrifos methyl has been completed; it will also be considered 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 chlorpyrifos methyl, as part of the tolerance reassessment process. The Agency has also revised occupational risk estimates for chlorpyrifos methyl.

As part of the EPA's effort to involve the public in the implementation of FQPA, the Agency is undertaking a special effort to establish 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 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 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 a Report on FQPA Tolerance Reassessment and 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. The Agency conducted such a conference call on December 20, 2000 for chlorpyrifos methyl.

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 are being developed. 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. Most issue papers have already been published for comment in the Federal Register and others will be published shortly.

In addition to the policy issues that resulted from the TRAC process, the Agency published in the *Federal Register* on a Pesticide Registration Notice that presents EPA's 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 from organophosphate pesticides. Generally, protective measures such as additional 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 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 chlorpyrifos methyl use patterns and usage. Section III summarizes the human health assessment. Section IV presents the Agency's regulatory position on this chemical. Section V discusses what the manufacturer's obligations are with respect to further actions required, and finally, Section VI provides information on how to access all 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. A Notice of Availability for this document will be published in the Federal Register.

A Notice of Availability for this document has been published in the *Federal Register*.

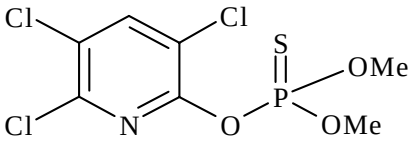
## II. Chemical Overview

### A. Regulatory History

Chlorpyrifos methyl was first registered in the United States in 1985 for use as an insecticide. This interim tolerance reassessment review is the Agency's first reevaluation of chlorpyrifos methyl since its initial registration in 1985.

### B. Chemical Identification

Chlorpyrifos methyl




| | | |
|---|---|---|
| ! | **Common Name:** | Chlorpyrifos methyl |
| ! | **Chemical Name:** | O,O-Dimethyl-O-(3,5,6-trichloro-2-pyridyl) phosphorothioate |
| ! | **Chemical Family:** | Organophosphate |
| ! | **CAS Registry Number:** | 5598-23-0 |
| ! | **OPP Chemical Code:** | 59102 |
| ! | **Empirical Formula:** | $C_7H_7CL_3NO_3PS$ |
| ! | **Trade and Other Names:** | Reldan® |
| ! | **Basic Manufacturer:** | Dow AgroSciences |

A detailed discussion on the physical properties of chlorpyrifos methyl can be found in the Chlorpyrifos methyl human health revised risk assessment: "Human Health Risk Assessment, Chlorpyrifos methyl (April 19, 2000)" which is available in the docket and on the

Internet.

### C. Use Profile

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

**Type of Pesticide:** Insecticide

**Summary of Use Sites**: Direct grain treatment, empty flour bins, commercial storage or warehouses and top dressing for grain in trucks and bins

Food: Stored grain (grain crops, barley, oats, rice, sorghum, wheat, oil crops, animal feed, grain, cereal).

Nonfood: None

Residential: No residential uses.

**Target Pests:** Chlorpyrifos methyl is used to control beetles, grain beetles, lesser grain borers, and red flour beetle.

**Formulation Types Registered**: End-use product formulations: dusts containing 2% or 3% active ingredient (7501-98) and (7501-99), and a liquid containing 43.2% active ingredient, Reldan® 4E (7501-41) and (62719-43).

**Method and Rates of Application**:

Equipment - Automated admixture systems for direct treatment of grain. Liquid application to the walls of empty grain storage containers using hand sprayers, such as backpack or high-pressure hand wands. Dusts may be applied by hand or power-duster on top of grain in storage containers, or by mixing the product with a shovel while the grain is still in the truck.

Method and Rate - The liquid Reldan 4 E® is diluted by mixing a label-specified quantity (depending on the type of grain) of pesticide with 5 gallons of water for each 1000 bushels of grain; application rates range from 3.1 to 11.5 fluid oz of product (0.097 to 0.36 lbs a.i).

High-pressure handwand or backpack sprayer for empty grain bins (5% of the annual usage); grain is treated by hand or power dusting

(top-dressing), and automated systems for liquid and dust formulations.

Reldan 2% Dust is applied at a rate of 15 lbs. of product (0.3 lbs. a.i) per 1000 bushels, and Reldan 3% Dust at 10 lbs. product (0.3 lbs. a.i) per 1000 bushels.

**Use Classification:** Chlorpyrifos methyl currently is an unclassified chemical.

### D. Estimated Usage of Pesticide

Based on 1989 through 1998 usage information, the Agency estimates that chlorpyrifos methyl's total domestic usage averages approximately 80,000 pounds active ingredient for 267,497,000 bushels treated. About 80% of the total pounds of chlorpyrifos methyl a.i. is applied to wheat. Approximately 8% of all stored wheat, 5% of sorghum and 5% of barley are treated with chlorpyrifos methyl.

## III. Overview of Chlorpyrifos methyl Human Health Risk Assessment

Following is a summary of EPA's human health risk findings for the organophosphate pesticide chlorpyrifos methyl, as fully presented in the document, "Chlorpyrifos methyl. Human Health Risk Assessment. Chemical Number 059102" dated April 19, 2000. The risk assessment forms the basis of the Agency's risk management decision for chlorpyrifos methyl. However, the Agency must complete a cumulative assessment of the risks of all organophosphate pesticides which will include consideration of the chlorpyrifos methyl tolerances.

Using relevant data, published scientific literature, and available surrogate data, the Agency assessed the human health risks associated with using chlorpyrifos methyl on stored grain, including wheat, barley, oats, rice, sorghum and post-binning (grain storage bins). There are no residential or other non-occupational use sites and no water exposure is anticipated; therefore, in quantifying aggregate risks, the Agency considered exposures from food only. The results of the food analysis indicate that acute and chronic aggregate risk are not of concern.

An occupational risk assessment was also conducted for mixers, loaders, and applicators using chlorpyrifos methyl on and around stored grain. The results are summarized below in section D.

## 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 chlorpyrifos methyl alone and does not consider the cumulative risk from all other organophosphates. The No Observed Adverse Effect Level (NOAEL) of 1 mg/kg/day used in the acute dietary assessment was selected from a rat developmental study based on inhibition of red blood cell cholinesterase activity at a Lowest Observed Adverse Effect Level (LOAEL) of 12.5 mg/kg/day. The NOAEL = 0.1 mg/kg/day used in the chronic dietary assessment was selected from a combined rat chronic/carcinogenicity study based on plasma cholinesterase activity at a LOAEL of 1 mg/kg/day. At the LOAEL, cholinesterase activity decreased 40-45%. At the next highest dose tested, 50 mg/kg/day, plasma cholinesterase activity was depressed 85-94% and brain cholinesterase activity was depressed 37-47%.

### 2. FQPA Safety Factor

The FQPA 10x Safety Factor was retained. The inadequacy of the toxicological data base precluded an evaluation of potential increased susceptibility to infants and children. A total uncertainly factor of 1000x (10x for inter-species extrapolation; 10x for intra-species variability; and the 10x FQPA safety factor) applies to all subpopulations and for all durations of exposure. The potential for chlorpyrifos methyl to induce delayed neurotoxicity remains open because the acute study was considered equivocal and a repeat study is needed. A subchronic hen study did not indicate delayed neuropathy at levels up to and including 500 mg/kg/day. The developmental toxicity assessment is considered incomplete; only a rat study is available. No acceptable rabbit (or second species) study is available and there is no acceptable multi-generation reproduction study. In the rat developmental toxicity study there were no developmental effects observed at the highest dose tested (50 mg/kg/day); the maternal NOAEL was 1.0 mg/kg/day based on decreased cholinesterase activity at the LOAEL of 12.5 mg/kg/day. Since the developmental toxicity data base is incomplete, the assessment for increased susceptibility to fetuses and neonates is also incomplete.

### Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose (RfD) (the maximum dose of a substance that is anticipated to have no adverse human health effect when taken daily over a specific time period), that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor).

In the case of chlorpyrifos methyl, the FQPA safety factor is 10x; therefore, the acute or chronic RfD/10 = the acute or chronic PAD. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern. An acute Population Adjusted Dose (aPAD) of 0.001 mg/kg/day was used for the acute dietary risk assessment. For the chronic dietary risk

assessment, a chronic Population Adjusted Dose (cPAD) of 0.0001 mg/kg/day was used. The toxicological endpoints and uncertainty factors used in the assessments are summarized in Table 1.

**Table 1: Summary of Toxicological Endpoints Used in the Human Dietary Risk Assessment**

| Assessment | Dose | Endpoint | Study | UF | FQPA Safety Factor | PAD |
|---|---|---|---|---|---|---|
| Acute Dietary | NOAEL= 1.0 mg/kg/day LOAEL=12.5 | Inhibition of red blood cell cholinesterase | Developmental toxicity in rats | 100 | 10x | 0.001 mg/kg/day |
| Chronic Dietary | NOAEL= 0.1 mg/kg/day<br><br>LOAEL=1.0 | Inhibition of plasma cholinesterase | Combined chronic/ carcinogenicity in rats | 100 | 10x | 0.0001 mg/kg/day |

### 3. Exposure Assumptions

The Dietary Exposure Evaluation Model (DEEM™) was used to estimate the dietary exposure based on individual consumption data from USDA's 1989-1992 nationwide Continuing Survey of Food Intake by Individuals (CSFII). For the acute dietary assessment, risk is calculated considering what is eaten in one day (consumption) and residues potentially present on foods. For chronic exposures, dietary risk is calculated by using the average consumption value for food and average residue value. These estimates are highly refined using anticipated residues based on PDP monitoring data and percent crop treated.

### 4. Food Risk Characterization

Both acute and chronic dietary risk estimates for chlorpyrifos methyl are below the Agency's level of concern (<1 00% PAD) for all population subgroups. For the highest exposed population subgroup, children 1-6, 30% of the acute PAD is occupied, at the 99.9th percentile of exposure. For the highest exposed population subgroup, children 1-6, 52% of the chronic PAD is occupied.

## B. Dietary Risk from Drinking Water

Because of the use pattern for chlorpyrifos methyl (on stored grains and inside grain storage facilities), residues in water are not anticipated. Therefore, a drinking water exposure analysis was not conducted.

## C. Aggregate Risk

Because of the use pattern for chlorpyrifos methyl (no residential uses and no drinking water exposure) an aggregate assessment is not required.

## D. Occupational Risk

Occupational exposure to a pesticide can occur through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Handlers of chlorpyrifos methyl include: individuals who mix, load, and/or apply chlorpyrifos methyl on and around stored grain. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a NOAEL. The ratio of the estimated exposure to the NOAEL is referred to as the Margin of Exposure (MOE). For chlorpyrifos methyl, MOEs greater than 100 are not of concern.

### 1. Toxicity

For the occupational short-term dermal and inhalation risk assessments, a NOAEL of 1.0 mg/kg/day was selected from an oral rat developmental study based on inhibition of red blood cell (RBC) cholinesterase activity at the LOAEL of 12.5 mg/kg/day. For the intermediate-term assessments, a NOAEL of 0.1 mg/kg/day based on inhibition of plasma cholinesterase activity at the LOAEL of 1.0 mg/kg/day was selected from a combined oral rat chronic/carcinogenicity study. A dermal absorption of 3% was used based on comparison of the oral and dermal toxicity of chlorpyrifos-(-ethyl). This is considered reasonable due to the similarity of the physical characteristics affecting absorption for these two chemicals. Inhalation absorption was assumed to be 100%. The toxicological endpoints for chlorpyrifos methyl are summarized in Table 2.

**Table 2. Toxicology Endpoints Selected for Occupational Risk Assessment**

| Assessment | Dose (mg/kg/day) | Endpoint | Study | Absorption Factor |
|---|---|---|---|---|
| Short Term (1-7 days) (Dermal) | NOAEL = 1<br><br>LOAEL=12.5 | RBC cholinesterase inhibition (ChEI) | Developmental toxicity in rats (oral) | 3% |
| Intermediate Term<br>(7 days - several months) (Dermal) | NOAEL = 0.1 | Plasma cholinesterase activity | Combined chronic/ carcinogenicity in rats (oral) | 3% |
| Short Term (1-7 day)<br>(Inhalation) | NOAEL = 1 | RBC ChEI | Developmental toxicity in rats (oral) | 100% |
| Intermediate Term<br>(7 days - several months) (Inhalation) | NOAEL = 0.1 | Plasma cholinesterase activity | Combined chronic/ carcinogenicity in rats (oral) | 100% |

## 2. Exposure

EPA has determined that there are potential exposures to mixer/loaders, applicators, and other handlers for use-patterns associated with chlorpyrifos methyl. The major use patterns for chlorpyrifos methyl considered in the occupational risk assessment are discussed below.

Admixture: Pesticide is mixed with grain as it enters the storage container. The labels do not specify the type of equipment to use. For grain, Reldan ®2% Dust is applied at a rate of 15 lbs. of product (0.30 lbs. a.i) per 1000 bushels, and Reldan® 3% Dust at 10 lbs. product (0.3 lbs. a.i) per 1000 bushels. In contrast, the liquid Reldan® 4E is diluted by mixing a label-specified quantity (depending on the type of grain) of pesticide with 5 gallons of water for each 1000 bushels of grain. Wheat is the largest treated commodity, so the rate at which Reldan® 4E is applied to wheat (0.36 lbs. a.i per 1000 bushels) is used for assessment purposes.

Top-Dress Treatment: Pesticide is applied to the top surface of stored grain to act as a barrier to infestation. The grain may be fumigated with another product prior to the top-dressing. The worker/applicator may climb into the storage container to add the dust. This can be physically stressful as the worker will typically sink in to knee depth or deeper. Sometimes dust is blown into the container from the opening. If the grain is in a truck or wagon, the dust formulation is applied and then "cut into the grain with a shovel," prior to loading into the storage container. Due to the physical nature of this task, and based on consultation with agricultural authorities, the Agency estimates one applicator could treat a maximum of 3 large silos (2000 $ft^2$ each) or one farm truck per day. As a top-dressing, both the Reldan® 2% and 3% dust are applied up to 7 lbs. product per 1000 square feet. Reldan® 4E liquid is not used for top-dressing, based on the label.

Empty Bin Treatment: Reldan® 4E liquid is labeled for use as a bin treatment after removal of all grain and waste from the container. One pint of Reldan® 4E is mixed with 3 gallons of water to provide an approximately 1% spray, which is then applied to walls and floors at one gallon per 650-1250 square feet. For assessment purposes, a one gallon/650 square feet rate (maximum label rate) was chosen. The application rate per day was based upon the Agency's policy for practical maximum daily spray volumes multiplied by square footage per gallon.

Current labels for both dust and liquid formulation require rubber gloves and eye protection. Table 3 shows the levels of personal protective equipment (PPE) assumed in the occupational assessment.

**Table 3 : PPE Assessed in Occupational Assessment for Chlorpyrifos methyl**

| Level of PPE | Loaders and Mixers | Loaders/Mixers/Applicators |
|---|---|---|
| Minimum | Long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, protective eyewear. | Long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, protective eyewear. |
| Maximum | Coveralls over long-sleeved shirt and long pants, shoes plus socks, chemical- resistant gloves, protective eyewear, respirator. | Coveralls over long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, protective eyewear, respirator |

Handler Exposure Estimates

For several scenarios, exposure data were very limited or unavailable. The most reliable exposure data are for mixing and loading the liquid formulation (i.e., for automated admixture systems) and for mixer/loader/applicators of the liquid formulation to empty grain storage bins. But only 5% of the annual usage of a.i. (based on Quantitative Usage Analysis dated 4/19/98 by BEAD) is for treatment of empty grain storage bins, and approximately 95% is for grain protection. Little exposure information is available for application of either the dust or liquid product to grain. Therefore, most of the exposure estimates were surrogate values derived from the Pesticide Handler Exposure Database (PHED) Version 1.1.

Because no PHED or EPA-reviewed study data were available for occupational exposure from application of insecticide dust, an attempt was made to characterize the magnitude of exposure, and also the risk, by using a study from the scientific literature. The study selected was reported by the American Chemical Society. The study measured exposures by passive dosimetry of 12 volunteers applying three different formulations of carbaryl - dust, wettable powder, and aqueous suspension - to corn and beans in a garden for 15 minutes to each crop. Although the assumption that clothing is 50% protective from dust may overestimate exposure, and the dust formulation measured in the study was 5% a.i (vs. Reldan® 3%), the application scenario may be a reasonable surrogate for hand applications to grain. Because the worker applying dust to grain can be standing in the grain, it is expected that dermal exposure would be greater than dusting plants in a garden. The risk estimates are based only on dermal exposure because the Agency has inadequate data to assess inhalation exposure from dust formulations. However, these data are used to provide an initial attempt to characterize the applicator's dose. Table 4 summarizes the occupational scenarios assessed and the assumptions used for chlorpyrifos methyl.

**Table 4: Assumptions Used in Estimating Worker Short- and Intermediate-Term Exposure**

| Exposure Scenario | Application Rate (lbs. ai/gal or /1000 $ft^2$ or /1000 bu.) | Daily Bushels, $Ft^2$, or Gallons Treated [1] |
|---|---|---|
| Mixer/Loader Exposure | | |
| Loading Dusts for Automated Application Systems [2] | 10 lbs. Reldan® 3%/1000 bu<br>or<br>15 lbs. Reldan® 2%/1000 bu<br>= 0.3 lbs. ai/1000 bu | 10,000 bu/hr*8hrs=<br>80,000 bu |
| Mixing/Loading Liquids for Automated Application [3]<br>[ex: wheat] | 1% solution =<br>11.5 oz Reldan® 4E/5 gal $H^2O$/1000 bu =<br>0.36 lbs. ai/1000 bu | 10,000 bu/hr*8hrs=<br>80,000 bu |
| Mixer/Loader/Applicator Exposure | | |
| Handheld Dust Pump [4] for (a) treating wagon or truckload or (b) top dressing grain in storage container | 10 lbs. Reldan® 3%/1000 bu =<br>0.3 lbs. ai/1000 bu<br>7 lbs. Reldan® 2-3%/1000 $ft^2$ =<br>0.21 lbs. ai/1000 $ft^2$ | 300-1000 bu/farm wagon or truck * 10<br>or<br>7 bins/day = 3,150 $ft^2$ |
| Power Duster [5] for (a) treating wagon or truckload or (b) top dressing grain | b)10 lbs. Reldan® 3%/1000 bu<br>or<br>15 lbs. Reldan ® 2%/1000 bu<br>= 0.3 lbs. ai/1000 bu<br>a)7 lbs. Reldan ® 3%/1000 $ft^2$ =<br>0.21 lbs. ai/1000 $ft^2$ | 300-1000 bu / farm wagon or truck * 10<br>or<br>7 bins/day = 3,150 $ft^2$ |
| Backpack Sprayer [6]<br>for Grain Bin and Warehouse (for spraying walls) | 1% = 8oz Reldan ® 4E/3 gal $H^2O$=<br>0.25 lbs. ai/3gal<br>1 gal 1% solution/650 $ft^2$ | 24 gal (diluted)<br>(15,600 $ft^2$) |
| High Pressure Handwand (for spraying walls) [7] | 1% = 8oz Reldan ® 4E / 3 gal $H^2O$=<br>0.25 lbs. ai/3gal<br>1 gal 1% solution/650 $ft^2$ | 40 gal (diluted)<br>26,000 ft |

[1] Daily area treated (or gallons applied) values are from EPA estimates of area (or gallons) that could be treated in a single day for each exposure scenario. Assistance was received from agricultural extension agents. For example:

- Estimate of Mixer/Loader exposure for application of liquid Reldan 4E (43% ai) to grain (wheat): wheat application rate for final concentration of 6 ppm = 11.5 oz product/5gal water/1000 bushels = 0.09 gal product / 5 gallons water/ 1000 bu; = 0.09 gal x 4 lbs. ai/ gal; = 0.36 lbs. ai / 1000 bu; estimated 80,000 bushels/day [10,000 bu/hr loading x 8 hrs] x 0.36 lb ai/ 1000 bu = 29 lbs. ai/day
- Hand-held duster application for truck load treatment assumes 1000 bushels/truck load.
- Hand-held duster application for grain top-dressing assumes 60,000 bu bins @ 450 $ft^2$ x 7/ day = 3150 $ft^2$
- Insufficient data to characterize application rate for power duster in truck, bin, or silo
- Backpack sprayer (3 gallons) assumed to apply maximum of 8 tanks per day due to practical limitations, assuming one person mixing, loading and applying (MLAP). Therefore 3 gal/tank x 8 tanks=24 gal x 650 $ft^2$ /gal= 15,600 $ft^2$; 0.25 lbs. ai/tank x 8 tanks = 2 lbs. ai/day.
- High pressure handwand application assumed to apply maximum of 40 gallons per day = 40gal x 650 $ft^2$/gal = 26,000 $ft^2$; 40gal/day x 0.25 lbs. ai/3gal tank = 3.3 lbs. ai/day.

Mixer

[2]Open loading dusts [wettable powder] for automated application systems (800 lbs. of 3% dust or 24 lbs. ai per day)

[3]Mixing/Loading liquids for automated application (400 gallons of dilute liquid or 29 lbs. ai per day)

[4] (a) Treating grain in trucks with a hand-held duster (100 lbs. of 3% dust or 3 lbs. ai per day)
(b) Top dressing grain with dust by hand pump inside bins (0.66 lb. ai per day)

[5] (a) Treating grain in trucks with a power duster (no data)

(b) Top dressing grain with dust by power duster (no data)
[6] Mixing, loading, and spraying empty bins with backpack sprayers (24-40 gallons or 2-3.3 lb ai per day)
[7] Mixing, loading, and spraying empty bins with high pressure handwand sprayer (24-40 gallons or 2-3.3 lbs. ai per day)

Postapplication Exposure

Postapplication risks include bystander exposure to dusts generated by grain being conveyed into, out of, or within storage containers, and dermal exposure when sampling treated grain. Personnel rarely have direct contact with the stored grain; therefore, dermal exposure is only a concern during short exposures for testing of grain. Bystander dust exposure may be significant for either the employee of a grain elevator or farmer/operator who operates a portable auger to load treated grain into a bin.

Little data are available to quantify post-application risks to workers or bystanders. Exposure to pesticide residues on grain dust during off-loading to rail cars or vessels is a potential health hazard, as is inhalation of the grain dust itself.

## 3. Handler Risk Characterization

Of the six exposure scenarios assessed, all but direct grain treatment of liquid product using an automated system are of concern, even with maximum PPE. For mixing/loading scenario for automated application, hand-held duster application, only dermal exposure was assessed because no data are available for inhalation exposure. Consequently, the risk estimate shown below may underestimate risk. The following table summarizes mixer/loader/applicator risks:

**Table 5: Summary of Combined Dermal and Inhalation MOEs**

| Scenario | lbs a.i/day | Minimum PPE [1] | | Maximum PPE[2] | |
|---|---|---|---|---|---|
| | | Short-Term | Intermediate- Term | Short-Term | Intermediate-Term |
| Mixer/Loader | | | | | |
| Open loading dust for automated application system [3] | 24 | 53 | 6.0 | 200 | 23 |
| Mixing/Loading Liquids for automated application [4] | 29 | 1000 | 130 | 2700 | 320 |

| Mixer/Loader/Applicator | | | | | |
|---|---|---|---|---|---|
| Hand-Held Duster (a [5]) Treating Grain in Trucks or (b [5]) Top-dressing Grain with dust by hand-pump | 3 | 3.3 [dermal only] | 0.39 [dermal only] | 4.7 [dermal only] | 0.54 [dermal only] |
| | 0.66 | 15 [dermal only] | 1.8 [dermal only] | 21 [dermal only] | 2.5 [dermal only] |
| Power Duster (a [6]) treating grain in trucks or (b [6]) top dressing grain with dust by power duster | No Data | No Data | No Data | No Data | No Data |
| Backpack Sprayer for empty bin treatment [7] | 2 | 290 | 34 | 560 | 64 |
| High Pressure Handwand Sprayer for empty bin treatment [8] | 3.3 | 93 | 11 | 260 | 29 |

[1] Minimum PPE consist of wearing a long-sleeved shirt.
[2] Maximum PPE consist of wearing a long-sleeved shirt plus coveralls and a respirator.
[3] Open loading dusts [wettable powder] for automated application systems (800 lbs. of 3% dust or 24 lbs. ai per day)
[4] Mixing/Loading liquids for automated application (400 gallons of dilute liquid or 29 lbs. ai per day)
[5] (a) Treating grain in trucks with a hand-held duster (100 lbs. of 3% dust or 3 lbs. ai per day)
(b) Top dressing grain with dust by hand pump inside bins (0.66 lb. ai per day)
[6] (a) Treating grain in trucks with a power duster (no data)
(b) Top dressing grain with dust by power duster (no data)
[7] Mixing, loading, and spraying empty bins with backpack sprayers (24-40 gallons or 2-3.3 lb ai per day)
[8] Mixing, loading, and spraying empty bins with high pressure handwand sprayer (24-40 gallons or 2-3.3 lbs. ai per day)

### 4. Postapplication Risk Characterization

Postapplication risks include bystander exposure to dusts generated by grain being conveyed into, out of, or within storage containers, and dermal exposure when sampling treated grain. Personnel rarely have direct contact with the stored grain and therefore dermal exposure is only a concern during short exposures for testing of grain, maintenance, or other intermittent activities. Bystander dust exposure may be significant for either the employee of a grain elevator or farmer/operator who operates a portable auger to load treated grain into a bin. Chemical-specific data for postapplication exposure to insecticidal dust would be needed to complete the risk assessment.

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

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

This evaluation presents the Agency's current position on products containing the active ingredient chlorpyrifos methyl. The Agency has sufficient information on the human health effects of chlorpyrifos methyl to make interim decisions as part of the tolerance reassessment

process under FQPA. Based on its current evaluation of chlorpyrifos methyl alone, the Agency has determined that chlorpyrifos methyl products, as labeled, will not present unreasonable dietary risks of concern, but the occupational risks exceed the Agency's level of concern. Recently, the registrants, Gustafson and Dow AgroSciences, submitted a request to voluntarily cancel all chlorpyrifos methyl product registrations in response to a Data Call-In for neurotoxicity data.

This document reflects the Agency's final decision on the registration of chlorpyrifos methyl. The Agency will finalize the decision for chlorpyrifos methyl tolerances after evaluating the cumulative risk of the organophosphate class of pesticides. 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 food residue tolerances as required by section 408(q) of FQPA. When the Agency has completed the cumulative assessment, chlorpyrifos methyl's reassessment decisions for the remaining import 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 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 evaluation does not limit the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future. If the Agency determines, 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 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 April 28, 2000 in a Federal Register Notice (65 FR 83, Page 24954-24955). Interested parties were provided a 60-day period to submit comments, including risk mitigation proposals. Comments received during the 60-day public comment period were from Hansen Mueller, Central Washington Grain Growers, Inc., OSU Pesticide Applicator Education Office, Gustafson LLC-Western Region.

Gustafson and the grain industry submitted information on worker exposure. The grain industry has requested that it be allowed to continue using chlorpyrifos methyl for pest control until a suitable alternative is available. Some users stated that additional data requests from the Agency are too costly. They also questioned why EPA rejected human data for chlorpyrifos-methyl, while human data were used in malathion and pirimiphos-methyl risk assessments.

The Agency is aware of the importance of chlorpyrifos methyl to a segment of the grain

industry. This document describes the phase-out for this pesticide which the Agency believes provides the opportunity for a reasonable transition away from chlorpyrifos methyl containing products. The chlorpyrifos methyl usage information submitted by the registrant and others were limited and generally consistent with the assumptions used in the Agency's assessment. The Agency does not have a human study for chlorpyrifos methyl nor is the Agency aware of one. The Agency is reviewing its policy regarding the use of human studies. The Agency's interim policy is that we will not rely on any human testing for toxicity in making final decisions under the FQPA until we have a robust policy in place that can ensure that any such studies meet the highest scientific and ethical standards.

In addition to the comments received during the formal comment period, the Agency received several hundred letters from the user community. These letters stress the importance of chlorpyrifos methyl to a segment of the grain industry and that there are no registered alternatives for direct grain treatment. They request the use of chlorpyrifos methyl be allowed for a sufficient period of time to allow for the registration of a viable alternative pesticide product. The Agency acknowledges the importance of this pesticide for a segment of the grain industry. The phase-out period is intended to allow time to transition to alternative pest management strategies.

## 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 based on available data, risk from exposure to chlorpyrifos methyl is within its own "risk cup." In other words, if chlorpyrifos methyl did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for chlorpyrifos methyl on stored grain 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. Because of the use pattern for chlorpyrifos methyl (no residential uses and no drinking water exposure) an aggregate assessment is not required.

The chlorpyrifos methyl tolerances remain in effect. However, in the near future, the Agency intends to issue a proposed notice to revoke tolerances that will no longer be necessary

and reduce other tolerances. These modifications would take into account the time necessary for legally treated grain to clear the channels-of-trade.

### b. Tolerance Summary

Table 6 provides the current tolerance levels for chlorpyrifos methyl [O,O-Dimethyl-O-(3,5,6-trichloro-2-pyridyl)phosphorothioate], as defined in 40 CFR §180.419, as well as proposed changes based on EPA assessment. It also includes the tolerances that the Agency will propose to revoke or reduce effective after the cancellation has occurred and legally treated commodities have moved through the channels-of-trade.

When the cancellation of all chlorpyrifos methyl products has occurred, grain related tolerances, except for wheat gluten will be revoked because they will no longer be needed. The tolerance for the wheat will be modified to be for the wheat processed commodity bran and germ at 20 ppm. The poultry and egg tolerances will be reduced by ten-fold or more. The remaining milk, meat, and egg tolerances will be considered in the Agency's cumulative assessment of the organophosphates. Therefore, these tolerance actions are interim pending the completion of the cumulative assessment of the organophosphates.

**Table 6: Tolerance Summary for Chlorpyrifos methyl**

| Commodity | Tolerance Listed Under 40CFR § 180.419 (ppm) | Proposed Tolerance (1999 Revised EPA Risk Assessment) |
|---|---|---|
| Barley | | |
| grain | 6.0 | Revoke |
| milling fractions (except flour) | 90.0 | Revoke |
| Oats | | |
| grain | 6.0 | Revoke |
| milling fractions (except flour) | 130.0 | Revoke |
| Rice, grain | | |
| grain | 6.0 | Revoke |
| milling fractions (except flour) | 30.0 | Revoke |
| Sorghum | | |
| grain | 6.0 | Revoke |
| milling fractions (except flour) | 90.0 | Revoke |
| Wheat | | |
| bran | 30.0 | 20.0 (processed commodity) _____ |
| germ | 30.0 | 20.0 (processed commodity) _____ |
| Cattle, fat | 0.5 | 0.5 |
| Cattle, meat | 0.5 | 0.5 |
| Hogs, fat | 0.5 | 0.5 |
| Hogs, meat by products | 0.5 | 0.5 |
| Milk | 0.05 | 0.05 |
| Milk, fat | 1.25 | 1.25 |
| Poultry, fat | 0.5 | 0.05 |
| Poultry, meat byproducts | 0.5 | 0.01 |
| Poultry, meat | 0.5 | 0.01 |
| Eggs | 0.1 | 0.01 |
| Sheep, fat | 0.5 | 0.05 |
| Sheep, meat | 0.5 | 0.05 |
| Sheep, meat by-products | 0.5 | 0.05 |

### 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, chlorpyrifos methyl may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

### 3. Label Modifications

The regulatory rationale for each risk mitigation measure is discussed below. Specific labeling is in Table 7.

## D. Regulatory Rationale

### 1. Dietary (Food) Risk Mitigation

Based on analyses of both acute and chronic dietary risk, the Agency has determined that the risk estimates are below the Agency's level of concern; therefore, no mitigation measures are necessary at this time.

### 2. Dietary (Water) Risk Mitigation

No drinking water exposure is anticipated from current uses; therefore, no mitigation is necessary at this time.

### 3. Aggregate (Food + Water) Risk Mitigation

No mitigation for aggregate risk mitigation is necessary because no exposure is likely from drinking water and there are no residential uses.

### 4. Occupational Risk Mitigation

The Agency is concerned about exposures resulting to handlers of dust and liquid formulations of chlorpyrifos methyl. Levels of concern are exceeded for all but one scenario; mixing and loading liquids for direct grain treatment using an automated system. The data available to estimate exposures are limited or nonexistent for most scenarios, which increases the concern of risk to workers. Of particular concern is the risks posed from applications involving the dust formulations. Given the manner in which these formulations are applied (as previously discussed), the opportunity for exposure is great, particularly through the inhalation route. The registrants have, in response to the Agency's concerns, agreed to the voluntary cancellation of all dust formulations with existing stocks permitted to be sold and distributed by the registrant until March 30, 2001, and use until December 31, 2001.

The registrants have also agreed to measures that address the risks from handling liquid formulations. Two uses will be allowed to continue until December 31, 2004, at which time these uses will be canceled. The other uses of the liquid formulation will be voluntarily canceled immediately. The two uses that will be allowed to continue are the empty bin treatment and the direct treatment of stored grain with an automated system. To reduce exposure from treating empty bins, the labeling will be amended to only allow treatment as a downward spray from outside the bin (as opposed to the applicator spraying while inside the bin). By requiring the applicator to be outside the bin during treatment and requiring the use of a respirator in addition to the minimum PPE (long sleeved shirt, long pants, shoes, socks, chemical resistant gloves, and eye protection), the Agency believes that exposures will be mitigated to the greatest extent possible during the time this use is allowed to continue. The other use of the liquid that will be allowed to continue until 2004 is the direct grain treatment in automated systems. This use does not pose risks of concern to mixers and loaders, assuming use of minimum PPE. The last use date for these two uses will be December 31, 2004.

## V. What Registrants Need to Do

### A. Generic Data Requirements

The data base supporting the continued registration of chlorpyrifos methyl has been reviewed and there are significant data gaps. Chemical-specific data for handler and postapplication exposure to insecticidal dust are required to complete the risk assessment, and the following data gaps remain:

| | |
|---|---|
| 870.1100 | Acute oral toxicity-Rat |
| 870.1200 | Acute dermal toxicity -Rabbit |
| 870.1300 | Acute inhalation study- Rat |
| 870.2400 | Primary ocular irritation-Rabbit |
| 870.2500 | Primary dermal irritation-Rabbit |
| 870.2600 | Dermal sensitization study- Guinea pigs |
| 870.6100 | Delayed neurotoxicity study - Hens |

| | |
|---|---|
| 870.6200 | Acute neurotoxicity study - Rat |
| 870.3200 | Subchronic dermal toxicity study - Rat or Rabbit |
| 870.4100 | Chronic toxicity-Dog |
| 870.3700 | Prenatal developmental study - Rabbit |
| 870.3800 | Two-generation reproduction study - Rat |
| 870.6300 | Developmental neurotoxicity study -Rat |
| 870.7485 | General metabolism-Rat |
| 860.1500 | Crop Field Trial- Aspirated Grain Fraction |

A Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA. DCI requirements included acute, subchronic, and developmental neurotoxicity studies. In lieu of developing data to address the neurotoxicity and other data gaps, the registrant has decided to voluntarily cancel registered uses. The tolerances for import uses will remain effective, and will not be canceled. However, since these tolerances have been reduced by 10-fold or more, they are not a concern because the levels are non-detectable.

To address some of the data gaps and allow EPA to better characterize the risks associated with chlorpyrifos methyl during the phase out period, the registrant has agreed to provide EPA with an acute delayed neurotoxicity study in December 2001, and a two-generation rat reproduction study in December, 2002.

### B. Manufacturing Use Products

Labels changes are necessary to assure that end-use products can only be produced that conform with the amendments listed in Table 7.

### C. 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 7.

### D. Existing Stocks

The existing stocks provision will be determined after EPA has considered all comments received on the chlorpyrifos methyl 6(f) notice, i.e., Notice of Receipt of Request for Voluntary Cancellation. Barring substantive comments, EPA anticipates the dates would be as follows:

<u>For dust formulations</u>:

- Products would not be sold or distributed by registrants after March 31, 2001.
- All other persons would not sell, distribute or use after December 31, 2001.

<u>For liquid formulations</u>:

-Registrants would not sell or distribute products bearing old labeling after the stamped approval date of new labels, i.e., labels that conform to the provisions of this document.
-Registrants could sell, and distribute products bearing labeling that conforms to Table 7 and other provisions set forth in this document until December 31, 2003.

EPA is concerned that no use of chlorpyrifos methyl on grain takes place after December 31, 2004. Since it takes approximately four years for treated grain to cycle through the channels of trade, the Agency intends to revoke most tolerances in 2008. Thus the use of chlorpyrifos methyl after December 31, 2004 may result in adulterated commodities. In lieu of putting end use dates on the label, registrants have agreed to notify their distributor of the last use date and the rationale for it.

### E. Transition Strategy

E. Transition Strategy

EPA recognizes the importance of chlorpyrifos methyl to grain storage, particularly for on-farm storage and the smaller country elevators. The Agency also understands that USDA policy is to encourage growers to increase on-farm grain storage capacity. Because of the importance of chlorpyrifos methyl to on-farm grain storage, a reasonable transition to alternative means of pest control is provided as the voluntary cancellation proceeds. Researchers at land grant universities and the USDA Agricultural Research Service are working to identify potential alternatives to chlorpyrifos methyl. EPA is committed to continue work with USDA, registrants, and growers to assure that stored grain is adequately protected from pest pressure. The Agency is working very closely with USDA to assess pesticide and integrated management approaches currently being evaluated as potential replacements for chlorpyrifos methyl. EPA and its stakeholders will expeditiously assess the viability of any compounds identified as alternatives to chlorpyrifos methyl. In this vein, the Agency is evaluating possible alternatives such as cyfluthrin and spinosad which may need to be used in combination with other active ingredients.

Prior to the cancellation of chlorpyrifos methyl liquid products, the Agency in consultation with USDA will assess progress being made toward developing alternatives. If it can be determined that all reasonable efforts have been made towards developing a reduced risk alternative to chlorpyrifos-methyl, and if a viable alternative is not found or available, the Agency will reevaluate the phase-out, and determine if an extension of the phase out is appropriate. This reevaluation would occur around the middle of 2003.

## F. Labeling

**Table 7: Summary of Labeling Changes for Chlorpyrifos methyl**

| Description | Amended Labeling Language | Placement on Label |
|---|---|---|
| | | |
| On all MUPs | Only for formulation into liquid insecticide products intended for the following uses: Empty grain bin treatment; Direct grain treatments when applied through automated systems only.<br>This product may not be formulated into end use products after December, 31 2003.<br>The registrant will notify users of the last use date. | Directions for Use |
| One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group | This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."<br><br>"This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." | Directions for Use |
| Environmental Hazards Statements based on the RED and Agency Label Policies | This product is toxic to fish, birds, and other wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA." | Precautionary Statements |

**Table 7: Summary of Labeling Changes for Chlorpyrifos methyl**

| Description | Amended Labeling Language | Placement on Label |
|---|---|---|
| | | |
| Handler PPE Requirements[1] | "Personal Protective Equipment (PPE)<br><br>Mixers, Loaders, Applicators and other handlers systems: must wear:<br><br>long-sleeved shirt and long pants,<br>chemical-resistent gloves (such as[2])<br>shoes plus socks<br>and protective eyewear[3]<br><br>In addition, applicators applying to empty grain bins must wear:<br><br>A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C[*] *or* a NIOSH-approved respirator with any N[4] R, P, or HE filter.<br><br>See Engineering Controls for additional requirements." | Precautionary Statements: Hazards to Humans and Domestic Animals |
| User Safety Requirements | "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." | Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following the PPE requirements) |
| Engineering Controls | "Engineering Controls<br><br>Handlers applying directly to grain must use an automated admixture system. The system must apply the pesticide directly to the grain and transfer treated grain directly into stationary storage facilities." | Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following PPE and User Safety Requirements.) |

**Table 7: Summary of Labeling Changes for Chlorpyrifos methyl**

| Description | Amended Labeling Language | Placement on Label |
|---|---|---|
| User Safety Recommendation | "Users and persons in the treated area should avoid inhalation of treated grain dust."<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: Hazards to Humans and Domestic Animals (immediately following Engineering Controls) |
| Environmental Hazards Statement | This pesticide is toxic to fish, birds, and other wildlife. Do not apply directly to water. Do not contaminate water by cleaning of equipment for disposal of wastes. Do not discharge directly or indirectly to surface water. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. | Precautionary Statements |
| 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."<br><br>"Empty grain bin treatment applications are only permitted from outside of the bin. Only downward spray is permitted. All openings, except for the point of application, must be closed during application.'<br><br>"This product may only be applied to empty grain bins using high pressure hand held or automated spray equipment." | Directions for Use |
| Entry Restrictions | "Do not enter or allow others to enter until sprays have dried."<br><br>"Avoid contact with treated grain until liquid has dried." | Directions For Use |

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

[2] Registrant inserts correct glove material as per Supplement Three of PR Notice 93-7.

[3] Usually, eye protection is not mentioned at this stage in the process; however, because this chemical is not subject to product reregistration nor is a product specific DCI being issued, eye protection is included in this document.

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

Instructions in the “Amended Labeling Language” section appearing in quotations represent the exact language that should appear on the label.

### G. Procedure and Timing for Label Amendment

Registrants have submitted applications for amended registration on April 20, 2001. Any additional amendments to the registration 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:

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

Attn: Dennis McNeilly
Insecticide/Rodenticide Branch (7505C)

## 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 October 6, 1999. On December 5, 1999, the first public comment period closed. EPA then considered comments, revised the risk assessment, and placed the revised risk assessment in the docket on April 28, 2000. 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/op/).

**References:**


1. Gary Bangs (USEPA/OPPTS/OPP/HED), Chlorpyrifos methyl. Human Health Risk Assessment. Chemical Number 059102. (DP Barcode D292273) 4/19/2000.

2. Gary Bangs (USEPA/OPPTS/OPP/HED)Chlorpyrifos methyl-Revised HED Occupational and Residential Exposure Chapter for the HED Risk Assessment. Chemical Number 059102. DP Barcode (D265058) 04/17/2000.

3. Sarah Levy (USEPA/OPPTS/OPP/HED), Revised Chlorpyrifos methyl: Residue Chemistry Chapter of the RED, 11/01/1999.

4. Sarah Levy (USEPA/OPPTS/OPP/HED), Chlorpyrifos methyl: Revised Acute and Chronic Dietary Exposure Analyses, 10/28/1999).

5. John Doherty USEPA/OPPTS/OPP/HED), Chlorpyrifos Methyl: Toxicology Section of the RED Chapter. 04/17/2000.

**Appendix A: Use Patterns Allowed during Phase-out**

## Chlorpyrifos methyl

| Application Type of Equipment | Timing of Application | Formulation | Maximum Rate | Restrictions/ Comments |
|---|---|---|---|---|
| Direct Grain Treatment | | | | |
| Automated Admixture System | As grain enters storage bin | 4E (43% a.i.) | 8 oz./3 gal of water | Avoid contact with treated grain until liquid has dried |
| Empty Bin Treatment | | | | |
| High Pressure Hand Held or Automated System | To empty bin only | 4E (43% a.i.) | 8 oz./3 gal of water | Do not allow entry until dusts have dried |