United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-R-00-014 September 2000

Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision

Mevinphos

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Manufacturer:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary and revised human health risk assessment for the organophosphate pesticide mevinphos. The public comment period on the revised risk assessment phase of the tolerance reassessment process is closed. The enclosed "Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for Mevinphos," which was approved on September 27, 2000, summarizes the Agency's assessment of the dietary risk from mevinphos as part of the tolerance reassessment process for this chemical, presents a summary of the related food tolerances for this single chemical, and provides the Agency's current risk management decision based on the risk assessment. Mevinphos has no U.S. registrations but does have fifteen import tolerances. The dietary risk analysis indicates that the risk is below the Agency's level of concern. Therefore, no mitigation is necessary at this time.

A Notice of Availability for this "Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for Mevinphos" is being published in the *Federal Register*. To obtain a copy of this document, please contact the OPP Public Regulatory Docket (7502C), U.S. EPA, Ariel Rios Building, 1200 Pennsylvania Avenue, N.W., Washington, D.C., 20460, telephone (703) 305-5805. Electronic copies of this report and the technical documents supporting it are available on the internet and can be found on the Agency's web page, "www.epa.gov/pesticides/op."

This document is based on the updated technical information found in the mevinphos public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, but also now includes the revised risk assessment for mevinphos, and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessment submitted by the chemical manufacturer, AMVAC Chemical Corporation, as well as comments submitted by the general public and stakeholders during the comment period on the risk assessment. A technical briefing was not held for mevinphos since it has no U.S. registrations, only import tolerances, and aggregate risk consists of risk from food only.

This document and the process used to develop it are the results of a pilot process to facilitate greater public involvement and participation in the reregistration and /or FQPA tolerance reassessment decisions on pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), 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 idea of using such an open process was developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body which advised the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the organophosphate pesticides are following this new process.

Please note that the mevinphos risk assessment concerns only this particular organophosphate. Because the FQPA directs the Agency to consider available information on cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with cholinesterase, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after completing risk assessments for the individual organophosphates. The Agency is working to complete a methodology to assess cumulative risk, and individual assessments of each organophosphate are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures where necessary. The Agency will issue the final tolerance reassessment decision for mevinphos once the cumulative assessment for all of the organophosphates is complete.

If you have questions on this document, please contact the Chemical Review Manager, Joseph Nevola at (703) 308-8037.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

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

TABLE OF CONTENTS

MEVINPHOS TEAM

Office of Pesticide Programs:

Health Effects Risk Assessment

William Hazel
Christine Olinger
Felecia Fort
Virginia Dobozy

Use and Usage Analysis

David Widawsky

Risk Management

Joseph Nevola

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

EPA has completed its review of public comments on the revised risk assessment for mevinphos, and is, in this document, issuing its interim decision on tolerance reassessment and risk mitigation for this chemical. The revised risk assessment is based on review of the required target data base supporting the mevinphos import tolerances and information received during the public comment periods in the pilot process developed through the Tolerance Reassessment Advisory Committee (TRAC). Mevinphos is not registered under FIFRA and may not be sold, distributed, or used in the U.S. In 1995 EPA reached an agreement with AMVAC Chemical Corporation to cancel all registrations of mevinphos because of agricultural worker exposure and safety concerns. Subsequently, most of the mevinphos tolerances were revoked, except for fifteen tolerances which were maintained for import purposes. EPA's revised risk assessment for mevinphos indicates that the dietary risk does not exceed the Agency's level of concern; therefore, no risk mitigation is necessary at this time. Tolerances exist for mevinphos use in/on broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce, melons, peas, peppers, spinach, summer squash, strawberries, tomatoes, and watermelon.

The final tolerance reassessment decision for mevinphos will be issued once the cumulative assessment for all of the organophosphates is completed. The Agency may need to issue risk management measures for mevinphos at the time the organophosphate cumulative assessment is finalized.

I. INTRODUCTION

This report on the progress toward tolerance reassessment of mevinphos is the result of the pilot process developed through the TRAC to facilitate greater public involvement in the ongoing FIFRA reregistration and FQPA tolerance reassessment initiatives on pesticides. Mevinphos is subject only to FQPA tolerance reassessment because it is not registered in the U.S.; but it does have import tolerances. However, some history and background of 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 U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require EPA review of all tolerances in effect when FQPA was enacted. 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 mevinphos has been completed. Since mevinphos shares a common mode of activity with other organophosphates, a cumulative risk assessment must be conducted prior to determining whether the safety requirements of FQPA have been satisfied.

Mevinphos is not registered for use in the United States; however, there are fifteen import tolerances for this chemical; i.e., tolerances for broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce, melons, peas, peppers, spinach, summer squash, strawberries, tomatoes, and watermelon. Because it is not registered in the U.S., it is not subject to the reregistration process. However, it is subject to the requirements of FQPA tolerance reassessment; therefore, a dietary risk assessment was completed. This document presents the Agency's dietary risk assessment for mevinphos, as part of the tolerance reassessment process. 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 mevinphos has already been subject to numerous public comment periods, and a further comment period was deemed unnecessary. A Notice of Availability for this document 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 Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- Applying the FQPA 10-Fold Safety Factor
- Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments
- How to Interpret "No Detectable Residues" in Dietary Exposure Assessments
- Refining Dietary (Food) Exposure Estimates
- Refining Dietary (Drinking Water) Exposure Estimates
- Assessing Residential Exposure
- Aggregating Exposure from all Non-Occupational Sources

- How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- Whether and How to Use Data Derived from Human Studies

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

This document consists of six sections. Section I contains the regulatory framework for tolerance reassessment as well as a description of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides. Section II provides a profile of the usage of the chemical. Section III gives an overview of the dietary risk assessment for mevinphos, including a discussion of any revisions that were made to the preliminary assessment. Section IV presents the Agency's progress towards tolerance reassessment, its interim decision and the 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 related documents. The entire revised risk assessment is not included in this document, but is available on the Agency's web page (www.epa.gov/pesticides/op), and in the Public Docket.

II. CHEMICAL OVERVIEW

A. Regulatory History

Mevinphos is a contact/systemic insecticide-acaricide. It is not registered under FIFRA and may not be sold, distributed, or used in the United States. However, fifteen tolerances remain for residues of mevinphos on the following commodities; at 1.0 ppm in/on broccoli, cabbage, cauliflower, celery, spinach, and strawberries; at 0.5 ppm in/on grapes, lettuce, melons, and watermelon; at 0.25 ppm in/on peas, peppers, and summer squash; and at 0.2 ppm in/on cucumbers and tomatoes (40 CFR §180.157). Since there are currently no domestic registrations for mevinphos, these tolerances serve as "import tolerances." Data have been or currently are being developed to determine whether these tolerances need to be modified.

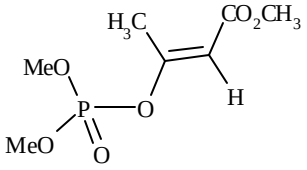
Mevinphos is a List A reregistration chemical and was the subject of a Registration Standard, dated March 31, 1988, which presented the regulatory decisions on the available data and specified additional data required for reregistration purposes. Due to concerns over agricultural worker exposure and safety, EPA was prepared on June 30, 1994 to issue a Notice of Intent to Suspend all mevinphos registrations. Instead, AMVAC requested voluntary cancellation of all its U.S. registrations for products containing mevinphos. The Agency granted this request and all U.S. registrations for

mevinphos were canceled effective July 1, 1994 (*59 FR 38973, August 1, 1994*); this cancellation order was later amended (*60 FR 17357, April 5, 1995*) to extend the distribution, sale, and use of AMVAC's mevinphos-containing products to November 30, 1995. The Agency subsequently proposed to revoke all mevinphos tolerances (*60 FR 39302, August 2, 1995*). In its proposal, the Agency also noted that a preliminary acute dietary risk assessment based upon the available data indicated a concern for acute exposure to mevinphos, particularly for infants and children. In response to this proposal, AMVAC requested (letter dated October 31, 1995) that the Agency not revoke 13 tolerances for mevinphos residues in/on selected fruits and vegetables as AMVAC was supporting the continued use of mevinphos in Mexico on commodities that are imported into the U.S. AMVAC also provided (letter dated November 20, 1995) its own acute dietary exposure analysis for mevinphos residues based upon the crop uses they were continuing to support. AMVAC revised its commitment on June 7, 1996 to include cauliflower as an import tolerance, and on July 6, 1999 to maintain the watermelon tolerance in combination with melons. With the exception of those 15 tolerances which AMVAC agreed to support for import purposes, the Agency revoked all other mevinphos tolerances effective November 1, 1999 (*64 FR 41818, August 2, 1999*).

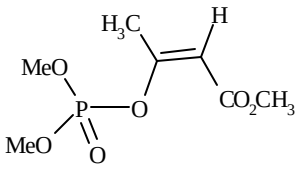
A preliminary human health risk assessment for mevinphos, dated October 19, 1999, was followed by a revised human health risk assessment, dated May 17, 2000, as part of the tolerance reassessment process.

B. Chemical Identification

alpha-Mevinphos



beta-Mevinphos



- **Common Name:** Mevinphos
- **Chemical Name:** methyl 3-[(dimethoxyphosphinyl)oxy]butenoate, alpha and beta isomers
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 7786-34-7
- **OPP Chemical Code:** 015801

- **Empirical Formula:** $C_7H_{13}O_6P$
- **Molecular Weight:** 224.16
- **Trade and Other Names:** Phosdrin
- **Basic Manufacturers:** AMVAC Chemical Corporation

A detailed discussion on the physical properties of mevinphos can be found in the EPA document entitled "Mevinphos: Revised Human Health Risk Assessment," dated May 17, 2000.

C. Use Profile

The following information is based on the current uses of mevinphos outside of the United States, and includes an overview of use sites and application methods.

Type of Pesticide: Insecticide-acaricide.

Summary of Use Sites: Mevinphos is registered outside the U.S. for use in/on broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce, melons, peas, peppers, spinach, summer squash, strawberries, tomatoes, and watermelon. Mevinphos is not registered under FIFRA and may not be sold, distributed, or used in the U.S.

Target Pests: Insects.

Formulation Types: Emulsion concentrate and Liquid concentrate.

Method and Rates of Application:

Method and Rate - Maximum use rate range 220 g ai/ha (0.2 lb ai/A) to 440 g ai/ha (0.39 lb ai/A), at PHIs ranging from 3 to 10 days.

Timing - Single broadcast application per crop season.

Use Classification: Not registered for use in the U.S.

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of mevinphos. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various sources.

Mevinphos is used to control insects that attack fruit and vegetable plants. Mexico is a major source of commodities treated with mevinphos that are imported into the United States. Based on the Mexican field trial data, a single broadcast application of mevinphos can be applied per crop season ranging from 220 g ai/ha (0.2 lb ai/A) to 440 g ai/ha (0.39 lb ai/A), and at PHIs ranging from 3 days to 10 days. As no Mexican field trials were conducted on head lettuce, EPA assumed the maximum use rate is 440 g ai/ha (0.39 lb ai/A).

Monitoring data indicate that residues of mevinphos in fruits and vegetables are significantly lower than the established tolerances. Residues were typically below the limit of detection (LOD), between the LOD and the limit of quantitation (LOQ), or at or just above the LOQ.

III. SUMMARY OF MEVINPHOS RISK ASSESSMENT

The following is a summary of EPA's revised human health risk findings and conclusions for the organophosphate pesticide mevinphos, as fully presented in the revised risk assessment document, "Mevinphos: Revised Human Health Risk Assesment," dated May 17, 2000. The risk assessment presented here forms the basis of the Agency's interim risk management decision for mevinphos only; the Agency must complete a cumulative assessment of the risks of all organophosphate pesticides before it can complete its reassessment of the mevinphos tolerances.

Because mevinphos is not currently registered for use in the U.S., only a human health dietary assessment from exposure to this chemical through food was necessary.

Human Health Risk Assessment

The Human Health Risk assessment incorporates the salient portions of the following Tolerance reassessment process chapters as well as several memoranda and Agency committee reports: the Toxicology Chapter prepared by V. Dobozy (August 16, 1999; D251794), the Residue Chemistry Chapter prepared by W. Hazel (October 19, 1999; D259802), the anticipated residue/dietary risk memorandum by C. Olinger and F. Fort (October 18, 1999; D259803), the Hazard Identification Assessment Review Committee report by V. Dobozy and B. Tarplee dated April 13, 1999, and the FQPA Safety Factor Committee report by B. Tarplee dated September 28, 1999.

Dietary Risk from Food

Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that while the mevinphos data base is not complete, there are sufficient data from the available studies for selecting acute and chronic dietary endpoints for an import tolerance. Further details on the toxicity of mevinphos can be found in the May 17, 2000 Revised Risk Assessment. A brief overview of the studies used for the dietary risk assessment is outlined in Table 1 of this document.

FQPA Safety Factor

In the case of acute risk assessments, the FQPA safety factor for all population subgroups other than infants, children, and females of child-bearing age (13+ years), was removed (reduced to 1X). Acute aggregate risk consists solely of food sources of dietary exposure to mevinphos and since the acute dietary exposure assessment was highly refined, the Agency does not think that acute dietary exposure is underestimated.

The FQPA safety factor for acute assessments was reduced to 3X for infants, children, and females of child-bearing age (13+ years). When assessing Acute Dietary Risk to Females 13-50 and to the Infants and Children Subgroups, the Safety Factor can be reduced to 3X since no increased susceptibility was observed following *in utero* exposure to rats or rabbits in the developmental studies (which could potentially occur after a single dose); and the concern for this exposure scenario is the uncertainty associated with the data gap for the developmental neurotoxicity study. The developmental neurotoxicity study is designed to evaluate neurotoxic effects on the mother and fetus from the time of implantation of the fertilized egg into the wall of the uterus through birth. This study may provide additional information on possible adverse effects of mevinphos on the developing organism.

In the case of chronic risk assessments, the FQPA Safety Factor could not be removed. It is 10X for all population subgroups since there is concern for increased susceptibility of the young demonstrated after repeated oral exposures in the range-finding study for the 2-generation reproduction study (which is designed to assess the effects of the pesticide on male and female reproductive processes, from egg and sperm production and mating through pregnancy, birth, nursing, growth and development, and maturation); and since there are data gaps in the toxicology data base for the subchronic neurotoxicity study in rats and the developmental neurotoxicity study in rats.

Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose, either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). In the case of mevinphos, for infants, children, and females (13+ years), the

acute Population Adjusted Dose (aPAD) level is 0.0003 mg/kg/day (acute RfD level of 0.001 mg/kg/day divided by the FQPA Safety Factor of 3X); for all other subpopulations, the aPAD is 0.001 mg/kg/day (acute RfD level of 0.001 mg/kg/day divided by the FQPA Safety Factor of 1X). The chronic Population Adjusted Dose (cPAD) level is 0.000025 mg/kg/day for all population subgroups (chronic RfD level of 0.00025 mg/kg/day divided by the FQPA Safety Factor of 10X). A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

Exposure Assumptions

The acute and chronic dietary risk assessments for mevinphos were quite refined, and included the use of monitoring data as the source of anticipated residues, correction for percent commodity imported and percent commodity treated, and a probabilistic acute assessment.

The mevinphos dietary exposure analyses were based largely on USDA/PDP (grapes and tomatoes) and FDA monitoring data (all other crops except head lettuce and cabbage). Only monitoring data from imported commodities were used for these dietary exposure assessments. Field trial data were used in the cases of head lettuce (U.S. field trial data) and cabbage (Mexican field trial data). Available field trial and monitoring data included all residues of regulatory and toxicological concern, i.e., the alpha- and beta-isomers of mevinphos.

Both acute and chronic dietary exposure assessments included correction for percent of crop imported and percent crop treated figures provided by OPP's Biological and Economic Analysis Division (BEAD; August 10, 1999 and September 27, 1999 D. Widawsky reports, see D259803, Attachment 1). Residues were typically below the limit of detection (LOD), between the LOD and the limit of quantitation (LOQ), or at or just above the LOQ. The monitoring data indicate that residues of mevinphos in fruits and vegetables are significantly lower than the established tolerances.

As grape and tomato processing studies were not available, default concentration factors were used in the dietary exposure assessments; submission of such studies would permit further risk refinement.

The chronic and acute analyses do not take into consideration the potential for reduction of mevinphos residues in cooked/canned/processed products since there are no chemical-specific cooking studies. The Agency will refine the mevinphos dietary exposure analyses if such data become available.

Dietary risk analyses for mevinphos were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992.

Table 1. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Mevinphos.

Assessment	Study	Dose	Endpoint	UF	FQPA Safety Factor	PAD
Acute Dietary	acute neurotoxicity study in rats (MRID 42985401)	NOAEL= 0.1 mg/kg/day	Plasma and brain ChE inhibition	100	1X 3X	0.001 mg/kg/ day (gen.pop.) 0.0003 mg/kg/ day (females 13+, infants, children)
Chronic Dietary	combined chronic toxicity/ carcinogenicity study in rats (MRID 43088601)	NOAEL= 0.025 mg/kg/day	Plasma and brain ChE inhibition	100	10X	0.000025 mg/kg/ day

Acute Food Risk

Acute dietary risk is calculated considering what is eaten in one day and maximum, or high-end residue values in food. The toxicity endpoint is the inhibition of plasma and brain cholinesterase observed in an acute neurotoxicity study in rats (NOAEL= 0.1 mg/kg/day). The FQPA 10X Safety Factor was reduced to 3X for infants, children, and females of child-bearing age (13+ years) since no increased susceptibility was observed following in uteroexposure to rats or rabbits in the developmental studies, and the concern for this exposure scenario is the uncertainty associated with the data gap for the developmental neurotoxicity study. For all other subpopulations, the FQPA Safety factor was removed (reduced to 1X).

A risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD) (the dose at which an individual could be exposed on any given day that would not be expected to result in adverse health effects) does not exceed the Agency's risk concern. In the acute dietary assessment for mevinphos, risk at the 99.9th percentile of exposure is reported since the probabilistic (Monte Carlo) analysis was highly refined using residue distribution files adjusted by the proportion of U.S.

consumption of each food that has been treated. At the 99.9th percentile of exposure, the most highly exposed population subgroup is children (1-6 years), with 17% of the aPAD consumed. Estimated acute dietary exposure to the general U.S. population is much lower, corresponding to 2% aPAD. Therefore, estimated acute dietary exposure and risk are below the Agency's level of concern for mevinphos; i.e., less than 100% of the aPAD is utilized.

The acute dietary assessment is very highly refined. However, the acute analysis does not take into consideration the potential for reduction of mevinphos residues in cooked/ canned/processed products since there are no chemical-specific cooking studies. Additional refinements could include the conduct of grape and tomato processing studies to derive mevinphos-specific processing factors. (Import tolerances may be needed for mevinphos residues in/on grape and tomato processed commodities if residues are concentrated upon processing, and if they are likely to be processed in the U.S., or if their processed commodities are imported from Mexico. Alternatively, the manufacturer may provide data indicating that mevinphos treated grapes and tomatoes are unlikely to be used for processing in either Mexico or the U.S.).

Chronic Food Risk

Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. The toxicological endpoint is plasma and brain cholinesterase inhibition, established in a 2-year oral rat study (NOAEL = 0.025 mg/kg/day). The FQPA 10X Safety Factor was retained for all population subgroups since there is a concern for increased susceptibility of the young, and since there are data gaps in the toxicological data base.

A risk estimate that is less than 100% of the chronic Population Adjusted Dose (cPAD) (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) does not exceed the Agency's risk concern. Estimated chronic dietary exposure and risk for mevinphos are significantly below the Agency's level of concern. The most highly exposed population subgroup is children (1-6 years), with an estimated exposure corresponding to 1.7% of the cPAD. Estimated dietary exposure to the general U.S. population is even lower, corresponding to 0.8% cPAD.

The risk assessment for mevinphos was conducted using highly refined anticipated residues (PDP and FDA monitoring data, except for lettuce and cabbage where field trial data were used) and percent of crop imported and percent crop treated figures. The chronic dietary analysis could be refined with chemical-specific cooking studies and conduct of grape and tomato processing studies to derive mevinphos-specific processing factors.

Substantive Revision To Preliminary Risk Assessment

During the error-only comment period of Phase 1 on the mevinphos preliminary risk assessment, AMVAC Chemical Corporation, the manufacturer, submitted substantive comments in addition to the technical corrections that were requested by EPA in that phase. AMVAC questioned the need to submit a developmental neurotoxicity study, additional field trial data requirements, including field trial data for grapes in countries where AMVAC stated that it does not currently market mevinphos, and studies to satisfy the 1991 mutagenicity test guidelines.

The Agency believes that the range-finding study associated with the two-generation rat reproduction study showed clinical signs of toxicity and increased acute lethality in offspring, and mevinphos is neurotoxic in mammals; therefore, a developmental neurotoxicity study is necessary.

Additional field trials are necessary to permit mevinphos tolerance reassessment. The Agency also requires use directions that will appear on the Mexican label(s). A different formulation was used in the Mexican field trials than were used in the trials conducted in the U.S., in many cases residues resulting from the trials conducted in the U.S. were higher than those conducted in Mexico, and parameters of the field trials do not agree with the current Mexican label. Also, samples of grapes from Chile were identified through the PDP monitoring program as having detectable residues of mevinphos (1994-1995). However, PDP shows no residues of mevinphos were detected in/on grapes (1996). Grapes were not sampled in 1997 or 1998, but no residues of mevinphos were detected in grape juice (1998). Consistent with the Import Tolerance Guidance (*65 FR 35069, June 1, 2000*), the Agency believes that additional field trial data for grapes in countries where mevinphos is used in/on grapes are necessary.

The Agency agrees that, in the case of mevinphos, nothing would be gained from pursuing genetic toxicology testing in light of the negative response for a carcinogenic effect and the absence of reproductive effects that would suggest a heritable concern. The requirement to submit fully acceptable studies to satisfy the 1991 mutagenicity test guidelines is, therefore, waived for mevinphos. This was the only substantive revision to the risk assessment.

IV. FQPA TOLERANCE REASSESSMENT PROGRESS & INTERIM RISK MANAGEMENT DECISION

A. Tolerance Reassessment Progress & Interim Risk Management Decision

The Agency has completed its assessment of the dietary risk of mevinphos but has not considered the cumulative effects of organophosphates as a class. Based on a review of these generic data and public comments on the Agency's revised risk assessment for the active ingredient mevinphos, EPA has sufficient information on the human health effects of mevinphos to make some interim

decisions as part of the tolerance reassessment process under FFDCA, as amended by FQPA. Although the Agency has not yet completed its cumulative risk assessment for the organophosphates, the Agency has completed its assessment of risk from dietary exposure to mevinphos alone in order to determine whether any risk reduction measures are necessary to allow the continued importation of broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce, melons, peas, peppers, spinach, summer squash, strawberries, tomatoes, and watermelon containing this chemical, pending completion of the cumulative assessment.

As a result of its assessment, EPA has determined that dietary risk from exposure to mevinphos is not a concern for the Agency. Therefore, no risk mitigation is necessary and no further actions are warranted at this time. The Agency may determine that action is necessary after assessing the cumulative risk of the organophosphate class. At that time, the Agency will also address any other outstanding risk concerns that may arise. 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.

Because the Agency has not yet completed the cumulative risk assessment for the organophosphates, this interim decision does not specifically address the reassessment of the existing mevinphos food residue import tolerances as called for by the FQPA. When the Agency has completed the cumulative assessment, the mevinphos tolerances will be reassessed in that light. At that time, the Agency will reassess mevinphos along with the other organophosphate pesticides to complete the FQPA requirements. Nothing in this report will preclude the Agency from making further FQPA determinations and tolerance-related rulemaking that may be required on this pesticide or any other in the future.

If the Agency determines, before finalization of the FQPA assessment for mevinphos, that any of the determinations described in this 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

EPA released its revised risk assessment for mevinphos to the public on June 30, 2000 (*65 FR 40631*) and provided a 60 day comment period for interested parties to submit information, including risk mitigation suggestions or proposals. Three comments were received during the comment period.

Comment. A private citizen disagreed with retention of mevinphos import tolerances in view of a 17% acute Population Adjusted Dose (aPAD) for the highest risk group and in view of cumulative organophosphate risks. Also, the commenter claimed that EPA's regulations will be less stringent than the international standards of Codex. In addition, the commenter claimed that in R.E.D. Facts,

Mevinphos, September 1994, EPA identified dietary risks as a concern in canceling mevinphos registrations and that retention of import tolerances appears to be inconsistent with dietary risks and FFDCA section 408(l)(2) on tolerance revocation.

Response. In response to the commenter's concern that EPA is retaining the mevinphos import tolerances despite the fact that the Agency has not yet conducted the cumulative risk assessment, it should be noted that the tolerance decision presented in this document for mevinphos is only an interim decision. EPA will conduct a cumulative risk assessment of all organophosphates (OPs). Further changes to the mevinphos tolerances could be required as necessary as a result of that cumulative assessment for OPs.

In response to the commenter's assertion that the mevinphos tolerances are not as stringent as the Codex MRLs, Codex currently shares the same tolerance levels on 6 crops for mevinphos, while U.S. tolerance levels are currently higher than Codex on only 3 crops for mevinphos; i.e., melons (except watermelon), peas, and spinach. There is no determination for the tolerances on peas and spinach at this time. The interim tolerance decision for melons of 0.1 ppm is based on field trial data and the Agency has made the determination that the 0.1 ppm tolerance level is safe. For one crop, cucumbers, EPA's interim decision is to lower the tolerance from 0.2 ppm, the Codex level, to 0.05 ppm based on field trial data.

In regard to the final point, the primary reason behind the 1994 cancellation actions for mevinphos was risk concern for agricultural workers (59 FR 38973, August 1, 1994; R.E.D. Facts, Mevinphos, September 1994). The commenter is correct that in its proposal of August 2, 1995 (60 FR 39302), the Agency noted that a preliminary acute dietary risk assessment for mevinphos, based on available data at the time, indicated a concern for acute exposure to mevinphos, particularly for infants and children. However, EPA also noted that it recognized that the dietary risk concern may be diminished if interested parties were to submit adequate exposure and/or toxicity data. (This recognition also appears as follows: "If better data are submitted to the Agency, the Agency would reassess risk," as noted in R.E.D. Facts, Mevinphos, September 1994, p. 3). Currently, there are sufficient data from available studies for selecting acute and chronic dietary endpoints for an import tolerance. The Agency's assessments of acute dietary risk and chronic dietary risk are considered to be highly refined. Both estimated acute dietary exposure and risk (17% aPAD) and chronic dietary exposure and risk (1.7% cPAD) are below EPA's level of concern for mevinphos.

Comment. The California Desert Grape Administrative Committee (CDGAC) stated that U.S. imports from countries other than Mexico which use mevinphos should be included in the risk assessment. Also, the CDGAC believes that EPA used an incorrect production figure for 1996 and an incorrect 1995-1996 average U.S. grape production level because of a misplaced decimal point. The CDGAC also expressed concern about temporal differences in the U.S. consumption of imported grapes on exposure.

Response. EPA agrees that grape imports from countries other than Mexico should be included in the risk assessment. In "Mevinphos: Dietary Exposure and Risk Analyses ... ," the second page of Attachment 1 shows an updated estimate which includes grapes imported from Chile. EPA has made a determination based on available data that the current tolerance level remains safe. However, there is no interim tolerance level set for grapes.

The commenter is correct that a decimal "typographical error" appears in "Mevinphos: Dietary Exposure and Risk Analyses ...," Attachment 1 incorrectly shows the 1996 U.S. production of grapes (537.062 should be 537,062) and 1995-1996 average U.S. production level (320963.531 should be 589,226). However, the second page of Attachment 1 shows an updated estimate of grape production. It was this correct production level that was used in the risk assessment.

The temporal differences in U.S. consumption of imports has been indirectly considered in the probabilistic analysis. The Agency conducts dietary risk assessments using the Dietary Exposure Evaluation Model, which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. Surveys are conducted annually during the four different seasons across the country. For chronic dietary risk assessments, the three-day average of consumption for each subpopulation is combined with average residues in commodities to determine average exposure. For acute dietary risk assessments, the entire distribution of consumption events for individuals is multiplied by a distribution of residues to obtain a distribution of exposures; this is a probabilistic analysis known as "Monte Carlo," with risk at the 99.9th percentile of exposure reported. The Agency believes that it is not underestimating U.S. exposure.

Comment. The manufacturer, AMVAC Chemical Corporation, requests that it not be required to submit a subchronic neurotoxicity study and a developmental neurotoxicity study. AMVAC believes that no additional field trials are necessary under EPA's import tolerance guidance (65 FR 35069, June 1, 2000) on the basis that crops imported from all countries where mevinphos is registered is lower than 5% of U.S. consumption (35076 p.). Further, AMVAC believes that it has already complied with requirements for field trials in Mexico. AMVAC questions the need basis for additional field trials for grapes in those countries where AMVAC claims mevinphos is not registered or sold. In addition, AMVAC questions the need for the 10X safety factor in chronic dietary risk. AMVAC notes that it has submitted storage stability data and grape processing data. AMVAC believes that there is no need to conduct a tomato processing study, and notes that it has submitted a waiver request for tomato processing data. AMVAC does state that it will revise the Mexican label to agree with the parameters in the submitted Mexican field trial data.

Response. AMVAC has already submitted "A Subchronic (13 week) Neurotoxicity Study of Mevinphos in Rats," MRID45099101. The developmental neurotoxicity study, field trial studies, and Mexican label revisions are necessary for tolerance reassessment (see this document Part V, section A on data requirements). The Agency believes the developmental neurotoxicity study is necessary because there was some indication of increased sensitivity of offspring treated postnatally in the range-

finding study associated with the two-generation rat reproduction study; i.e., the range-finding study showed clinical signs of toxicity and increased acute lethality in offspring. Additionally, mevinphos is neurotoxic in mammals. Therefore, EPA will begin the process of requiring that data in an upcoming Federal Register Notice. AMVAC can make any further arguments about the necessity of that study in the context of that data call-in process.

On the import guidance, the commenter is incorrectly asserting that they are exempt from field trial requirements because the crop imports from all countries were less than 5% of U.S. consumption. The guidance does not refer to a "consumption" level but actually refers to an "imported" level. The Import Tolerance Guidance of June 1, 2000 states that field trials will generally need to be conducted in all countries that export at least 5% of the total amount of a specific commodity "imported" into the U.S. (35076 p.). Therefore, the field trial data requirements are in accordance with the Import Tolerance Guidance.

Additional field trials are needed from Mexico because tolerances may not be set higher than necessary, which may occur using the existing database. Current monitoring data suggest that lower tolerances will likely be appropriate in many cases.

EPA believes that it is necessary to conduct field trials for grapes and that the trials need to be representative of all countries where mevinphos is registered or used on grapes. This is necessary because a tolerance is not country-specific. Once the tolerance level is set, the tolerance will apply to all countries from which grapes are imported into the U.S. If it can be demonstrated that for a particular country mevinphos is not registered or used on grapes, and the Agency also has no information showing that mevinphos is registered or used on grapes in that country, then EPA will not require field trials for grapes in that country.

Regarding the need basis for the 10X safety factor in chronic dietary risk, the Agency believes that the 10X FQPA safety factor could not be removed due to concern for increased susceptibility of the young in the range-finding study for the 2-generation reproduction study; and due to data gaps in the toxicological database.

Storage stability data, grape processing data, and a waiver request for tomato processing data have been received by the Agency and are in review. The Agency is still waiting for the revised Mexican labels to be submitted. These labels are needed because the parameters of the field trial data which have been submitted do not agree with current Mexican labels.

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 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 mevinphos is within its own "risk cup." In other words, if mevinphos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the import tolerances for mevinphos on broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce, melons, peas, peppers, spinach, summer squash, strawberries, tomatoes, and watermelon 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 not conducted for mevinphos, because there are no domestic uses; i.e., there is no U.S. residential or drinking water exposure. But, results of the acute and chronic food assessments indicate that exposures are within acceptable levels; that is, risk from exposure to mevinphos "fits" within the individual risk cup. Therefore, although additional storage stability data are required to support the cucumber and melon field trial data and provided that revised Mexican label directions agree with field trial parameters, available data indicate the import tolerances for cucumbers and melons should be lowered to 0.05 ppm and to 0.1 ppm, respectively. With the exception of the tolerance for watermelon, which should be reassigned since it is covered by melons, an interim tolerance decision for the other existing tolerances cannot be determined because additional data are required and should remain in effect at their existing tolerance levels. Tolerances may be reassessed only upon completion of the cumulative risk assessment of all organophosphates.

b. Tolerance Summary

The established tolerances for residues of mevinphos in/on plant commodities are currently expressed in terms of residues of mevinphos per se (methyl 3-[(dimethoxyphosphinyl)oxy]butenoate, alpha and beta isomers) [40 CFR § 180.157]. It should be noted, however, that the preferred chemical name for mevinphos is methyl 3-[(dimethoxyphosphinyl)oxy]butenoate.

Mevinphos residues of concern in plants include the alpha- and beta-isomers of mevinphos. Based upon the available animal metabolism data, quantifiable residues of mevinphos are unlikely to occur in livestock [40 CFR § 180.6(a)(3)]; therefore, tolerances in animal commodities are not

required. Tolerances for residues of mevinphos in/on plant raw agricultural commodities (RACs) have been established under 40 CFR § 180.157 and range from 0.2 ppm in/on cucumbers and tomatoes to 1.0 ppm in/on broccoli, cabbage, cauliflower, celery, spinach, and strawberries.

AMVAC is only supporting import tolerances for mevinphos residues in/on the following commodities: broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce (leaf and head), melons, peas (succulent), peppers, summer squash, spinach, strawberries, and tomatoes. The tolerance for watermelons should be removed (reassigned) since the use is covered by the tolerance for melons (Crop subgroup 9-A).

For risk assessment purposes, adequate plant and animal metabolism data are available. However, acceptable residue data are tentatively available only for imported cucumbers and melons. Additional residue data are needed to reassess import tolerances for broccoli, cabbage, cauliflower, celery, grapes, lettuce, peas, peppers, spinach, squash, strawberries and tomatoes. To support the existing residue data on cucumbers, melons, pea pods, peppers, strawberries, and tomatoes, data are necessary depicting the storage stability of mevinphos residues in these frozen commodities at defined lengths of storage time. Additional field trials are needed for broccoli, cabbage, celery, grapes, leaf lettuce and head lettuce, succulent peas, peppers, spinach, strawberries, summer squash, and tomatoes. Field trial data on broccoli will be translated to cauliflower.

Provided acceptable mevinphos labels are submitted and deficiencies pertaining to storage stability of residues are resolved, sufficient data are available to reassess tolerances for mevinphos in/on cucumbers and melons imported from Mexico. Although additional storage stability data are necessary to support the cucumber and melon field trial data, the available data indicate the established tolerances could be lowered to 0.05 ppm for cucumbers and 0.1 ppm for melons if the revised Mexican label directions agree with the field trial parameters and if the existing cucumber residue data are validated by storage stability data (a storage stability study MRID 45089101, entitled "Frozen Storage Stability of Mevinphos Residues in/on Tomatoes, Strawberries, Broccoli, Lettuce, and Cucumbers" has been submitted and is currently in review). Additional residue data are needed for broccoli, cabbage, cauliflower, celery, grapes, lettuce, peas, peppers, spinach, summer squash, strawberries, and tomatoes before the existing tolerances can be reassessed.

In addition, no residue data are available for grape and tomato processed commodities (a grape processing study MRID 45021501 and a waiver request for the tomato processing study have been submitted and are currently in review). Tolerances may be needed for mevinphos residues in/on grape and tomato processed commodities. However, before the need for such tolerances can be assessed, residue data are necessary depicting mevinphos residues in grape and tomato processed commodities or information showing that mevinphos treated grapes and tomatoes are unlikely to be used for processing in either Mexico or the U.S.

Table 2. Tolerance Summary for Mevinphos

Commodity	Tolerance Listed Under 40 CFR § 180.157	Interim Tolerance Decision [a]	Comment
Broccoli	1.0 ppm	TBD[b]	Additional residue data are required.
Cabbage	1.0 ppm	TBD[b]	Additional residue data are required.
Cauliflower	1.0 ppm	TBD[b]	Additional residue data are required [d].
Celery	1.0 ppm	TBD[b]	Additional residue data are required.
Cucumbers	0.2 ppm	0.05	*Cucumber* Import tolerance based upon Mexican field trial data.
Grapes	0.5 ppm	TBD[b]	*Grape* Additional residue data are required.
Lettuce	0.5 ppm	TBD[b]	Additional residue data are required.
Melons (incl. cantaloupes, honeydew melon, and muskmelon, determined on the edible portion with rind removed)	0.5 ppm	0.1	*Melon (Crop subgroup 9-A)* Import tolerance based upon Mexican and U.S. field trial data.
Peas	0.25 ppm	TBD[b]	*Pea, succulent* Additional residue data are required.
Peppers	0.25 ppm	TBD[b]	*Pepper* Additional residue data are required.
Spinach	1.0 ppm	TBD[b]	Additional residue data are required.
Squash, summer	0.25 ppm	TBD[b]	Additional residue data are required.
Strawberries	1.0 ppm	TBD[b]	*Strawberry* Additional residue data are required.
Tomatoes	0.2 ppm	TBD[b]	*Tomato* Additional residue data are required.
Watermelon	0.5 ppm	Reassign	Covered by melons (Crop subgroup 9-A)

Commodity	Tolerance Listed Under 40 CFR § 180.157	Interim Tolerance Decision [a]	Comment
Tolerances potentially needed under 40 CFR §180.157:			
Grape, juice	None	TBD[c]	Data depicting residues in grape processed fraction are required.
Grape, raisin	None	TBD[c]	Data depicting residues in grape processed fraction are required.
Tomato, paste	None	TBD[c]	Data depicting residues in tomato processed fraction are required.
Tomato, puree	None	TBD[c]	Data depicting residues in tomato processed fraction are required.

[a] Tolerances may be reassessed only upon completion of the cumulative risk assessment of all organophosphates. The tolerance levels provided here are for this single chemical, if no cumulative assessment was required, that is supported by all of the submitted residue data. The Agency will commence proceedings to revoke, modify the existing tolerances, and correct commodity definitions.

[b] TBD = To be determined. Tolerance cannot be determined at this time because additional data are required. The raising of any tolerances will be deferred, pending the outcome of the cumulative assessment.

[c] TBD = To be determined because additional data are needed and the establishment of any new tolerances will be deferred, pending the outcome of the cumulative assessment.

[d] Field trial data on broccoli will be translated to cauliflower.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, mevinphos may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

D. Regulatory Rationale

Mevinphos has fifteen import tolerances, and no U.S. registrations; therefore, only a dietary risk assessment for food was conducted. Based on analyses of both acute and chronic dietary risk, the Agency has determined that the risk estimates are not of concern for the Agency; therefore, no risk mitigation measures are necessary at this time.

V. WHAT MANUFACTURERS NEED TO DO

A. Additional Data Requirements

EPA is requiring acute, subchronic, and developmental neurotoxicity studies for all organophosphates, including those with no domestic registrations (i.e., tolerances are established only to allow treated commodities to be imported into the U.S.). A subchronic study MRID 45099101 has been submitted and is currently in review. A developmental neurotoxicity study in rats (with expanded protocol to extend the postnatal treatment period and to measure cholinesterase inhibition in offspring) and neurotoxic esterase (NTE) data on the hen are needed. Although mevinphos has no U.S. registrations and therefore is not subject to a FIFRA DCI, it does have tolerances for residues in or on broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce, melons, peas, peppers, spinach, summer squash, strawberries, tomatoes, and watermelon that are imported into the U.S. If EPA needs additional data to support the continuance of a tolerance or exemption, but there are no U.S. registrants from whom the Agency can obtain the data under FIFRA, EPA may require data under section 408(f) of FFDCA. Section 408(f) of FFDCA allows the Agency to publish a Notice in the Federal Register describing the type of data needed and inviting persons willing to submit the necessary data to support the tolerance to identify themselves. Tolerances may be revoked if no person commits to supply the necessary data or if the appropriate data are not submitted in a timely manner. If the proposed GC/FPD (phosphorous mode) tolerance enforcement method remains the manufacturer's choice for enforcement, an independent laboratory validation of that method must be conducted prior to validation of the method by the Agency (W. Hazel, October 19, 1999; D196769 and D248311). Alternatively, FDA Multiresidue Protocol A or D had been demonstrated to be adequate for tolerance enforcement.

The Agency needs use directions that will appear on the Mexican label(s), additional field trial data for broccoli, cabbage, celery, grapes, lettuce, peas, peppers, spinach, strawberries, summer squash, and tomatoes; and storage stability data for cucumbers, melons, peas, peppers, strawberries, and tomatoes to permit mevinphos tolerance reassessment. The field trials are all to be conducted in Mexico; however, for grapes field trials are necessary in other countries where mevinphos is registered

or used in or on grapes. A storage stability study MRID 45089101 has been submitted and is currently in review. Processing studies on grapes and tomatoes are needed to support tolerances for these crops if the imported crops are likely to be processed in the U.S. or if their processed commodities are imported from Mexico, unless the Agency is provided with data indicating that mevinphos treated grapes and tomatoes are unlikely to be used for processing in either Mexico or the U.S. A grape processing study MRID 45021501 and request for a waiver from the tomato processing study requirement have been submitted and are currently in review. Results of these studies may further refine the risk assessments. EPA will be taking the necessary steps to secure these data in the near future.

B. Risk Mitigation Requirements

As discussed in this document, the acute and chronic food risk from the use of mevinphos on imported broccoli, cabbage, cauliflower, celery, cucumbers, grapes, lettuce, melons, peas, peppers, spinach, summer squash, strawberries, tomatoes, and watermelon is not of concern to the Agency; therefore, no mitigation is necessary at this time. The Agency may need to pursue risk management measures for mevinphos once the cumulative assessment is finalized.

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 pm.

The docket initially contained preliminary risk assessments and related documents as of January 12, 2000. On March 13, 2000 the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal “Response to Comments” document and the revised risk assessment to the docket on June 30, 2000.

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

APPENDIX A: BIBLIOGRAPHY

MRID	CITATION
00036989	Shell Development Company (1956) Determination of OS2046 in Agricultural Products and Animal Tissues: Enzyme Inhibition--Spectrophotometric Method. Method ARMS-C-12/56 (Tentative) dated May 15, 1956. (Unpublished study received Jun 5, 1956 under PP0078; CDL:092358-D).
00036990	Casida, J.E. (19??) Enzymatic Determination of OS 2046 in Agricultural Crops: Enzyme Inhibition--delta pH Method. (Unpublished study received Jun 5, 1956 under PP0078; prepared by Univ. of Wisconsin, submitted by Shell Chemical Co., Washington, D.C.; CDL:092358-E).
00089559	Shell Chemical Corporation (1957) Determination of Anticholinesterase in Plant and Animal Tissues. Method dated Mar 1957. (Unpublished study received Apr 15, 1957 under PP0123; CDL:090154-Z).
00113309	Shell Chemical Corp. (1958) [Phosdrin: Residues in Oranges and Other Crops]. (Compilation; unpublished study received on unknown date under PP0200; CDL:098743-A).
00113334	Shell Development Co. (1964) Determination of Phosdrin Insecticide in Crops and Animal Products: Analytical Method MMS-6/64. (Unpublished study received Jul 1, 1964 under unknown admin. no.; CDL:129696-A).
00147425	Shell Oil Co. (1985) Residue Decline of Phosdrin Insecticide on Various Agricultural Crops. Unpublished compilation. 218 p.
40201401	Schroeder, R., Daly, I. (1987) A Teratology Study in Rats with Mevinphos. Bio/dynamics, Inc.: Study Number: 85-3009, March 2, 1987. Unpublished.
40570701	Auletta, C. (1988) Acute Oral Toxicity Study in Rats with Mevinphos: Final Report: Project No. 4644-87. Unpublished study prepared by Bio/dynamics Inc. 31 p.
40570702	Aulletta, C. (1988) Acute Dermal Toxicity Study in Rabbits with Mevinphos: Final Report: Project No. 4645/87. Unpublished study prepared by Bio/dynamics Inc. 31 p.

BIBLIOGRAPHY

MRID	CITATION
40570703	Auletta, C. (1988) Dermal Sensitization Study in Guinea Pigd with Mevinphos: Final Report: Project No. 4648-87. Unpublished study prepared by Bio/dynamics Inc. 35 p.
40600001	Hoffman, G. (1988) An Acute Inhalation Toxicity Study of Mevinphos in the Rat: Project No. 87-8050. Unpublished study prepared by Bio/dynamics, Inc. 92 p.
40775901	Barrett, D. (1988) Acute Delayed Neurotoxicity Study in Mature Hens with Mevinphos. Bio/dynamics Inc., Study Number 4685-87, July 26, 1988. Unpublished.
41016201	Atkinson J. (1989) An Eighteen Month Oncogenicity Study in Mice with Mevinphos. Bio/dynamics, Inc., East Millstone, NJ. Project No. 86-3006, February 23, 1989. Unpublished.
41295001	San, R.; Schadly, M. (1989) Salmonella/Mammalian-microsome PlateIncorporation Mutagenicity Assay (Ames Test) with a Confirmatory Assay with Mevinphos: Lab Project Number: T8858/501014. Unpublished study prepared by Microbiological Associates, Inc. 62 p.
41306301	Harbell, J. (1989) CHO/HGPRT Mutation Assay with Confirmation with Mevinphos: Final Report: Lab Project Number: T8858/332001. Unpublished study prepared by Microbiological Associates, Inc. 32 p.
41378701	Putman, D.; Morris, M. (1990) Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells with Mevinphos: Final Report: Lab Study No. T8858.337. Unpublished study prepared by Microbiological Associates, Inc. 29 p.
41378702	Curren, R. (1990) Unscheduled DNA Synthesis in Rat Primary Hepatocytes with Mevinphos: Final Report: Lab Study No.: T8858.380. Unpublished study prepared by Microbiological Associates, Inc. 26 p.
41546501	McKane, E.; Miller, M. (1990) Analysis of Field Residue Study Samples with Two Formulations of Phosdrin on Two Varieties of Lettuce: Lab Project Number: AL-102: AL-103. Unpublished study prepared by Pan-Agricultural Laboratories, Inc. 131 p.

BIBLIOGRAPHY

MRID CITATION

41546502 Amvac Chemical Co. (1990) Phosdrin Incident Reports on Lettuce. Unpublished study. 46 p.

41636801 West J. and K. Roberts (1990) Supplement to An Eighteen Month Oncogenicity Study in Mice with Mevinphos (Supplements MRID 41016201). Jellinek, Schwartz, Connolly & Freshman, Inc., Washington, D.C. Project ID JCODE 1562.1, August 31, 1990. Unpublished.

41823801 Beyer, B.K., (1991) Teratology Study in Rabbits. EXXON Biomedical Sciences, Inc., East Millstone, NJ. Laboratory Project Id. 233134RB, February 22, 1991. Unpublished.

41951801 Reddy, V., Freeman, T., Litle, L., Cannon, M. (1991) Disposition and Metabolism of ^{14}C-Labeled Mevinphos in Rats. Midwest Research Institute, Kansas City, Mo., Laboratory Project Id. 9485-B, April 4, 1991. Unpublished.

42122201 Beyer, B. (1991) Multi-Generation Rat Reproduction Study MRD-88-331:Mevinphos: Final Report: Lab Project Number: 233135. Unpublished study prepared by Exxon Biomedical Sciences, Inc. 484 p.

42422201 Beyer, B.K., (1991) Teratology Study in Rabbits (Revision). EXXON Biomedical Sciences, Inc., East Millstone, NJ. Laboratory Project Id. 233134RB, February 22, 1991. Unpublished.

42475601 Velagaleti, P.; Denison, J.; Cristy, T. (1992) Nature of the Residue of [Carbon 14]-labeled Mevinphos in Leaf Lettuce: Final Report: Lab Project Number: SC910004. Unpublished study prepared by Battelle. 152 p.

42476701 Craine, E. (1992) A Residue Chemistry Study in the Dairy Goat with [carbon 14]-Mevinphos: Lab Project Number: WIL-163001: RPT0086. Unpublished study prepared by WIL Research Labs, Inc. 307 p.

42540101 Velagaleti, P.; Denison, J.; Cristy, T. (1992) Nature of the Residue of [carbon 14]-Labeled Mevinphos in Strawberries: Final Report: Lab Project Number: SC910069: SPONSOR. Unpublished study prepared by Battelle. 182 p.

BIBLIOGRAPHY

MRID CITATION

42588501 Keefe, R. (1992) 90-Day Subchronic Oral Toxicity Study in Rats with Mevinphos (MRD-88-331): 233170B. EXXON Biomedical Sciences, Inc., Los Angeles, CA. Laboratory Project ID 233170B, November 4, 1992. Unpublished.

42659201 Craine, E. (1993) A Residue Chemistry Study in the Laying Hen with (carbon 14)-Mevinphos: Lab Project Number: WIL-188001. Unpublished study prepared by WIL Research Labs., Inc. 320 p.

42674001 Velagaleti, P.; Denison, J.; Cristy, T. (1993) Nature of the Residue of (carbon 14)-Mevinphos in Turnips: Final Report: Lab Project Number: SC910070. Unpublished study prepared by Battelle. 189 p.

42964601 Schweitzer, M.; Andrews, K. (1993) Enforcement Validation for the Determination of Mevinphos Residues in Crop Samples: Lab Project Number: SC930248. Unpublished study prepared by Battelle. 36 p.

42985401 Lamb, I.C., (1993) A Range-Finding Acute Study of Mevinphos in Rats. WIL Research Laboratories, Inc., Ashland, OH, Laboratory Study No. WIL-188005, October 12, 1993 . Unpublished.

42985402 Lamb, I.C., (1993) An Acute Neurotoxicity Study of Mevinphos in Rats. WIL Research Laboratories, Inc., Ashland, OH, Laboratory Study No. WIL-188006, October 13, 1993. Unpublished.

43088601 Plutnick, R.T., (1994). 2-Year Chronic Toxicity/Oncogenicity Study in Rats with Mevinphos (MRD-88-331). EXXON Biomedical Sciences, Inc., East Millstone, NJ., Laboratory Project Id. 233170C, January 3, 1994. Unpublished.

44595201 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Broccoli Grown in Mexico: Lab Project Number: AMV96001. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 69 p. {OPPTS 860.1500}

BIBLIOGRAPHY

MRID CITATION

44595202 Kent, Y; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Cabbage Grown in Mexico: Lab Project Number: AMV96002. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 68 p. {OPPTS 860.1500}

44595203 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Spinach Grown in Mexico: Lab Project Number: AMV96003. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 69 p. {OPPTS 860.1500}

44595204 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Leaf Lettuce Grown in Mexico: Lab Project Number: AMV96004. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 69 p. {OPPTS 860.1500}

44595205 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Melons in Mexico: Lab Project Number: AMV96005. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 67 p. {OPPTS860.1500}

44595206 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Peas Grown in Mexico: Lab Project Number: AMV96006. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 69 p. {OPPTS860.1500}

44595207 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Spinach Grown in Mexico: Lab Project Number: AMV96007 Project Number: AMV96007. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 69 p. {OPPTS 860.1500}

44595208 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Strawberries Grown in Mexico: Lab Project Number: AMV96008. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 70 p. {OPPTS 860.1500}

BIBLIOGRAPHY

MRID CITATION

44595209 Kent, Y.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Squash Grown in Mexico: Lab Project Number: AMV96009. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 68 p. {OPPTS860.1500}

44595210 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Peppers Grown in Mexico: Lab Project Number: AMV96010. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 90 p. {OPPTS 860.1500}

44595211 Taylor, A.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Tomato Grown in Mexico: Lab Project Number: AMV96011. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 123 p. {OPPTS860.1500}

44595212 Kent, Y.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Grapes Grown in Mexico: Lab Project number: AMVAC96012. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 122 p. {OPPTS860.1500}

44595213 Kent, Y.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Cucumber Grown in Mexico: Lab Project Number: AMV96013. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 134 p. {OPPTS 860.1500}

44595213 Kent, Y.; Obrist, J. (1998) Determination of Magnitude of Residues of Mevinphos in/on Cucumber Grown in Mexico: Lab Project Number: AMV96013. Unpublished study prepared by Pesticides Regulatory Advisory and ABC Laboratories. 134 p. {OPPTS 860.1500}

44595214 Obrist, J. (1997) Magnitude of Mevinphos Residues in Celery: Lab Project Number: 957SARS-93-07: SARS-93-CA-16C: 41278. Unpublished study prepared by ABC Laboratories and Stewart Agricultural Research. 190 p.

BIBLIOGRAPHY

MRID	CITATION
44595215	Obrist, J. (1997) Magnitude of Mevinphos Residues in Succulent Peas: Lab Project Number: 41342: SARS-93-10: SARS-94-MN-19B. Unpublished study prepared by ABC Labs. 237 p.
44595216	Obrist, J. (1997) Magnitude of Mevinphos Residues in Strawberries: Lab Project Number: 93335: SARS-93-12. Unpublished study prepared by ABC Laboratories. 222p.
44595217	Obrist, J. (1997) Magnitude of Mevinphos Residues in Spinach: Lab Project Number: 41277: SARS-93-06. Unpublished study prepared by ABC Laboratories. 189 p.
44595218	Obrist, J. (1997) Magnitude of Mevinphos Residues in Cabbage: Lab Project Number: 41273: SARS-93-02. Unpublished study prepared by ABC Labs. 169 p.
44595219	Obrist, J. (1997) Magnitude of Mevinphos Residues in Grapes: Lab Project Number: 93325: SARS-93-11. Unpublished study prepared by ABC Laboratories. 180 p.
44595220	Obrist, J. (1997) Magnitude of Mevinphos Residues in Cantaloupe: Lab Project Number: 93-08: 41279. Unpublished study prepared by ABC Laboratories. 125 p.
44595221	Obrist, J. (1997) Magnitude of Mevinphos Residues in Leaf Lettuce: Lab Project Number: SARS-93-05: 41276. Unpublished study prepared by ABC Laboratories. 257 p.
44608501	Obrist, J. (1997) Magnitude of Mevinphos Residues in Broccoli: SARS-93-01: Lab Project Number: 41270: SARS-93-01:SARS-93-CA-10A. Unpublished study prepared by ABC Labs., Inc. 192 p.
44608502	Obrist, J. (1997) Magnitude of Mevinphos Residues in Head Lettuce: SARS-93-04: Lab Project Number: 41275: SARS-93-04:SARS-93-CA-13A. Unpublished study prepared by ABC Labs., Inc. 225 p.
45021501	Leppert, B. (1994) Magnitude of Mevinphos in Grapes for Processing: SARS-93-16: Lab Project Number: SARS-93-16:SARS-93-CA-25. Unpublished study prepared by Pan-Agricultural Labs., Inc. 228 p.

BIBLIOGRAPHY

MRID CITATION

45089101 Gant, A. (1999) Frozen Storage Stability of Mevinphos Residues in/on Tomatoes, Strawberries, Broccoli, Lettuce, and Cucumbers: Lab Project Number 44693. Unpublished study prepared by ABC Labs., Inc. 599 p.

45099101 Lamb, I. (1994) A Subchronic (13 Week) Neurotoxicity Study of Mevinphos In Rats: Lab Project Number WIL-188007. Unpublished study prepared by WIL Research Labs., Inc. 2005 p.

CITATIONS WITHOUT MRID NUMBERS

HED DOC. NO. 013334: Mevinphos - Report of the Hazard Identification Assessment Review Committee, Memorandum from Virginia Dobozy and Brenda Tarplee, dated April 13, 1999.

HED DOC. NO. 013678: Mevinphos Cancer Issues, Memorandum from William L. Burnam, dated August 4, 1999.

HED DOC. DP Barcode D251794: Mevinphos: Toxicology Chapter for RED, Memorandum from Virginia Dobozy, dated August 16, 1999.

HED DOC. NO. 013752: Mevinphos - Report of the FQPA Safety Factor Committee, Memorandum from Brenda Tarplee, dated September 28, 1999.

HED DOC. DP Barcode D259803: Mevinphos. Dietary Exposure and Risk Analyses for the HED Preliminary Human Health Risk Assessment, Memorandum from Christine Olinger, dated October 18, 1999.

HED DOC. DP Barcode D259802: Mevinphos: Residue Chemistry Chapter of the Reregistration Eligibility Decision Document, Memorandum from William Hazel, dated October 19, 1999.

HED DOC. DP Barcode D196769 and D248311: Radiolabeled Method Validation Data for proposed Enforcement Method and Magnitude of the residue Data Supporting Import Tolerances for Mevinphos, Memorandum from W. Hazel, dated October 19, 1999.

APPENDIX B: LIST OF AVAILABLE RELATED DOCUMENTS

These documents are available from the Public Docket Office or at the following web site: http://www.epa.gov/pesticides/op/mevinphos.htm

1. Hazard Assessment of the Organophosphates
2. FQPA Safety Factor Recommendations for the Organophosphates
3. Frequently Asked Questions
4. *Federal Register* Notice Vol. 65, Number 8, Pages 1867-1869, January 12, 2000 (Comment period ending March 13, 2000)
5. Report of the Hazard Identification Assessment Review Committee
6. *Federal Register* Final Rule Vol. 64, Pages 41818-41823, August 2, 1999; Tolerance Actions
7. Toxicology Chapter for RED
8. Note to reader
9. Report of the FQPA Safety Factor Committee
10. Dietary Exposure and Risk Analyses for the HED Preliminary Human Health Risk Assessment
11. Preliminary Human Health Risk Assessment
12. Residue Chemistry Chapter of the Reregistration Eligibility Decision Document.
13. Registrant's Response to Residue Chemistry Data Requirements
14. Letter to AMVAC Transmitting Preliminary Risk Assessment
15. AMVAC's Comments on the Preliminary Risk Assessment
16. AMVAC's Letter on Studies Resubmitted in Response to the Preliminary Risk Assessment
17. Questions and Answers
18. Response to Registrant's Error Comments on the Preliminary Risk Assessment
19. Letter to AMVAC Requesting Studies
20. *Federal Register* Notice Vol. 65, Number 127, Pages 40631-40632, June 30, 2000 (Comment period ending August 29, 2000)
21. Revised Human Health Risk Assessment.
22. Overview of Mevinphos Revised Risk Assessment
23. Mevinphos Summary
24. Response to Public Comments on Preliminary Risk Assessment