US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Phosalone

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

Combined PDF document consists of the following:

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

- Phosalone TRED

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

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

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

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

TO: Jim Jones, Director
Office of Pesticide Programs

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

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

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

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

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

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

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

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

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

Attachment A:

Organophosphates included in the OP Cumulative Assessment

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

United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508C)
EPA 738-R-01-001
January 2001

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

United States Environmental Protection Agency | Prevention, Pesticides and Toxic Substances (7508C) | EPA 738-F-01-001 January 2001

Phosalone Facts

EPA has assessed the dietary risks of phosalone and prepared a "Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision" for this organophosphate (OP) pesticide. Phosalone fits into its own "risk cup"-- its individual risks are within acceptable levels.

Phosalone has no U.S. registrations and nine import tolerances, on almond (hulls), almonds, apples, apricots, cherries, grapes, peaches, pears, and plums (fresh prunes). Phosalone treated crops do not pose risk concerns, and no risk mitigation is necessary at this time.

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

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

The OP Pilot Public Participation Process

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

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

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

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

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

Uses

- An insecticide/acaricide, phosalone is used to control various insect species in/on almonds, apples, apricots, cherries, grapes, peaches, pears, and plums in Algeria, Austria, Belgium, Canada, Croatia, Czech Republic, France, Greece, Hungary, Iraq, Italy, Japan, Kuwait, Morocco, Poland, Portugal, Russia, Slovak Republic, Spain, Switzerland, Taiwan, Tunisia, Turkey, and Ukraine. It is not registered under FIFRA and may not be sold, distributed, or used in the U.S.

- Nine import tolerances are established for residues of phosaone in/on imported almonds, apples, apricots, cherries, grapes, peaches, pears, and plums. It is estimated that less than 1.5% of the apples (fresh and dried), 0.1% of pears, 0.05% of peaches, and 0.2% of plums available in the U.S. are imported from countries with phosalone registrations. Total imports treated with phosalone is approximately 13.0 %; 6.0 % of which is from apple juice.

Health Effects

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

Risks

- Dietary exposures from eating food crops treated with phosalone are below the level of concern for the entire U.S. population, including infants and children. Dietary exposure through drinking water is not expected because there is no domestic usage.

Risk Mitigation

- Dietary risk from exposure to phosalone does not exceed EPA's level of concern. Therefore, no mitigation is necessary and no further actions are warranted at this time.

Next Steps

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

- When the cumulative risk assessment for all organophosphate pesticides is completed, EPA will issue its final tolerance reassessment decision for phosalone and may request further risk mitigation measures. For all OPs, raising and/or establishing tolerances will be considered once a cumulative assessment is completed.

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the revised risk assessment for the organophosphate pesticide phosalone. The public comment period on the revised risk assessment phase of the tolerance reassessment process is closed. The attached document summarizes the Agency's assessment of the dietary risk from phosalone as part of the tolerance reassessment process for this chemical, presents a summary of the related food tolerance for this single chemical, and provides the Agency's current risk management decision based on the risk assessment. Phosalone is not registered in the U.S. However, there are nine 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 phosalone" is published in the *Federal Register*. This document and the technical documents supporting it are available for viewing in the Office of Pesticide Programs' Public Docket and can also be found on the Agency's web page, "www.epa.gov/pesticides/op/phosalone.htm."

This document is based on the updated technical information found in the phosalone 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 phosalone, 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, Aventis CropScience, as well as comments submitted by the general public and stakeholders during the comment period on the risk assessment.

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 phosalone 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 phosalone once the cumulative assessment for all of the organophosphates is complete.

If you have questions on this document, please contact the Special Review and Reregistration Division representative, John Pates at (703) 308-8195.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

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

TABLE OF CONTENTS

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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.

GLOSSARY OF TERMS AND ABBREVIATIONS

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

GLOSSARY OF TERMS AND ABBREVIATIONS

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
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 and is issuing its risk management decisions for phosalone, an organophosphate insecticide. The decisions outlined in this document do not include the final decisions for phosalone. The revised risk assessment is based on review of the required target data base supporting the nine phosalone import tolerances and information received during the public comment periods in the open process developed through the Tolerance Reassessment Advisory Committee (TRAC).

Overall Risk Summary

All phosalone containing products registered in the U.S., as of 1992, have been canceled; human exposure to this pesticide is strictly through the consumption of imported foods. This risk assessment involves consideration of only the hazard component of the risk and food sources of dietary exposure. Residential and occupational exposures as well as dietary exposure through drinking water are not expected because there is no domestic use of phosalone. Therefore, aggregate acute and chronic risks are attributable only to food sources of dietary exposure. EPA's revised risk assessment for phosalone indicates that acute and chronic dietary risk is below the Agency's level of concern; therefore, no risk mitigation is necessary at this time.

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

I. Introduction

This report on the progress toward tolerance reassessment of phosalone 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. Phosalone is subject only to FQPA because it has only import tolerances and is not registered for use in the U.S. However, some history and background of FIFRA is included here for informational purposes and to provide a discussion of the existing laws governing pesticides.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amended FFDCA to require that all tolerances be reassessed within a 10-year period and that those, which are considered to be the riskiest, are reassessed first and foremost. It also requires that by August 2006, EPA review all tolerances in effect on the day before the date of the enactment of the FQPA. Since organophosphates share a common mechanism of toxicity and are considered some of the riskiest of all chemicals, it has been deemed necessary that these particular chemicals be grouped together. The Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after completing risk assessments for the individual organophosphates. Although not subject to the reregistration process, due to no domestic registrations, phosalone does have import tolerances that could factor into dietary risk. 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. The individual dietary assessment for the organophosphate phosalone has been completed, and will be used in the cumulative assessment of all of the organophosphate chemicals, to satisfy the requirements of FQPA.

Phosalone is not registered for use in the United States; however, there are nine import tolerances on almonds, grapes, pome and stone fruits for this chemical. Because it is not registered in the U.S., it is not subject to the reregistration process. It is subject to the requirements of FQPA; therefore, a dietary risk assessment was completed. This document presents the Agency's dietary risk assessment for phosalone, as part of the tolerance reassessment process. Note that there is no comment period for this document. As part of the process developed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessment for phosalone 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 Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period, depending on the content of the risk management decision.

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 reregistration/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 phosalone, 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/phosalone.htm), and in the Public Docket.

II. CHEMICAL OVERVIEW

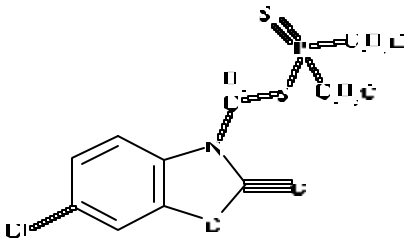
A. Regulatory History

Phosalone is an organophosphate insecticide/acaricide first registered in 1969. All U.S. registrations were voluntarily canceled in 1989 by the registrant at that time, Rhone-Poulenc Ag Company (RPAC). The Agency proposed to revoke all phosalone tolerances in 1998 (63 FR 3057). However, in response to this proposal, RPAC (now Aventis CropScience) requested that the Agency not revoke tolerances for phosalone residues in/on almonds, grapes, pome fruits (apples and pears), and stone fruits (apricots, cherries, peaches, and plums) so that these commodities bearing phosalone could continue to be imported legally into the U.S. In the Final Rule published in the Federal Register

of 10/26/98, the Agency maintained existing tolerances for residues of phosalone in/on the specified commodities: almond (hulls), almonds, apples, apricots, cherries, grapes, peaches, pears, and plums (fresh prunes), while revoking the remaining phosalone tolerances under (40 CFR §180.263) and (40 CFR §186.4800).

Permanent tolerances of 0.1 to 50.0 ppm(s) have been established by the U.S. EPA under 40 CFR §180.263 for residues of phosalone in/on almonds, almond hulls, grapes, apples, apricots, cherries, peaches, pears, and plums imported into this country. Products containing the active ingredient phosalone are registered and marketed in a number of countries (mostly in Europe), primarily to tree crops and grapes, which may be treated and exported from those countries to the U.S. However, the current use pattern is very limited in comparison to what may be specified on the label because of the entry of other pest control products, use within IPM systems, marketing strategies and changed grower practices.

B. Chemical Identification



- **Common Name:** Phosalone
- **Chemical Name:** (O,O-diethyl S-[(6-chloro-2-oxobenzoaxzolin-3-yl)methyl] phosphorodithioate)
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 2310-17-0
- **OPP Chemical Code:** 097701
- **Empirical Formula:** $C_{12}H_{15}ClNO_4PS_2$
- **Molecular Weight:** 367.80
- **Trade and Other Names:** Zolone, Rubitox
- **Basic Manufacturers:** Aventis CropScience

A detailed discussion on the physical properties of phosalone can be found in the EPA document entitled "Phosalone: Preliminary Human Health Risk Assessment," dated November 1, 1999.

C. Use Profile

The following information is based on the current uses of phosalone outside of the United States, and includes an overview of use sites and application methods. Phosalone is registered in: Algeria, Austria, Belgium, Canada, Croatia, Czech Republic, France, Greece, Hungary, Iraq, Italy, Japan, Kuwait, Morocco, Poland, Portugal, Russia, Slovak Republic, Spain, Switzerland, Taiwan, Tunisia, Turkey, and Ukraine for use on almonds, grapes, pome and stone fruits. Phosalone is not registered under FIFRA and may not be sold, distributed, or used in the U.S.

Type of Pesticide:	Insecticide/Acaricide
Summary of Use Sites:	*Import only*: Almond (hulls), Almonds, Apples, Apricots, Cherries, Grapes, Peaches, Pears, Plums (fresh prunes).
Target Pests:	Phosalone is used to control mites, apple rust mite, broad mite, brown almond mite, brown mite, spruce spider mite, citrus red mite, European red mite, Pacific spider mite, two-spotted spider mite, thrips, citrus thrips, Colorado potato beetle, plum curculio, pecan weevil, chrysanthemum leafminer, cherry fruit fly, walnut husk fly, apple maggot, whiteflies, aphids, citrus aphids, pecan aphids, buckthorn aphid, apple aphid, green apple aphid, leafcurl plum aphid, thistle aphid, black peach aphid, walnut aphid, rosy apple aphid, wooly apple aphid, potato aphid, rose, aphid, filbert aphid, black cherry aphid, green peach aphid, hop aphid, black pecan aphid, pecan spittlebug, leafhoppers, potato leafhopper, grape, leafhopper, variegated leafhopper, pecan phylloxera, grape phylloxera, pear psylla, European apple sawfly, peach twig borer, potato tuberworm, green fruitworm, orangedog, plume moths, pecan nut casebearer, mineola moth, European corn borer, fruittree leafroller, redbanded leafroller, obliquebanded leafroller, omnivorous leafroller, European leafroller, filbert leafroller, oriental fruit moth, hickory shuckworm, codling moth, filbert worm, grape berry moth, eyespotted bud moth.

Formulation Types: There are three basic formulations manufactured: emulsifiable concentrate (2.91 lb/gallon/ai), flowable concentrate (4.17 lb/gallon/ai), and wettable powder (30%). In a very few countries, a local formulation is used. Local formulations are simply more dilute versions of either the (2.91 lb/gallon/ai) EC or the 30% WP, using the same inerts but in higher quantity to achieve a lower assay.

Method and Rates of Application:

Equipment- Ground and/or aerial equipment.

Method and Rate - Phosalone is applied as broadcast foliar applications using ground or aerial equipment. The maximum use rate per season on labels ranges from 1.6 lb ai/acre/season to 4.0 lb ai/acre/season, however, labels for non-EU countries (Turkey, Czech Republic, and Slovak Republic) do not specify the maximum number of applications allowed.

Timing - Actual use practices typically result in significantly longer (<35 days) preharvest intervals, no more than 2-3 applications per year at timings determined by pest pressure and official recommendations.

Use Classification: N/A -- 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 phosalone. 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.

The market share of phosalone among the exporting countries (preceding section labeled: Summary of Use Sites) is minimal. The percent of almonds, apples, apple juice, apricots, cherries, grapes, raisins, peaches, pears, and plums derived from countries possessing phosalone registrations was assessed using statistics submitted by RPAC (now Aventis CropScience) quantifying the amount of each commodity available for U.S. consumption from both domestic and foreign sources. It is

estimated that less than 1.5% of the apples (fresh and dried), 0.1% of pears, 0.05% of peaches, and 0.2% of plums available in the U.S. are imported from countries with phosalone registrations. These statistics, which reflect U.S. production data from the USDA National Agricultural Statistics Service averaged from 1992-1996 plus U.S. import data from the U.S. Department of Commerce averaged from 1992-1996, were used to generate the values summarized in Table 1. The FDA monitoring data for 1992-1998 support these numbers.

Table 1. Phosalone Usage Information

Crop	Commodity	Total Available for U.S. Consumption from Domestic + Foreign Sources (1000 lbs.)	Total from Domestic Sources (1000 lbs.)	Total from Foreign Sources [a]	Total from Exporting Countries with Phosalone Registered (1000 lbs.)	Total from Exporting Countries without Phosalone Registered [a] (1000 lbs.)	% from Countries with Phosalone Registered
Almonds	nutmeat	532,714	532,600	114	1	113	0.0002 %
Apples	fresh + dried	8,332,009	8,024,340	307,669	117,171	190,498	1.41 %
	juice	4,913,086	2,458,660	2,454,426	294,785	1,775,168	6.0 %
Apricots	fresh + dried + pulp/prepared or preserved + kernel (peach, plum or other stone fruits)	222,569	193,644	28,925	857	28,068	0.39 %
Cherries (Sweet & Tart Varieties)	fresh	184,006	172,384	11,622	938	10,684	0.51 %
Grapes	fresh + juice + wine	11,005,780	9,463,988	1,541,792	418,220	1,046,579	3.8 %
	raisins (fresh basis)	3,282,885	3,199,120	83,765	14,861	68,904	0.45 %
Peaches (including nectarines)	fresh	1,583,569	1,482,580	100,989	845	100,144	0.05 %
Pears	fresh (including quince) + nesoi	9,413,574	9,279,200	134,374	6,051	128,323	0.06 %
Plums	fresh + dried (fresh basis)	1,589,478	1,543,604	46,874	2,756	44,118	0.17 %

[a] The values in these columns do not account for countries without phosalone registrations that are responsible for <1% of the corresponding commodity imported by the U.S.

III. Summary of Phosalone Risk Assessment

Following is a summary of EPA's revised human health risk findings and conclusions for the organophosphate pesticide phosalone, as fully presented in the revised risk assessment document, "Phosalone: Revised Human Health Risk Assessment," dated June 12, 2000. The risk assessment presented here forms the basis of the Agency's interim risk management decision for phosalone only; the Agency must complete a cumulative assessment of the risks of all organophosphate pesticides before it can complete its reassessment of the phosalone tolerances.

Because phosalone 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.

A. Human Health Risk Assessment

During the comment periods on the phosalone human health risk assessment, the only comments received were from the registrant, Aventis CropScience. The Agency reviewed the comments and no substantive revisions were made to the risk assessment. However, based on these comments and recently submitted data, the Agency has decided to waive and/or reduce the number of field trials required to support tolerance reassessment. Since phosalone has no U.S. registrations, the assessment did not address ecological, drinking water, or occupational risk issues. The only source of possible human exposure is through residues in imported foods and the conclusion of the assessment indicated that food risk from phosalone is below the Agency's level of concern.

1. Dietary Risk from Food

a. Toxicity

EPA has determined that it is appropriate to treat the organophosphates (OPs) as sharing a common mechanism of toxicity because of their common mode of action, which inhibits cholinesterase (ChE) activity. As required by FQPA, a cumulative assessment will need to be conducted to evaluate the risk from food, water, and non-occupational exposure resulting from all uses of OPs.

Information from blood cholinesterase inhibition data is considered to provide important insights into potential hazard. Although red blood cell (RBC) measures of acetylcholinesterase (AchE) are generally preferred over plasma measures of cholinesterase activity, the Agency may use plasma cholinesterase inhibition data under certain circumstances, such as if red blood cell data are insufficient, of poor quality, or unavailable; if there is a lack of dose-dependency for the red blood cell acetylcholinesterase inhibition; or, if the dose responses for inhibition of plasma cholinesterase more closely approximate those for AchE inhibition in the nervous system than do the dose responses for RBC acetylcholinesterase inhibition.

NOAELs were not determined for plasma ChE inhibition in the acute rat neurotoxicity study; for systemic effects or plasma, RBC, or brain ChE inhibition in the subchronic rat neurotoxicity study; for plasma ChE inhibition in the chronic dog study; for plasma or RBC ChE inhibition in the mouse carcinogenicity study; or for RBC ChE inhibition in the reproduction study. The lack of NOAELs in these studies did not interfere with endpoint selection and the toxicology database is considered adequate and of good quality.

The Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicological database for phosalone and selected toxicity endpoints for dietary exposure. The ensuing table (Table 2) contains a summary of the doses and toxicity endpoints selected for use in the human health risk assessment.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Phosalone.

Exposure	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary (General population including infants and children)	LOAEL = 10	Plasma ChE inhibition	Acute neurotoxicity in rats
	UF =300	**Acute RfD = Acute PAD = 0.03 mg/kg /day**	
Acute Dietary (Females 13+)	Developmental NOAEL = 1	Post-implantation loss	Developmental toxicity in rabbits
	UF =100	**Acute RfD = Acute PAD = 0.01 mg/kg /day**	
Chronic Dietary	NOAEL = 0.2	Plasma and RBC ChE inhibition (both sexes), decreased testicular weight and lesions	2-Year Rat Study
	UF =100	**Chronic RfD = Chronic PAD = 0.002 mg/kg/day**	

b. FQPA Safety Factor

The FQPA Safety Factor was reduced to 1X. The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute *in utero* exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Adequate actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary exposure. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children. Therefore, the additional 10X factor as required by FQPA was reduced to 1X.

It must be noted that in the prenatal developmental toxicity study in rats and the two-generation reproduction study in rats, effects in the fetuses/offspring were observed at doses higher than those

producing maternal/paternal effects. The effects observed in the fetuses/offspring are not considered a true quantitative increase in fetal sensitivity, due to two reasons. First, the endpoint of 1 mg/kg/day is a very conservative indicator of toxicity because it is based on total resorptions and is not a litter effect. Second, although cholinesterase activity was not determined in the study, it is likely that significant cholinesterase inhibition occurred at 20 mg/kg/day, considering the severity of the maternal clinical signs (labored breathing, abdominal cramps, extension spasms, prostration). Based upon information from other studies, it is presumed that cholinesterase activity was also inhibited in the maternal rabbits at 10 mg/kg/day. Therefore, ChE determinations would most likely have shown the maternal NOAEL to be the same as the developmental NOAEL or lower.

c. 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). For the acute dietary assessment, risk is calculated considering what is eaten in one day (consumption) and residue values in the food. For chronic exposures, dietary risk is calculated by using the average consumption value for food and average residue value. In the case of phosalone, the FQPA safety factor is 1X; therefore, the acute or chronic Reference Dose (RfD) = the acute or chronic Population Adjusted Dose (PAD). A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

d. Exposure Assumptions

Revised acute and chronic dietary risk analyses for phosalone were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Survey of Food Intakes by Individuals (CSFII), 1989-91. Acute and chronic dietary analyses were also conducted using anticipated residues (ARs) based on FDA Surveillance Monitoring data. Anticipated residues on almonds and cherries were calculated from field trial results due to lack of sufficient monitoring data. Although USDA/PDP data were available for some commodities, the FDA data were preferable due to a larger number of samples of foods imported from countries having phosalone registrations. In the case of almonds where there were non-detectable residues, ½ the limit of detection was used in the dietary exposure assessments. The acute and chronic analyses take into consideration the reduction of phosalone residues in certain processed foods.

Based on available livestock metabolism and feeding studies, it has been determined that there is no reasonable expectation of finite residues being transferred into livestock commodities from feed items bearing phosalone residues, i.e., a 180.6(a)(3) classification is appropriate. With regards to wet apple pomace, the majority of apple imports are in the form of juice (84%), with 9% of apple imports being fresh fruit. It is unlikely that these imported apples will be used for processing; therefore, domestic livestock are unlikely to be fed wet apple pomace bearing phosalone residues. In addition, of the countries with registered uses of phosalone on apples, only Canada exports significant quantities of

beef (3% of available commodity) to the U.S. If the percentage of the apple crop treated with phosalone in Canada (6.5%) is also considered, then only 0.2% of the available beef supply could possibly contain phosalone residues. As a result, tolerances for phosalone residues in livestock commodities are not necessary. Consequently, the dietary exposure assessments reflected no consumption of livestock commodities.

e. Acute Food Risk

An acute dietary assessment was conducted for phosalone. A Tier 3 probabilistic (Monte Carlo) technique was used in order that the high-end (or low end) consumer had an equal chance of getting a high or low dose residue level. A risk estimate that is less than 100% of the (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. Results at the 99.9th percentile of exposure for all population subgroups ($\leq$0.74% of the aPAD) confirm that the current residue levels do not exceed the Agency's risk concern. This estimate has been highly refined using Monte Carlo analysis and FDA monitoring data as the principal source of anticipated residues.

The aPAD for the general population (including infants and children) is 0.03 mg/kg/day. This endpoint is from an acute neurotoxicity study in the rats with a LOAEL of 10 mg/kg/day, the lowest dose tested. Although a NOAEL for plasma cholinesterase was not determined in this study, the LOAEL is believed to be close to a NOAEL, as neither brain nor RBC cholinesterase were statistically significantly inhibited at 10 mg/kg or 25 mg/kg in this study. Uncertainty factors total 300X (10X for interspecies extrapolation, 10X for intraspecies variation, and 3X for lack of a NOAEL).

f. Chronic Food Risk

The chronic dietary risk assessment is achieved by combining the average consumption values for food and average residue values for those foods, for each population subgroup, over a 70-year lifetime to determine average exposure in mg/kg/day. Based upon achieved modeling numbers, DEEM estimates that all population subgroups are chronically exposed to phosalone at a level less than the phosalone chronic Population Adjusted Dose (cPAD). Chronic risks to all population subgroups was 0.1% or less of the cPAD. The chronic dietary risk from phosalone residues in food alone is also below the Agency's level of concern.

In summary, acute risks to all population subgroups were $\leq$0.74% of the aPAD and chronic risks to all population subgroups were $\leq$0.1% of the cPAD, well below the Agency's levels of concern. Below in Table 3 is a representation of these risk estimates.

Table 3. Summary of Phosalone Acute & Chronic Non-cancer Dietary Exposure and Risk Estimates [1]

Population Subgroup	Acute Assessment (99.9th %-ile of Exposure)				Chronic Assessment	
	General U.S. Population Including All Infants and Children Subgroups		Females 13+			
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.000049	0.16	N/A	N/A	0.000001	0.0
All Infants (<1 yr)	0.000084	0.28	N/A	N/A	0.000001	0.1
Children (1-6 yrs)	0.000221	0.74	N/A	N/A	0.000002	0.1
Children (7-12 yrs)	0.000132	0.44	N/A	N/A	0.000001	0.0
Females (13-50 yrs)	0.000016	0.05	0.000017	0.17	0.000000	0.0
Males (13-19 yrs)	0.000014	0.05	N/A	N/A	0.000000	0.0
Males (20+ yrs)	0.000017	0.06	N/A	N/A	0.000000	0.0

[1]The Acute Population Adjusted Doses (aPADs) are 0.03 mg/kg/day for the "General U.S. Population Including All Infants and Children Subgroups" and 0.01 mg/kg/day for "Females 13+." The Chronic PAD (cPAD) is 0.002 mg/kg/day for all population subgroups.

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 phosalone 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 phosalone, EPA has sufficient information on the human health effects of phosalone to make some interim decisions as part of the tolerance reassessment process under 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 phosalone alone in order to determine whether any risk reduction measures are necessary to allow the continued importation of almonds, apples, apricots, cherries, grapes, peaches, pears, and plums containing this chemical, pending completion of the cumulative assessment.

As a result of its assessment, EPA has determined that dietary risk from exposure to phosalone does not exceed the Agency's level of concern. Therefore, no mitigation is necessary and no further actions are warranted at this time. The Agency may determine, however, that further 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 phosalone food residue import tolerances as called for by the FQPA. When the Agency has completed the cumulative assessment, the phosalone tolerances will be reassessed in that light. At that time, the Agency will reassess phosalone 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 phosalone, 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 phosalone to the public in July 26, 2000, and provided a 60 day comment period for interested parties to submit information, including risk mitigation suggestions or proposals. During this time, no comments were received in relation to this comment period.

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 phosalone is within its own "risk cup." In other words, if phosalone did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the import tolerance for phosalone on almonds, grapes, apples, apricots, cherries, peaches, pears, and plums meets 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 phosalone, because there are no domestic uses. But, results of the acute and chronic food assessments indicate that exposures are within acceptable levels; that is, risk from exposure to phosalone "fits" within the individual risk cup. Therefore, the import tolerance remains in effect and unchanged until a full reassessment of the cumulative risk from all organophosphates is completed.

b. Tolerance Summary

The established tolerance for residues of phosalone in/on plant commodities is currently expressed in terms of residues of phosalone per se (S-(6-chloro-3-(mercaptomethyl)-2-benzoxazolinone)O,O,-diethyl phosphorodithioate) [40 CFR §180.263]. It should be noted, however, that the preferred chemical name for phosalone is (O,O-diethyl S-[(6-chloro-2-oxobenzoxazolin-3-yl)methyl] phosphorodithioate). The referenced tolerances for residues of phosalone in/on plant commodities are outlined in Table 4 of this document.

Because the grape use will be deleted from French labels in the near future, it has been decided that additional field trial studies need to be conducted solely in Canada reflecting their Good Agricultural Practices (GAP). The tolerances are to reflect the Canadian use pattern on grapes, apples, pears, cherries, peaches, and plums. In response to Aventis' comments, the Agency has decided to waive pear field trials and reduce the number of trials required on peaches and plums. However, several side-by-side field trials have been determined necessary to compare residues resulting from the application of two major formulation classes.

It is recommended that both the EC and either the WP or FLC be applied in side-by-side studies involving two major grape growing regions and that the re-treatment intervals being tested should mirror common commercial practice.

The same scenario is true for side-by-side studies involving apples, but only one additional trial, conducted in Canada in one major grape growing region, is recommended. The field trial is to encompass the EC and either the WP or FLC to be applied in side-by-side Canadian trials. In conjunction, due to the very low percentage of imported pears available for consumption, the Agency has decided not to require pear field trials. It is important to state that a pome fruit crop group tolerance may not be established without the additional two pear field trials which would reflect the Canadian GAP.

The new Canadian cherry field trials tentatively satisfy the requirements to support an import tolerance. Depending upon whether or not these side-by-side studies on other crops indicate differences between residues, resulting from different formulation classes, additional cherry field trials may be required testing the EC formulation.

In respect to peaches and plums, EPA is reducing the number of trials to be conducted from three to two each, but to require side-by-side trials testing the EC and either the FLC or WP. These trials should reflect the Canadian GAP.

Table 4. Tolerance Reassessment Summary for Phosalone.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Tolerances listed under 40 CFR §180.263:			
Almonds	0.1	0.1	Almond, nutmeat
Almonds, hulls	50.0	Revoke	Almond hulls are not imported.
Apples	10.0	TBD [a]	The available data indicate that the established tolerances are too high and may be lowered to 1.0 ppm for residues in/on grapes and stone fruits, and 2.0 ppm for residues in/on pome fruits. However, additional data reflecting the slightly higher use rate of the Canadian GAP are required before the tolerances can be reassessed.
Apricots	15.0		
Cherries	15.0		
Grapes	10.0		
Peaches	15.0		
Pears	10.0		
Plums (fresh prunes)	15.0		
Tolerances needed under 40 CFR §180.263			
Raisins	None	TBD	Additional data on grapes are needed to assess an appropriate tolerance for residues in raisins. Phosalone residues concentrate by ~2X in raisins.
Prunes	None	TBD	To assess an appropriate tolerance for residues in prunes, data are needed from field trials on plums. Phosalone residues concentrate by a maximum of ~2x in prunes.
Pome fruits	None	TBD	The available residue data on imported apples, pears, peaches, and cherries suggest that crop group tolerances may be appropriate for pome and stone fruits. If the requested residue data on pome and stone fruits from Canadian studies are similar to the available data from Europe and Japan, then crop groups should be established for pome fruits and stone fruits concomitant with revoking the individual tolerances for the members of these crop groups.
Stone fruits	None	TBD	

[a] TBD = To be determined. Tolerance cannot be determined at this time because additional data are required.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its

Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific 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, phosalone may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

D. Regulatory Rationale

Phosalone has nine 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 below the Agency's level of concern; therefore, no mitigation measures are necessary at this time.

V. What Manufacturers Must 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.). Although phosalone has no U.S. registrations and therefore is not subject to a FIFRA DCI, it does have a tolerance or tolerances for almonds, grapes, pome and stone fruits that are imported into the U.S. EPA is currently working to require the submission of acute, subchronic, and developmental neurotoxicity studies under the authority of FFDCA. Results of these studies may further refine the risk assessments.

In addition, the *In Vitro* Unscheduled DNA Synthesis (UDS) Assay has been recommended to be repeated in order to confirm the findings of an earlier study indicating weak UDS-inducing activity. Likewise, the General Metabolism Study (in rats) has been deemed unacceptable, due to the majority of the radioactivity in urine not being identifiable. Additional data have been requested in order to upgrade the study to an acceptable status. In compliance with regulatory policy, the registrant (Aventis CropScience) has planned a new rat metabolism study for initiation in approximately April 2000. This study is being initiated in connection to the requested additional data, metabolite identification in urine**,** which was not possible due to the unavailability of samples for further analysis.

Additional Field Trials:

Peach and Plum field trials have been reduced from three to two each, but to require side-by-side trials testing the EC and either the FLC or WP. These trials should reflect the Canadian GAP.

Grape field trials are to include both the EC and either the WP or FLC to be applied in side-by-side studies involving two major grape growing regions and that the re-treatment intervals being tested mirror common commercial practice.

An **apple** field trial study is to be conducted in Canada in one major grape growing region, involving one additional side-by-side trial encompassing the EC and either the WP or FLC. *It is important to state that a pome fruit crop group tolerance may not be established without the additional two pear field trials which would reflect the Canadian GAP.*

*****(New Canadian **cherry** field trials tentatively satisfy the requirements to support an import tolerance. Depending upon whether or not these side-by-side studies on other crops indicate differences between residues, resulting from different formulation classes, additional cherry field trials may be required testing the EC formulation).

B. Risk Mitigation Requirements

As discussed in this document, the acute and chronic food risk from the use of phosalone on almonds, grapes, and certain pome and stone fruits is not of concern to the Agency; therefore, no mitigation is necessary at this time. The Agency may need to pursue further risk management measures for phosalone 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 September 10, 1998. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal “Response to Comments” document and the revised risk assessment to the docket on July 7, 1999.

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

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