



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.<sup>1</sup> 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

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<sup>1</sup> 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](http://www.epa.gov/pesticides/cumulative) and in the docket (EPA-HQ-OPP-2006-0618).

**Attachment A:**  
Organophosphates included in the OP Cumulative Assessment

<b>Chemical</b>	<b>Decision Document</b>	<b>Status</b>
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



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**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 preliminary and revised risk assessments for the organophosphate pesticide tetrachlorvinphos. The public comment period on the revised risk assessment phase of the tolerance reassessment process is closed. Based on comments received during the public comment period and additional data received from the registrant, the Agency revised the human health risk assessment and made it available to the public on March 3, 2000. During Phase 5, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessment. This public participation and comment period closed on May 29, 2000.

The major means by which the Agency reassesses tolerances is through its reregistration process. Each pesticide registered prior to 1984 is subject to comprehensive evaluation of its effects on human health and the environment. Such an evaluation includes a determination of whether the tolerances are safe. Since tetrachlorvinphos was registered in 1966, it is subject to reregistration. The Agency issued a reregistration eligibility decision (RED) for tetrachlorvinphos in 1995, prior to the passage of Food Quality and Protection Act of 1996 (FQPA). However, tetrachlorvinphos tolerances are subject to reassessment in accordance with the Federal, Food, Drug, and Cosmetic Act (FFDCA) as amended by FQPA. This Act requires EPA to re-evaluate existing tolerances to ensure that children and other sensitive populations are protected from pesticide risk.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health risks associated with the current use of tetrachlorvinphos. EPA is now publishing its interim tolerance reassessment eligibility decision (TRED) which includes addenda to the 1995 reregistration eligibility decision and the risk management decisions for the current uses of tetrachlorvinphos. The tolerance reassessment decisions for tetrachlorvinphos will be finalized once the cumulative risks for all of the organophosphate pesticides are considered. The enclosed "Tolerance Reassessment Eligibility Decision for tetrachlorvinphos," which was approved on July 5, 2002, contains the Agency's

decision on the individual chemical tetrachlorvinphos.

A Notice of Availability for this is being published in the *Federal Register*. To obtain a copy of the TRED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the interim TRED and all supporting documents are available on the Internet. See <http://www.epa.gov/pesticides/op>.

The TRED is based on the updated technical information found in the tetrachlorvinphos public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessments for tetrachlorvinphos, and a document summarizing the Agency's Response to Comments. The Response to Comments document addresses corrections to the preliminary risk assessments submitted by chemical registrants, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket will also include comments on the revised risk assessment, and any risk mitigation proposals submitted during Phase 5. For tetrachlorvinphos, a proposal was submitted by Boehringer Ingelheim, the technical registrant. Comments on mitigation were also submitted by USDA.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in reregistration and/or tolerance reassessment decisions. 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. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that 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 tetrachlorvinphos risk assessment and the attached interim TRED concern only this particular organophosphate. This TRED presents the Agency's conclusions on the dietary and residential risks posed by exposure to tetrachlorvinphos alone. It also includes an updated assessment of the worker risks associated with the use of tetrachlorvinphos. No assessment for ecological risk was performed since those risks were considered during reregistration in 1995 and no new data were submitted which would warrant a new assessment. 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 enzyme, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after considering the risks for the individual organophosphates. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address the human health risks associated with the current uses of tetrachlorvinphos. The

Agency will issue the final tolerance reassessment decision for tetrachlorvinphos and finalize decisions on reregistration eligibility once the cumulative risks for all of the organophosphates are considered.

This document contains a generic Data Call-In (DCI) that outlines further data requirements for this chemical. Note that a complete DCI, with all pertinent instructions, is being sent to registrants under separate cover.

The Agency has determined that tetrachlorvinphos will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of tetrachlorvinphos may pose unreasonable adverse effects to human health and the environment, unless the risk mitigation measures identified herein are implemented. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Sections IV and V of this TRED describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this TRED.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by tetrachlorvinphos. Where the Agency has identified any unreasonable adverse effect to human health, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Demson Fuller at (703)308-8062.

Sincerely,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

Attachment

**Interim Tolerance Reassessment Eligibility Decision and  
Reregistration Eligibility Decision Addenda  
for  
Tetrachlorvinphos**

**Case No. 0321**

# Tetrachlorvinphos Facts

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EPA has assessed the risks of tetrachlorvinphos and completed a Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (or TRED) for this organophosphate (OP) pesticide. Provided that risk mitigation measures are adopted, individual, aggregate risks for tetrachlorvinphos are within acceptable levels.

EPA's next step is to consider the cumulative risks of the OP pesticides, which share a common mechanism of toxicity. The interim tolerance reassessment decision for tetrachlorvinphos will not be final until these cumulative risks also are considered. Further risk mitigation may be warranted at that time.

EPA completed a Reregistration Eligibility Decision (RED) before the Food Quality Protection Act (FQPA) of 1996 was enacted. At present, only food, occupational, and residential uses of tetrachlorvinphos are being reevaluated, and tolerances (legal limits for residues in food) must be reassessed to ensure that they meet the new safety standard effected by the FQPA.

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 food, drinking water, and other non-occupational exposures must be reassessed to make sure they meet the new FFDCSA safety standard, brought about by the FQPA.

The tetrachlorvinphos TRED was developed through the OP 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

## **The OP Pilot Public Participation Process**

The organophosphates (OPs) are a group of related pesticides that affect the functioning of the nervous system. They are among EPA's highest priority for review in implementing the Food Quality Protection Act (FQPA) of 1996.

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

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

Based on current information from interested stakeholders and the public, EPA is making interim risk management decisions for individual OP pesticides. The Agency will make final decisions after considering the cumulative risks of the OPs. (Please see [www.epa.gov/pesticides/cumulative.htm](http://www.epa.gov/pesticides/cumulative.htm) .)



document.

## Uses

1. An insecticide, tetrachlorvinphos is currently applied dermally to livestock to control flies and mites; used as a feed-through (oral) larvicide in cattle, hogs, goats, and horses; in cattle ear tags to control flies; in poultry dust boxes to control poultry mites; and as paint on and sprays in poultry houses. Tetrachlorvinphos also is used as a dust/powder, aerosol, and pump spray on pets and in pet sleeping areas, and in collars and shampoos for direct treatment of pets. It is used as a spray to control nuisance and public health pests (flies) in and around refuse sites, recreational areas, and for limited outdoor use as premise sprays for fleas, ticks, chiggers, and mites, around kennels, yards, campgrounds, and parks, and along foot paths and roadways leading to such areas. No tetrachlorvinphos end-use products are currently registered for use on any plant commodity.
2. Approximately 900,000 lbs a.i. of tetrachlorvinphos are used annually, according to Agency and registrant estimates.

## Health Effects

3. Tetrachlorvinphos 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. Tetrachlorvinphos is classified as a Group C, possible human carcinogen. The cancer potency factor ( $Q_1^*$ ) is  $1.83 \times 10^{-3}$ .

## Risks

4. Dietary risks from eating food items containing residues of tetrachlorvinphos are below the level of concern for the entire U.S. population, including infants and children. Drinking water is not a significant source of exposure.
5. Residential handler and post application risks were also not of concern for all exposure scenarios. However, the Agency has concern over the potential for over-application of powder products. Labels need to be modified to specify how much product to apply to treat pets of different sizes. Additionally, based on discussions with stakeholders, EPA believes that directions for outdoor uses as premise sprays around kennels, yards, campgrounds, and parks, and along foot paths and roadways leading to such areas, must clearly limit use to spot treatments only.
6. Worker risks are of concern with the maximum level of protection for mixers, loaders, and applicators in poultry egg production operations applying wettable powder formulations with a low-pressure handwand and paint-on application of the EC formulation. In addition, worker risks exceeded the Agency's level of concern with baseline PPE for handlers engaging in

backpack, dusting, groundboom, and low pressure handwand activities. Further, the Agency is concerned about workers handling ear tags, mineral blocks, and pellets when these items are put into place. The Agency does not have data for these scenarios, however the Agency has concluded that gloves will mitigate potential concerns which result from dermal contact with these products.

## **Risk Mitigation**

To reduce risks, the following mitigation measures are required:

### Worker risks

7. Delete the paint-on use with emulsifiable concentrate (EC) formulations.
1. Restrict the use of low pressure handwands for wettable powder (WP) applications to spot treatment in poultry facilities and require double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators engaging in low pressure handwand activities using the WP formulations in egg and broiler facilities.
  - Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment to apply WP formulation as dusts.
  - Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators engaging in paint-on activities using WP formulations.
  - Double layer clothing and gloves for workers when handling backrubber devices.
  - Single layer and gloves for loaders and others handling dust bags.
- f. Single layer clothing and gloves for mixers, loaders, and applicators engaging in groundboom activities using the EC and WP formulations.
  - Single layer clothing and gloves for mixers, loaders, and applicators engaging in low pressure handwand activities using the EC formulations in poultry facilities.
  - Single layer clothing and gloves for mixers, loaders, and applicators engaging in backpack spraying activities.
  - Single layer clothing and gloves for workers when handling ear tags, mineral blocks, and pellets (oral larvicide feed-through products).

### Residential risks

- Modify directions for use to specify 1/3 oz. of powder for every 10 pounds of body weight of

the cat or dog.

- Restrict outdoor premise uses to spot treatments, one time a year, and along woody borders of kennels, yards, campgrounds, recreational parks, and footpaths and roadways leading to such areas.
- Prohibit the use of outdoor premise treatments by homeowners.

### **Other Concerns**

- b. EPA has determined that labels for tetrachlorvinphos feed-through products for horses must state that the product is a cholinesterase inhibitor, describe signs of cholinesterase inhibition in horses, caution against use with other cholinesterase inhibiting compounds, and direct horse owners to consult a veterinarian before using products containing tetrachlorvinphos on debilitated, aged, breeding, pregnant or nursing animals.

### **Next Steps**

- c. Numerous opportunities for public comment were offered as this decision was being developed. The tetrachlorvinphos TRED therefore is issued in final without a formal public comment period. (Please see [www.epa.gov/pesticides/reregistration/status.htm](http://www.epa.gov/pesticides/reregistration/status.htm) or [www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op) ). The docket remains open, however, and any comments submitted in the future will be placed in this public docket.
- d. When EPA has considered the cumulative risks of the OP pesticides, the Agency will issue its final tolerance reassessment decision for tetrachlorvinphos and may request further risk mitigation measures. The Agency will revoke 8 tolerances and amend 16 tolerances for tetrachlorvinphos, now. For all OPs, tolerances will not be raised or established until cumulative risks have been considered.

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**TETRACHLORVINPHOS TEAM**

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**Risk Management**

**Demson Fuller  
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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 <sub>50</sub>	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 <sub>50</sub>	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
OPPTSEPA	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 <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
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 tetrachlorvinphos risk assessments and is issuing its risk management decision for tetrachlorvinphos. There are currently 11 tolerances for tetrachlorvinphos. The decisions outlined in this document do not include the final tolerance reassessment decision for tetrachlorvinphos; however, some tolerance actions will be undertaken prior to completion of the final tolerance reassessment. The final tolerance reassessment decision for this chemical will be issued once the cumulative risks for all of the organophosphates are considered. The Agency may need to pursue further risk management measures for tetrachlorvinphos once cumulative risks are considered.

The RED for tetrachlorvinphos was completed in 1995. At that time, the Agency assessed the risk for dietary, occupational, ecological, and residential concerns. With the passage of FQPA, the tolerances for tetrachlorvinphos needed to be reassessed according to the FQPA safety standard. In this current assessment, the Agency looked at dietary, occupational, and residential concerns. This assessment was further updated by a change in the toxicological endpoint than that used in the 1995 RED.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information which has been recently submitted. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on tetrachlorvinphos. After considering the revised risks, as well as mitigation proposed by Boehringer Ingelheim and Hartz Mountain Corporation, the technical registrants of tetrachlorvinphos, and comments and mitigation suggestions from other interested parties, including USDA, EPA developed its risk management decision for tetrachlorvinphos. This decision is discussed fully in this document.

Tetrachlorvinphos is an organophosphate insecticide. It is currently applied dermally to livestock to control flies and mites; used as a feed-through (oral) larvicide in cattle, hogs, goats, and horses; in cattle ear tags to control flies; in poultry dust boxes to control poultry mites; and as paint on and sprays in poultry houses. Tetrachlorvinphos also is used as a dust/powder, aerosol, and pump spray on pets and in pet sleeping areas, and in collars and shampoos for direct treatment of pets. It is used as a spray to control nuisance and public health pests (flies) in and around refuse sites, recreational areas, and for general outdoor treatment. No tetrachlorvinphos end-use products are currently registered for use on any plant commodity.

Tetrachlorvinphos was first registered in 1966. It is formulated as a wettable powder, dust, granular, emulsifiable concentrate, impregnated material, ready to use spray, and pressurized aerosol. Use rates vary, depending on animal size, from 0.0004 lb ai/animal on poultry to a maximum of 0.0208 lb ai/animal on livestock. The use rate for pets is 0.016 lb ai/animal. An annual estimate of tetrachlorvinphos total domestic usage is 853,000 pounds ai for 480,000,000 animals treated. The largest market in terms of total pounds ai is poultry and poultry premises (728,000 lbs. ai). The uses with a high percentage of their total animals treated include horses (16%) and poultry (6%), and households with dogs and/or cats (10%).

## Overall Risk Summary

Food risk, both acute and chronic, is below the Agency's level of concern. No dietary exposure to tetrachlorvinphos is expected through drinking water. There are no concerns for residential handlers or postapplication exposure based on chemical specific data provided by the registrant though some label modifications are necessary. There are no concerns for aggregate risks. There are concerns for mixer, loaders, and applicators using low pressure handwands on poultry and poultry premises. Additionally, there are concerns with occupational cancer risk.

## Dietary Risk

Available data indicate that estimated acute, chronic, and cancer dietary risks are below EPA's level of concern. Based on the supported use patterns, no dietary exposure to tetrachlorvinphos is expected through drinking water. Therefore, no mitigation is warranted at this time for dietary exposure through food or drinking water.

## Occupational Risk

Worker risks are of concern with the maximum level of protection for mixers, loaders, and applicators in poultry egg production operations applying wettable powder formulations with a low-pressure handwand (MOEs ranged from 14 - 80) and paint-on application of the EC formulation (MOEs ranged from 7 -55). Risk to other handlers can be mitigated with personal protective equipment. The Agency also has cancer risk concerns with some risks higher than  $1 \times 10^{-6}$  after adding PPE. The Agency will need the registrant to limit low-pressure handwand usage to "spot" treatment and delete the use of the paint-on EC formulation.

## Residential Risk

Estimated short-term and carcinogenic risk for residential handlers are not of concern for all handler scenarios. Residential post application risks were also not of concern for all exposure scenarios.

## Aggregate Risk

Aggregate risks for tetrachlorvinphos include dietary (food only), handler, and dermal post-application exposures for residential handlers (adults); and post-application dermal, oral (hand-to-mouth) and dietary (food only) exposures for toddlers. In addition, an aggregate cancer assessment was done for adults. Since dietary exposure through drinking water is not expected based on the use patterns, drinking water exposure is not included in the aggregate assessment. Aggregate acute, short-term, chronic, and cancer risks are not of concern. Likewise, aggregate risks for residential handlers are not of concern.

## Ecological Risk

The Agency has not conducted a new risk assessment for the environmental fate and effects of tetrachlorvinphos for the TRED. The conclusions reached in 1995 remain unchanged.

## Other Concerns

The Agency is concerned with tetrachlorvinphos feed-through products for horses. EPA believes that use of these products decrease cholinesterase levels in horses, and that until controlled studies show they pose no unacceptable risks to breeding horses, labels should carry warnings regarding the potential cholinergic effects and that these products have not been tested in breeding horses.

The Agency is issuing this interim TRED for tetrachlorvinphos, as announced in a Notice of Availability published in the *Federal Register*. This interim TRED document includes guidance and time frames for complying with any necessary label changes for products containing tetrachlorvinphos. As part of the process discussed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessments for tetrachlorvinphos have already been subject to several public comment periods, and a further comment period for tetrachlorvinphos was deemed unnecessary. Neither the tolerance reassessment nor the reregistration eligibility decision for tetrachlorvinphos can be considered final until the cumulative risks for all organophosphate pesticides are considered. The cumulative assessment may result in further risk mitigation measures for tetrachlorvinphos.

## **I. Introduction**

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 tolerance reassessment of all existing tolerances. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Tetrachlorvinphos belongs to a group of pesticides called

organophosphates, which share a common mechanism of toxicity - they all affect the nervous system by inhibiting cholinesterase. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

The 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.

In addition to the policy issues that resulted from the TRAC process, the Agency issued, on Sept. 29, 2000, a Pesticide Registration Notice (PR 2000-9) that presents EPA's approach for managing risks from organophosphate pesticides to occupational users. The Worker PR Notice describes the Agency's baseline approach to managing risks to handlers and workers who may be exposed to organophosphate pesticides, and the Agency expects that other types of chemicals will be handled similarly. Generally, basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased reentry intervals will be necessary for most uses where current risk assessments indicate a risk and such protective measures are feasible. The policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this interim RED are consistent with the Worker Pesticide Registration Notice.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health risk assessment resulting from public comments and other information. Section IV presents the Agency's interim decision on tolerance reassessment eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices lists Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page [www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op), and in the Public Docket.

## **II. Chemical Overview**

### **A. Regulatory History**

Tetrachlorvinphos was initially registered for use in the United States in 1966 by the U.S. Department of Agriculture. The original registrant of technical tetrachlorvinphos was Shell Chemical. The registration was subsequently transferred to E.I. duPont Nemours. In September, 1992, DuPont transferred ownership of technical tetrachlorvinphos data to Boehringer Ingelheim Animal Health Inc. (formerly Fermenta Animal Health Company) and Hartz Mountain Corporation. Boehringer and Hartz each received their own technical grade product registrations in 1992. DuPont voluntarily canceled its registration in December 1993. Boehringer is responsible for supplying generic data supporting livestock uses and Hartz is responsible for supplying generic data supporting pet uses.

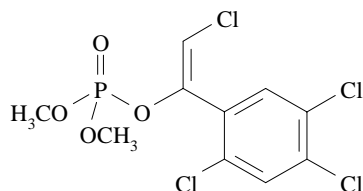
Tetrachlorvinphos was registered for use on various vegetables, feed crops, livestock, pet animals, and in or around buildings. However, the crop uses were voluntarily canceled in 1987. Currently, the primary uses of tetrachlorvinphos are for the control of manure flies in livestock applied as a feed through in the form of feed additives; flies and mites in livestock building premises applied as dusts and sprays; and ticks and fleas on domestic pets applied as dusts, sprays, dips, and collars.

A reregistration eligibility decision (RED) was issued for tetrachlorvinphos in 1995. Based on the reregistration eligibility decision, confirmatory data describing the residues in tissues resulting from dermal and feed-through (oral) larvicide uses in livestock are required. The requirement for the livestock use was deferred in 1995 because the feed additive tolerance was expected to be proposed for revocation; it is however, not going to be revoked. Therefore, these data are now required.

This interim tolerance reassessment review is the Agency's first reevaluation of tetrachlorvinphos since its reregistration in 1995.

## E. Chemical Identification

Tetrachlorvinphos:



- **Common Name:** Tetrachlorvinphos
- **Chemical name:** (Z)-2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate
- **Chemical family:** Organophosphate
- **Case number:** 0321
- **CAS registry number:** 2248-79-9 [(Z) - isomer]  
22350-76-1 [(E) - isomer]  
961-11-5 [mixed isomers]
- **OPP chemical code:** 083701
- **Empirical formula:** C<sub>10</sub>H<sub>9</sub>Cl<sub>4</sub>O<sub>4</sub>P
- **Molecular weight:** 366.0
- **Trade and other names:** Rabon , Gardona
- **Basic manufacturers:** Boehringer Ingelheim Animal Health Inc.  
Hartz Mountain Corporation

Technical tetrachlorvinphos is a tan to brown crystalline solid with a melting point of 93-98° C and a bulk density of 50-55 lb/ cu ft. The solubility of tetrachlorvinphos in water at 24° C is 15 ppm. Tetrachlorvinphos has limited solubility in most aromatic hydrocarbons (i.e., 40 ppm in chloroform and dichloromethane, 20 ppm in acetone, and 8 ppm in xylene at 0° C).

## F. Use Profile

The following information is based on the currently registered uses of tetrachlorvinphos:

**Type of Pesticide:** Insecticide

### Summary of Use Sites:

<u>Feed:</u>	Cattle feedlots
<u>Food:</u>	Agricultural/Farm Structures/Buildings and Equipment, Cattle Feedlots, Beef Cattle, Dairy Cattle, Swine, Livestock, Poultry
<u>Residential:</u>	Cats, Dogs, Domestic Indoor premises
<u>Public Health:</u>	Flies, Ticks
<u>Nonfood:</u>	Horses, Mink, Recreational Areas, Refuse/Solid Waste Sites (Outdoor)
<b>Target Pests:</b>	Fleas, ticks, lice, flies (adult and larvae), chiggers, mites, spiders, wasps, and cattle grubs

### Formulation Types Registered:

Technical:	98.7% a.i.
Wettable powder:	50% a.i.
Dust	1% to 3%
Granular:	0.2 % to 7.8% a. i. One product 97.3 % a. i.
Impregnated material:	13.7 % to 14.55 % a. i.
Ready-to Use Spray:	1% to 2% a.i.
Pressurized liquid:	1.1% a.i.
Emulsifiable concentrate	3% to 24% a.i.

### Method and Rates of Application:

Application methods include: dip applications to pets, backrubber devices in cattle lots, hand and power sprayers, groundboom applications in poultry facilities, mineral blocks, livestock feed supplements, poultry dust boxes and plungers and shaker cans, pour on treatments to livestock, paint on treatments in poultry facilities, pressurized aerosol cans and pump sprays for pets, pet collars, and cattle ear tags.

Use rates vary from a minimum of 0.0004 lb ai/animal to a maximum of 0.0208 lb ai/animal. The use rate for pets is approximately 0.016 lb ai/animal.

**Use Classification:** Tetrachlorvinphos is a general use pesticide. Although tetrachlorvinphos is a general use pesticide, there are several products classified as a restricted use due to high acute toxicity.



## G. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of tetrachlorvinphos based on available pesticide usage information for 1997 and 1998. A full listing of all uses of tetrachlorvinphos, with the corresponding use and usage data for each site, has been completed and is in the “Quantitative Use Assessment” document, which is available in the public docket and the EPA pesticide’s web site. The data, reported on an aggregate and site basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 900,000 lbs a.i. of tetrachlorvinphos are used annually, according to Agency and registrant estimates.

**Table 1. Tetrachlorvinphos Estimated Usage for Representative Sites**

Site	Lbs. Active Ingredient Applied (000)		Percent Treated	
	Wtd Avg	Est Max	Wtd Avg	Est Max
Beef Cattle	219	439	2%	3%
Dairy Cattle	68	136	1%	3%
Horses	3	6	6%	31%
Poultry	466	932	6%	11%
Swine	56	111	2%	3%
Dogs and Cats	97	193	10%	20%

## III. Summary of Tetrachlorvinphos Risk Assessment

The following is a summary of EPA’s human health risk findings for the organophosphate pesticide tetrachlorvinphos, as fully presented in the documents listed below:

- “Tetrachlorvinphos: Summary of Revised Residential Handler and Postapplication Toddler Exposure Risk” dated April 1, 2002
- “Further Revisions to Occupational Risk Assessment for Uses in the Poultry and Cattle Production Industries” dated March 28, 2002
- “Tetrachlorvinphos. Addendum to the HED Human Health Risk Assessment” dated April 5, 2002
- “Addendum to the Tetrachlorvinphos Occupational and Residential Exposure Risk Revision for the Reregistration Evaluation Decision” dated February 4, 2001
- “Tetrachlorvinphos: Addendum for Residential Exposures using updated Standard

Operating Procedures for Residential Exposure” dated June 8, 2001

- Addenda to Previous Occupational and Residential Risk Assessment (February 15, 2001)
- “Tetrachlorvinphos: Revised Occupational and Residential Exposure and Risk Assessment,” dated October 25, 1999
- “Tetrachlorvinphos: Revised Human Health Risk Assessment,” dated December 8, 1999
- “Tetrachlorvinphos, The Revised HED Chapter of the Reregistration Eligibility Decision Document” dated April 1, 1998

The purpose of this summary is to assist the reader by identifying the key features and findings of the risk assessments, and to enhance understanding of the conclusions reached in the assessments. The risk assessments presented here form the basis of the Agency's risk management decision for tetrachlorvinphos; the Agency must consider cumulative risks of all the organophosphate pesticides before any final decisions can be made.

#### **A. Human Health Risk Assessment**

EPA issued its preliminary human health risk assessment for tetrachlorvinphos in April 1998. This assessment was amended in November 1998 to incorporate toxicological endpoints for short-and intermediate-term risk. Consequently, the occupational/residential assessment was revised to reflect the new endpoints (November 1998).

In response to studies submitted by Hartz and other public comments received during Phase 3 of the public participation process, the occupational and residential risk assessment was further updated and refined on October 25, 1999. During this period, Hartz also committed to providing additional studies to support pet uses. On December 8, 1999, the Human Health Risk Assessment was revised to incorporate changes to the residential assessment and new Quantitative Usage Analysis (QUA) information.

On February 15, 2001, the Occupational Risk Assessment was revised to incorporate new usage information obtained by the Agency from key states that produced poultry including area treated, equipment used, and typical application rates. On June 8, 2001, the Residential Risk Assessment was again refined to reflect recent changes in the Residential Standard Operating Procedures (SOP's), as recommended by the FIFRA Scientific Advisory Panel (SAP). A meeting was held with Hartz in July 2001. Hartz submitted exposure and toxicity studies in November 2001. On February 4, 2002, the residential assessment was refined further to incorporate new applicator and postapplication exposure data submitted by Hartz; the toxicity study did not result in a change in the risk assessment. The residential assessment was again refined on April 1, 2002 to incorporate changes to the toxicological endpoint.

On April 5, 2002, the Human Health Risk assessment was again revised to reflect a recalculation of the short and intermediate term endpoint, new residue data to assess dietary concerns, and the new occupational and residential data mentioned above.

## 1. Dietary Risk from Food

### a. Toxicity

The Agency has reviewed all toxicity studies submitted and determined that the toxicity database is essentially complete and supports a tolerance reassessment determination for all currently registered uses. The interim determination pertains only to tetrachlorvinphos alone and does not consider the cumulative risk from all other organophosphates. Further details on the toxicity of tetrachlorvinphos can be found in the April 5, 2002, Human Health Risk Assessment, and the March 6, 1995, "Health Effects Division Carcinogenicity Peer Review Committee Report." A brief overview of the studies used for the dietary risk assessment and other relevant information is outlined in Table 2.

### b. FQPA Safety Factor

An uncertainty factor of 100 (the standard uncertainty factor) to account for both interspecies extrapolation and intraspecies variability was applied to both acute and chronic dietary risk assessments. The FQPA safety factor was reduced to 1X for tetrachlorvinphos due to the completeness of the toxicology database (developmental toxicity study, 2-generation reproduction study, acute and subchronic neurotoxicity studies with no treatment related neuropathology observed), lack of increased susceptibility in pre and post natal studies, and adequacy of the available exposure data. The Agency believes that the assumptions and models used in the assessments do not underestimate the potential risk for infants and children.

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

Assessment	Dose	Endpoint	Study	UF	FQPA Safety Factor	aPAD/cPAD
Acute Dietary	NOAEL = 6.7 mg/kg/day	Plasma/RBC ChE Inhibition at 13 weeks	Subchronic Rat MRID 43371201	100	1X	0.067 mg/kg/day
Chronic Dietary	NOAEL = 4.23 mg/kg/day	Histological liver and adrenal changes (LOAEL= 43.2); reduced weight gain/plasma ChE Inhibition in females	Chronic Rat MRID 42980901	100	1X	0.0423 mg/kg/day
Cancer	Q* = 1.83 x 10 <sup>-3</sup>	Based on adenomas/carcinomas and pheochromocytomas	Mouse carcinogenicity MRID 00126039	N/A	N/A	N/A

### **c. Population Adjusted Dose (PAD)**

The PAD is a relatively new 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 tetrachlorvinphos, the FQPA safety factor is 1; therefore, the acute or chronic RfD is equal to the acute or chronic PAD. A risk estimate that is less than 100 % of the acute or chronic PAD is not a risk concern.

### **d. Exposure Assumptions**

Acute and chronic dietary exposure and risk analyses for tetrachlorvinphos 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), 1989-91. For the acute dietary risk assessment, the entire distribution of single day food consumption events was combined with a distribution of residues. This is known as a probabilistic analysis. Risk is reported at the 99.9<sup>th</sup> percentile of exposure to obtain an exposure estimate in mg/kg/day. For the chronic dietary risk assessment, the three-day average food consumption for each sub-population member was combined with average residues to determine average exposure in mg/kg/day.

In the case of tetrachlorvinphos, a probabilistic acute dietary analysis was conducted using USDA Pesticide Data Program (PDP) monitoring data, metabolism studies, calculated livestock anticipated residues, and percent livestock treated information. Monitoring data from the USDA Food Safety and Inspection Service (FSIS) were also considered for characterization purposes only. FSIS analyzed livestock tissues and milk for tetrachlorvinphos during 1993-2000.

For the acute assessment, a tier 3 probabilistic analysis was completed using the acute anticipated residues, monitoring data, and livestock usage data. For the chronic assessment, a tier 2 analysis was conducted using anticipated residues in livestock commodities. For both the acute and the chronic assessments, use of refined anticipated residues in livestock commodities is still considered to be conservative because of the type of data used (i.e., results of livestock metabolism studies) and because no refinements were made for reduction of residues during cooking/baking.

### **e. Food Risk Characterization**

Generally, a dietary risk estimate that is less than 100% of the acute and chronic PAD is not of concern. The acute dietary risk from residues of tetrachlorvinphos in food alone is not of concern at the 99.9<sup>th</sup> percentile. The most highly exposed subgroup was children 1-6 years, with 8% of the acute PAD occupied. The chronic dietary risk from food alone is well below the Agency's level of concern. The most highly exposed subgroup is children 1 to 6 years old with < 1% of the chronic PAD occupied.

Using anticipated residues and percent livestock treated data the dietary cancer risk is estimated to be  $2 \times 10^{-7}$  for the general U.S. population, which is below the Agency's level of concern for carcinogenic dietary risk. Results of acute and chronic dietary risk analyses are presented in Table

3 below.

**Table 3. Tetrachlorvinphos: Acute and Chronic Dietary Exposure and Risk**

Population Subgroup	Acute Dietary Exposure 99.9th Percentile	Chronic Dietary Exposure	
	%aPAD	%cPAD	Cancer
U.S. Population	4	<1	$2 \times 10^{-7}$
All infants (<1 yr)	<1	<1	N/A <sup>a</sup>
Children (1-6 yrs)	8	<1	
Children (7-12 yrs)	5	<1	
Females (13-50 yrs)	4	<1	
Males (13-19 yrs)	5	<1	
Males (20+ yrs)	4	<1	
Seniors (55+ yrs)	3	<1	

<sup>a</sup> The Agency generally does not assess cancer risk for children. Agency policy states that when the low dose linear extrapolation approach (Q\*) is used for estimating cancer risk for both children and adults, cancer risk for the “general population” which includes infants and children, should be presented. Therefore, the estimate of 0.000093 mg/kg/day for the general U.S. population corresponds to a lifetime cancer risk of approximately  $2.7 \times 10^{-7}$ , which is below the Agency’s level of concern.

## 2. Dietary Risk from Drinking Water

The registered uses of tetrachlorvinphos allow use outdoors for the purpose of treating limited areas near kennels, barns, recreational and picnic areas and other outdoor living areas. However, the area of coverage is generally small, less than one acre in most instances. Therefore, potential for tetrachlorvinphos to contaminate drinking water sources is very small and a drinking water assessment was not conducted.

## 3. Occupational and Residential Risk

Occupational workers may be exposed to a pesticide through tasks such as mixing, loading, and applying a pesticide, or re-entering treated sites. Residents or homeowners can be exposed to a pesticide through mixing, loading, or applying a pesticide, or through entering or contacting treated sites. Occupational handlers of tetrachlorvinphos include individual farmers or ranchers who mix, load, and/or apply pesticides, and professional or custom agricultural applicators. Residential handlers include homeowner applicators treating their dogs and cats. Residential postapplication exposure to adults and children can also occur from contact with treated dogs and cats. Noncancer risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL), which is the highest dose given in studies at which no significant toxic effects were observed. Generally, MOEs greater than 100 are not of concern. For cancer, risks below  $1 \times 10^{-6}$ , or 1 in 1 million, are not of concern. For workers, if cancer risks are between  $1 \times 10^{-6}$  and  $1 \times 10^{-4}$  EPA will pursue risk mitigation where feasible.

**a. Toxicity**

The toxicity of tetrachlorvinphos is integral to assessing the occupational and residential risk. All risk calculations are based on the most current toxicity information available for tetrachlorvinphos. The toxicological endpoints and other factors used in the occupational and residential risk assessments for tetrachlorvinphos are listed below.

**Table 3a. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational and Residential Risk Assessment for Tetrachlorvinphos**

Assessment	Dose	Endpoint	Study	Absorption Factor
Short-/Intermediate-Term Dermal	NOAEL =6.7 mg/kg/day	Plasma/RBC ChE Inhibition at 13 weeks (LOAEL=142)	Subchronic Rat MRID 43371201	9.6%
Short-/Intermediate-Term Inhalation	NOAEL = 6.7 mg/kg/day	Plasma/RBC ChE Inhibition at 13 weeks (LOAEL=142)	Subchronic Rat MRID 43371201	100%
Cancer	Q* = 1.83 x 10 <sup>-3</sup>	Based on adenomas/carcinomas and pheochromocytomas	Mouse Carcinogenicity	N/A

Tetrachlorvinphos has relatively low acute toxicity in rats via the oral and inhalation routes, and low acute toxicity via the dermal route in rabbits. Based on studies conducted in guinea pigs, it is considered to be a dermal sensitizer.

**Table 3b. Acute Toxicity Profile for Occupational Exposure for Tetrachlorvinphos**

Route of Exposure	MRID No.	Results	Toxicity Category
Oral	41222504	LD <sub>50</sub> = 1480 mg/kg (M) 465-965 mg/kg (F)	III
Dermal	41222505	LD <sub>50</sub> >2000 mg/kg	III
Inhalation	00138933	LC50 > 3.61 mg/L	IV
Eye Irritation	41222506	moderate	III
Dermal Irritation	41222507	slight	IV
Dermal Sensitizer	41377902 42981001	sensitizer	--

**b. Exposure**

**1) Occupational Exposure**

Based on use patterns summarized above, EPA has identified the following major exposure

scenarios for workers who handle (mix, load, or apply) tetrachlorvinphos:

- mixing/loading emulsifiable concentrates for high pressure handwand applications on livestock or livestock premises,
- mixing/loading emulsifiable concentrates for groundboom applications in broiler facilities,
- mixing/loading emulsifiable concentrates for cattle backrubber applications for livestock,
- mixing/loading wettable powders for high pressure handwand applications on livestock or livestock premises,
- mixing/loading wettable powders for groundboom applications broiler facilities,
- mixing/loading wettable powders for paint-on fly control in poultry premises,
- mixing/loading wettable powders for dusting applications for livestock and poultry,
- applying with high pressure handwand on poultry and poultry premises,
- applying with groundboom in broiler facilities,
- mixing /loading/applying wettable powder with a low pressure handwand on poultry and poultry premises,
- mixing/loading/applying emulsifiable concentrate with a low pressure handwand on poultry and poultry premises,
- mixing/loading/applying with a backpack on poultry and poultry premises,
- mixing/loading/applying for paint-on application, undiluted emulsifiable concentrate for poultry premises,
- mixing/loading/applying for paint-on application, wettable powder for slurry paint-on for poultry premises.
- mixing/loading/ applying backrubbers for cattle.
- applying ear tags, feed-through pellets, and mineral blocks to livestock or livestock premises.

The risk assessment for tetrachlorvinphos addressed all elements of the poultry industry which included egg (also referred to as layer) and broiler production. These entities are very distinct from one another in cultural practices so the risks for each use were assessed separately. The Agency also estimated risks associated with beef cattle and dairy production. The uses for tetrachlorvinphos are similar for beef and dairy cattle; therefore, the two uses were grouped together for risk assessment purposes. Use patterns, application methods, and the range of application rates were derived from current labeling and Agency analysis.

One chemical-specific handler exposure study was submitted in support of the reregistration of tetrachlorvinphos in which separate mixer, loader, and applicator exposures were quantified during application of a wettable powder and liquid formulations in poultry houses (MRID 426223-01). These chemical-specific data were in the same range of exposures as those from the Pesticide Handlers Exposure Database (PHED), the database the Agency routinely uses for handler risk assessments when there is no chemical-specific study data available. In the current risk assessment (J. Dawson, March 28, 2002), only the results based on PHED data are summarized because they are similar to results using the chemical specific study, and PHED is a more robust database. Data were available to identify the typical and maximum application rates in poultry, beef cattle and dairy production. These bounding estimates were used for the cancer risk assessment.

## Tetrachlorvinphos Exposures Associated With Egg Production

Tetrachlorvinphos is used predominantly in egg production for control of northern fowl mite and to control flies and darkling beetles with direct treatment of birds and chicken litter and/or premises. There are various methods to apply tetrachlorvinphos in egg production. Liquid applications involve the use of handheld equipment, such as low pressure handwands, backpack sprayers, and high pressure handwands for direct treatment on birds or poultry premises. Dust applications involve power dusters, dust boxes, plungers, and shaker cans on birds and premises. Paint-on techniques are also used for fly control in poultry premises.

Application rates specified on tetrachlorvinphos labels for the different methods in egg production are 0.0218 - 0.0436 lb ai/100 birds (liquid applications), 0.01- 0.24 lb ai/gal (paint-on), 0.078 lb ai/50 birds or 0.078 - 0.030 lb ai/100 ft<sup>2</sup> (dust application).

Special care should be given when interpreting the results which have been calculated for the paint-on uses because data have been bridged to these scenarios. Preparation of the paint slurry solutions from wettable powders has been addressed using wettable powder mixer/loader data where a bag of material is typically loaded into a nurse tank and mechanically agitated. In slurry prep, material is usually added to a bucket/hopper where the user is in closer proximity and agitation is done by hand. Also, the painting element of this use pattern was assessed with data generated using typical indoor paint products. In fly-control paint-on applications, the viscosity of the slurries applied tends to be thicker and the active ingredient concentrations are typically much higher. When applying the paint-on, the aesthetics of the end result are not important. Therefore, less care is taken during the application process.

Likewise, there are several different application techniques could be used to apply dust materials including shaker cans, rotary dusters, power dusters, and plungers. The only exposure scenario that has been included in this assessment is for mixing/loading operations. No dust application scenarios have been included due to lack of data (e.g., no data are available for power, plunger, or rotary dusters). It is difficult to estimate what the exposures associated with use of these kinds of equipment might be. However, the Agency readily believes that there would be measurable, and likely, substantial exposure.

## Tetrachlorvinphos Exposures Associated With Broiler Production

Tetrachlorvinphos is used predominantly in broiler production for control of flies and other pests. Uses associated with broiler production involve direct application to the floors/litter within a broiler house and also as a paint-on for fly control. Applications occur with handheld equipment for spot treatments, with groundboom type equipment for larger areas (100,000 ft<sup>2</sup>), and paint-on methods to poultry structures.

Rates specified on tetrachlorvinphos labels for use in broiler production are 0.1 lb. ai/1000 ft<sup>2</sup> - 0.333 ai/1000 ft<sup>2</sup> for both handheld and groundboom equipment. Risks were calculated using PHED data and one chemical specific study (MRID 426223-01). Again, as mentioned above, only the



results based on PHED data are summarized because they are similar to results of the chemical specific study. Paint-on and dust uses are expected to be similar to those described above for egg production.

### Tetrachlorvinphos Exposures Associated With Cattle and Dairy Production

Tetrachlorvinphos is used predominantly for fly control in the cattle industry. The following uses exist for cattle: ear tags, mineral blocks, dust/dust bags, feed-through (oral larvicide) pellets, and backrubbers. The Agency does not have exposure data specific to ear tag, mineral block, and pellet uses, but considers these scenarios to have low potential for significant worker exposure if basic protective measures such as gloves are used.

The Agency quantitatively calculated the risks associated with the use of dust/dust bags and backrubbers in this assessment. Dust exposures are expected to be similar to the loading scenario described above for egg production. The dust scenario for egg production involves loading dusting equipment (power dusters, hand dusters, and plungers), which EPA considered equivalent to loading a dust bag. Therefore, the loader exposure values for egg production adequately represent uses in the cattle industry. The other use that was considered, cattle backrubbers, are charged with a liquid and hung in areas such as feedlots, loafing sheds, corrals, and entries to dairy facilities where cattle can contact the devices. The use of backrubbers involves mixing a solution to charge the device (concentration = 2 lb ai/25 gallons) then placing the device in an appropriate location. Data for mixers and loaders with liquids from PHED were used to calculate risks for mixing the solution and loading into a backrubber. No data were available for quantifying exposures that would be associated with placing the device. In comparison to mixing the solution and loading it into the backrubber, exposures to handlers placing the device could be significant.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE or cancer risk level (i.e., going from minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario, followed by, if required (i.e., MOEs are less than 100), increasing levels of risk mitigation (personal protective equipment (PPE) and engineering controls). The levels of protection that formed the basis for calculations of dermal and inhalation exposure from tetrachlorvinphos activities include:

Baseline:	Long-sleeved shirt and long pants, shoes and socks.
Minimum PPE:	Baseline + gloves (single layer clothing , gloves and no respirator)
Maximum PPE:	Baseline + double layer clothing + chemical resistant gloves + dust/mist respirator

### Post Application Exposure

Supported tetrachlorvinphos uses are not expected to result in significant occupational post application exposures. Therefore, an occupational post-application exposure and risk assessment was not performed.

The Agency has considered the potential post-application exposure arising from re-entering indoor premises, such as poultry houses. Given the nature of activities performed in a poultry house, such as visually checking the condition of caged birds, as well as feeding, and watering, contact of treated surfaces should be minimal. Tetrachlorvinphos can also be used as a feed-through. Given the mechanized systems for feed delivery in most feed-lots and the nature of manure removal, the Agency concludes that post-application exposure is minimal.

All occupational tetrachlorvinphos exposures were considered to be either short-(i.e., 1-30 days) or intermediate-term (i.e., 30 days to several months) in nature. Based on the registered use pattern, no chronic exposures are thought to exist for tetrachlorvinphos.

## **2) Residential Exposure**

For homeowner handler exposure assessments, the Agency does not believe a tiered mitigation approach like that used for assessing occupational handler risk is appropriate. Homeowners often lack access to personal protective equipment (PPE) and also do not possess expertise in the proper use of PPE. As a result, homeowner handler assessments are completed using a single scenario assuming that short-sleeved shirts and short pants are worn (i.e., common homeowner attire during the pesticide application season).

Residential exposure assessments for tetrachlorvinphos were conducted using the Agency's residential SOPs combined with chemical specific data provided by the registrant. Only short-term exposures were assessed, as the Agency does not believe homeowners who apply tetrachlorvinphos will be exposed for more than 30 days, although it should be noted that the same toxicity endpoint was selected for both short and intermediate term exposures. The Agency feels it is unlikely that a homeowner would be exposed to a product for more than 180 days based on the use pattern and the variety of other products on the market. The exposure scenarios included use of pet dips and application of pet collars, powders, aerosol sprays, and pump sprays. No postapplication exposure is calculated for treated indoor surfaces or turf, because tetrachlorvinphos is only registered for pet and pet bedding applications (i.e., not general area or crack and crevice). However, post application exposure for contact with pets was estimated.

The revised residential risk assessment (S. Hanley, October 25, 1999) was updated to include revisions to the residential SOPs (S. Hanley, June 8, 2001). The residential risk assessment was further revised to include handler and post application data submitted by Hartz Mountain Corporation (S. Hanley, February 4, 2002). These new studies incorporated label changes submitted by the registrant, and provided handler data for dips and powders; and dislodgeable fur residue data for aerosol, powder, and pump spray scenarios to assess post- application exposure from contact with treated pets. The studies were sufficient in scientific quality to refine the assessment. Hartz did not provide new data to assess post-application risks for dip and collar scenarios since the previous

assessment indicated these risks were not of concern. The residential risk assessment was again updated (S. Hanley, April 1, 2002) to incorporate the recalculation of the short and intermediate term endpoint.

The pet dip data used in the 1999 assessment were considered to be of low quality due to the methodology used. The new postapplication exposure data for aerosol, powder, and pump sprays are of much higher quality, and show results in the same range as the data used in the 1999 postapplication assessment for the dip use. This indicates that the low quality of the dip data will not result in an underestimate of exposure and risk from this scenario. Accordingly, the 1999 data for pet dips have been used in the current assessment to evaluate post application risks from this use.

Three products registered for use on livestock and poultry also include directions for limited outdoor use as premise sprays for fleas, ticks, chiggers, and mites, around kennels, yards, campgrounds, and parks, and along foot paths and roadways leading to such areas. Two of these are restricted-use products. Labeling directions are intended to limit applications to spot treatments in border areas, potentially frequented by people, as opposed to broadcast use over large areas. As such, EPA believes there is minimal potential for significant residential exposure; therefore, a residential risk assessment for outdoor uses has not been conducted.

### **c. Occupational & Residential Handler Risk Summary**

#### **1) Occupational Handler Risk**

##### Poultry Production

Risks for most exposure scenarios in egg and broiler production were not of concern at baseline clothing or with additional PPE (see table 4 below). There are two scenarios for which risks are above the level of concern, even at the maximum level of protection considered feasible: mixers, loaders, and applicators have MOEs ranging from 14 to 80 for handling wettable powder using a low pressure handwand; and, MOEs range from 7 to 55 for paint-on application of the EC formulation. Cancer risks are above the Agency's level of concern for both paint-on EC and low pressure WP scenarios with estimates ranging from  $2.1 \times 10^{-6}$  to  $5.7 \times 10^{-6}$ . Cancer risks for all other scenarios are in the range of  $10^{-9}$  to  $10^{-7}$ , which is below the Agency's level of concern.

##### Cattle Production

As mentioned above (part b), no data are available to assess the exposures for ear tag, mineral block, and pellet uses. However, risks from these scenarios are not of concern because handling of these materials are low and likelihood of high exposure is minimal if gloves are used. For dust applications, the risk are expected to be similar to those assessed for poultry, for both mixers, loaders and applicators. Estimated mixer/loader risks for dust are below the level of concern, with MOEs of 197 - 504. But no data are available for applicators who apply dust to cattle. For cattle backrubbers, estimated mixer/loader MOEs range from 421-821 at the baseline clothing scenario; cancer risks are in the  $10^{-7}$  range. EPA does not have data to assess workers hanging backrubber devices in cattle lots but expects exposures to be significant for this activity. Therefore, additional protective equipment such as double layer clothes and gloves will be needed for workers handling backrubber devices.

**Table 4. Summary of Occupational Handler Risks in Poultry Production.**

Poultry Type	Scenario/Formulation	Application Rate	Non-Cancer		Cancer	
			Minimum Required PPE	MOE	Minimum Required PPE	Risk
Egg Production	<b>MIXER/LOADER</b>					
	High pressure handwand/EC	0.0218 - 0.0436 lb ai/100 birds	Baseline	193-386	Baseline	4.4 - 8.3 x 10 <sup>-7</sup>
	High pressure handwand/WP	0.0417 lb ai/100 birds	Baseline	141	Minimum PPE	1.8 x 10 <sup>-7</sup>
	Paint-On/WP	0.01 to 0.24 lb ai/gal	Baseline	2458-58995	Baseline	2.8 x 10 <sup>-9</sup> - 6.8 x 10 <sup>-8</sup>
	Dusting/WP <sup>1</sup>	0.078 lb ai/50 bird or 100 ft <sup>2</sup>	Minimum PPE	252-504	Minimum PPE	3.3 - 6.7 x 10 <sup>-7</sup>
		0.03 lb ai/100 ft <sup>2</sup>	Baseline	197	Baseline	8.5 x 10 <sup>-7</sup>
	<b>MIXER/LOADER/APPLICATOR</b>					
	Low pressure handwand/EC	0.0218-0.0436 lb ai/100 birds	Minimum PPE	756-1512	Minimum PPE	1.1 - 2.2 x 10 <sup>-7</sup>
	Low pressure handwand/WP	0.0417 lb ai/100 birds	Maximum	80	Maximum	2.1 x 10 <sup>-6</sup>
	Backpack	0.0218 - 0.0436 lb ai/100 birds	Minimum PPE	200-400	Minimum PPE esp.	4.2 - 8.4 10 <sup>-7</sup>
	Paint-On/EC (undiluted)	2 lb ai/gal	Maximum	55	Maximum	3.0 x 10 <sup>-6</sup>
	Paint-On/WP (Slurry)	0.01 lb ai/gal	Baseline	1340	Baseline	1.3 x 10 <sup>-7</sup>
		0.24 lb ai/gal	Minimum PPE	382	Minimum PPE	4.4 x 10 <sup>-7</sup>
	<b>APPLICATOR</b>					
	High pressure handwand	0.0218 - 0.0436 lb ai/100 birds	Baseline	214-428	Baseline	3.9 - 7.8 x 10 <sup>-7</sup>
Broiler Production	<b>MIXER/LOADER</b>					
	High pressure handwand/EC	0.333 - 0.696 lb ai/1000ft <sup>2</sup> [typical = 0.10 lb ai/1000ft <sup>2</sup> ]	Baseline	121-841	Baseline	2.0 x 10 <sup>-7</sup>
	High pressure handwand/WP	0.333 lb ai/1000ft <sup>2</sup> [typ = 0.10]	Baseline	177-590	Baseline	2.8 x 10 <sup>-7</sup>
	Groundboom/EC	0.333 - 0.696 lb ai/1000ft <sup>2</sup> [typical = 0.10 lb ai/1000ft <sup>2</sup> ]	Minimum PPE	1981-4141	Baseline	1.0 x 10 <sup>-6</sup>
			Baseline	168		
Broiler Production	Groundboom/WP	0.333 lb ai/1000ft <sup>2</sup> [typical = 0.10 lb ai/1000ft <sup>2</sup> ]	Minimum PPE	236	Minimum PPE	2.1 x 10 <sup>-7</sup>
			Baseline	118		
<b>MIXER/LOADER/APPLICATOR</b>						
	Low pressure handwand/EC	0.333 - 0.696 lb ai/1000ft <sup>2</sup> [typical = 0.10 lb ai/1000ft <sup>2</sup> ]	Minimum PPE	474-3296	Minimum PPE	5.1 x 10 <sup>-8</sup>
	Low pressure handwand/WP	0.333 lb ai/1000ft <sup>2</sup> [typical = 0.10 lb ai/1000ft <sup>2</sup> ]	Maximum	100	Minimum PPE	7.5 x 10 <sup>-7</sup>
			Minimum PPE	122		

**Table 4. Summary of Occupational Handler Risks in Poultry Production.**

Poultry Type	Scenario/Formulation	Application Rate	Non-Cancer		Cancer	
			Minimum Required PPE	MOE	Minimum Required PPE	Risk
	Backpack	0.333 - 0.696 lb ai/1000ft <sup>2</sup> [typical = 0.10 lb ai/1000ft <sup>2</sup> ]	Minimum PPE	125-871	Minimum PPE	1.9 x 10 <sup>-7</sup>
	<b>APPLICATOR</b>					
	High pressure handwand	0.333 - 0.696 lb ai/1000ft <sup>2</sup> [typical = 0.10 lb ai/1000ft <sup>2</sup> ]	Baseline	134-933	Baseline	1.8 x 10 <sup>-7</sup>
	Groundboom	0.333 - 0.696 lb ai/1000ft <sup>2</sup> [typical = 0.10 lb ai/1000ft <sup>2</sup> ]	Baseline	3240-22550	Baseline	7.4 x 10 <sup>-9</sup>
Cattle Production	Backrubbers	2 lb ai/25 gallons	Baseline	421-821	Baseline	2.0 to 4.0 x 10 <sup>-6</sup>

<sup>1</sup>No Data are available for dust application scenarios, but EPA expects measurable, substantial exposure.

## 2) Post application Risk

Supported tetrachlorvinphos uses are not expected to result in significant occupational post application exposures. Therefore, an occupational post application exposure and risk assessment was not performed.

## 3) Horses

EPA is concerned with tetrachlorvinphos feed-through products used in horses. EPA has data from multiple sources that show tetrachlorvinphos feed-through products decrease cholinesterase levels. EPA is therefore requesting the registrants add label statements to horse oral larvicides which state that the product is a cholinesterase inhibitor, describe signs of cholinesterase inhibition in horses, caution against the use with other cholinesterase inhibiting compounds, and direct horse owners to consult a veterinarian before using products containing tetrachlorvinphos on debilitated, aged, pregnant or nursing animals.

Several comments were submitted during phase 5 associating reproduction problems in pregnant mares with use of tetrachlorvinphos feed-through products. The Agency does not have data from controlled studies to support a conclusion that such use leads to these problems. EPA notes that other organophosphates mostly used as equine anthelmintics (intestinal wormers) are regulated by the Food and Drug Administration (FDA). Generally, FDA requires reproductive toxicity studies for equine anthelmintics. However, in the absence of such data, products carry statements such as, "This product has not been tested in breeding animals." Therefore, EPA is requesting that tetrachlorvinphos feed-through labels state that testing in breeding horses has not been conducted.

### d. Residential (Homeowner) Risk Summary

#### 1) Residential Handler Risk

A total of four residential handler scenarios were identified: pet dip (sponge on and pour on); applying powders (dusting); applying ready-to-use pump sprayer and aerosol sprays; and applying a flea collar to pets. The target MOE is 100. The residential handler combined dermal and inhalation MOEs ranged between 240 and 26,000. Therefore, risks for residential handlers are not of concern. Based on the 2001 risk assessment which used high-end conservative assumptions with respect to the frequency of applications, cancer risks calculated for residential handlers were also below the Agency's level of concern for all pet uses (risks were in the range of  $2 \times 10^{-7}$  to  $9.3 \times 10^{-9}$ ).

**Table 5. Residential Handlers: Risk Concerns**

Product	TCVP used <sup>a</sup> (lb)	Dermal + Inhal. Exposure		
		Dose <sup>b</sup>	MOE <sup>c</sup>	Cancer Risk <sup>d</sup>
Dip, Pour-On	0.015	0.0013	5200	$9.3 \times 10^{-9}$
Dip, Sponge-On	0.0037	0.0025	2700	$1.8 \times 10^{-8}$
Spray, Aerosol	0.00086	0.00030	22000	$2.1 \times 10^{-9}$
Spray, Pump	0.00066	0.00026	26000	$1.9 \times 10^{-9}$

**Table 5. Residential Handlers: Risk Concerns**

Product	TCVP used <sup>a</sup> (lb)	Dermal + Inhal. Exposure		
		Dose <sup>b</sup>	MOE <sup>c</sup>	Cancer Risk <sup>d</sup>
Powder	0.0018	0.0027	2500	1.9 x 10 <sup>-8</sup>
Collar <sup>e</sup>	0.011	0.028	240	2.0 x 10 <sup>-7</sup>

- a TCVP used (lb); average value from handler study data [Dips and Powder] or Residential SOP's/label.  
b Total Absorbed Dose (mg/kg/day) = Dermal Dose (mg/kg/day) + Inhalation Dose (mg/kg/day).  
c MOE = NOAEL (6.7 mg/kg/day) ÷ Total Dose (mg/kg/day).  
d Cancer risks were calculated as follows: Total dose x (2 days/365 days) x (50 yrs/70 yrs) x 0.00183 (Q<sub>1</sub>\*)  
e Collar weight is 33 g., and 14.55% TCVP (total ai/collar = 4.8 g)

### 1) Residential Post Application Risk

Since tetrachlorvinphos is used for direct pet and pet premise treatment in a residential environment, post application exposure is expected to occur. Some significant short-term residential exposure scenarios that have been identified include contact with treated pets, toddler dermal contact (such as a child hugging a dog), and toddler exposures resulting from hand-to-mouth activity following contact with treated pets.

Assessments were based on the revised residential SOPs and chemical-specific data from submitted studies. Post application exposure to residues from pet collars is considered to be insignificant when compared with exposure to other products. Because other, higher exposure uses were not of concern, an assessment for collars was not conducted. Toddler post application dermal risks were below the Agency's level of concern with MOEs ranging between 412 - 1804 for dermal exposure to pets following treatment with dips, powders, pump sprays, and aerosols. Risks were below the Agency's level of concern for toddler hand-to-mouth exposures for dips, powders, pump sprays, and aerosols (MOEs ranging between 267 - 809). Combined risks for dermal and hand-to-mouth post-application exposures are below the Agency's level of concern for all scenarios (MOEs ranging between 130 and 560). Although postapplication risks were not determined for adults, toddler exposures represent the worst case due to typical mouthing behaviors and body weight and surface area considerations; therefore, the risk assessment for toddlers is protective of adults.

**Table 6. Postapplication Exposure: Risk Concerns**

Product	Dermal Exposure and Risk	Hand-to-Mouth Exposure and Risk	Aggregate Exposure and Risk
	MOE	MOE	MOE
Dip	985	447	310
Spray, Pump	595	267	180
Spray, Aerosol	412	267	130
Powder	1804	809	560

#### **4. Aggregate Risk**

An aggregate risk assessment combines risk from dietary exposure (food and drinking water routes) and residential exposure to a particular pesticide. For tetrachlorvinphos, three aggregate scenarios were considered: acute, short-term, chronic, and cancer.

Based on the supported use pattern for tetrachlorvinphos, no exposure is expected to occur through consumption of drinking water. Therefore, the acute aggregate assessment only considers dietary (food only) risk.

For short-term aggregate risk exposure to tetrachlorvinphos in food (chronic dietary exposure) and short-term residential exposures (handler and post-application) are combined. All identified residential exposure scenarios were considered to be short-term in nature, and therefore an intermediate-term aggregate assessment was not conducted.

Since there are no chronic residential exposure scenarios and no exposure through drinking water is expected based on tetrachlorvinphos use patterns, the chronic aggregate exposure and risk assessment also includes only food sources of exposure.

Generally, all non-cancer risks from these exposures must have MOEs of greater than 100 to be not of concern to the Agency. Adult aggregate risks for all scenarios were below the Agency's level of concern; the worst case scenario was collars with an MOE of 240. All other scenarios ranged from 2,400 to 19,000 for aerosols, dips, powders, and pump sprays. Aggregate risk for post application (toddlers) exposures were again below the Agency's level of concern for all scenarios. The lowest MOE was for pump sprays (130). The other risk estimates ranged between 180 and 550 for aerosols, dips, and powders.

Aggregate cancer risks for residential handlers were calculated using the chronic dietary food exposure and the cancer risk numbers generated for handlers applying dips, powders, sprays, and collars. Aggregate cancer risks less than  $1 \times 10^{-6}$  or one in 1 million, are not of concern to EPA. Aggregate cancer risks for all scenarios were below the Agency's level of concern. Risk estimates ranged from  $1.7 \times 10^{-7}$  to  $3.7 \times 10^{-7}$ .

#### **IV. Interim Risk Management and Reregistration Decision**

##### **A. Determination of Interim Reregistration Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing tetrachlorvinphos active ingredients.



The Agency has completed its assessment of the occupational and residential risks associated with the use of pesticides containing the active ingredient tetrachlorvinphos, as well as a dietary risk assessment that has not yet considered the cumulative effects of organophosphates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient tetrachlorvinphos, EPA has sufficient information on the human health effects of tetrachlorvinphos to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that tetrachlorvinphos is eligible for tolerance reassessment provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) cumulative risks considered for the organophosphates support a final reregistration eligibility decision. Label changes are described in Section IV. Appendix B identifies the generic data requirements that the Agency reviewed and lists the submitted studies that the Agency found acceptable.

Although the Agency has not yet considered cumulative risks for the organophosphates, the Agency is issuing this interim assessment now in order to identify risk reduction measures that are necessary to support the continued use of tetrachlorvinphos. Based on its current evaluation of tetrachlorvinphos alone, the Agency has determined that tetrachlorvinphos products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and/or FQPA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of tetrachlorvinphos.

For tetrachlorvinphos, if all changes outlined in this document are incorporated into the labels, then all current risks will be mitigated. Because this is an interim TRED, the Agency may take further actions, if warranted, to finalize the eligibility decision for tetrachlorvinphos after considering the cumulative risk of the organophosphate class. Such an incremental approach is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. 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 considered cumulative risks for the organophosphates, this does not fully satisfy the reassessment of the existing tetrachlorvinphos food residue tolerances as called for by FQPA. When the Agency has considered cumulative risks, tetrachlorvinphos tolerances will be reassessed in that light. By publishing this interim decision on tolerance reassessment eligibility and requesting mitigation measures now for the individual chemical tetrachlorvinphos, the Agency is not deferring or postponing FQPA requirements; rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending consideration of cumulative risks. This decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

If the Agency determines, before finalization of the TRED, that any of the determinations described in this interim TRED are no longer appropriate, the Agency will pursue appropriate action,

including but not limited to, reconsideration of any portion of this interim TRED.

## **B. Summary of Phase 5 Comments and Responses**

When making its interim reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. A detailed discussion of these comments received on the Human Health Risk Assessment is in the OPP docket for tetrachlorvinphos (Docket # 34175B). A brief summary of the comments and the Agency response is noted here.

*Comment:* The registrant Boehringer Ingelheim Vetmedica submitted comments during phase 5 on the Revised Risk Assessments. Boehringer noted a telephone conference call that was held on May 2, 2000, with USDA, EPA, registrants, scientists, and other stakeholders. The call, among other things, highlighted issues regarding the Quantitative Usage Analysis (QUA) report and poultry uses. Boehringer stated that they were concerned with how the Agency assessed backpack sprayers in the risk assessment. They proposed future discussions with the Agency to modify the label to be consistent with current use practices for their products.

*Response:* The QUA has been updated to include USDA National Agricultural Statistic Survey (NASS) data that gives current estimates of pesticide usage on livestock. For poultry uses, the Agency performed an analysis of use practices in poultry in December 2000. That data was used in the most recent occupational risk assessment (J. Dawson, March 27 2002). For backpack sprayers, due to the recent change in the toxicity endpoint for tetrachlorvinphos (short and intermediate term endpoint is now 6.7 mg/kg/day), risk to backpack sprayers for poultry uses is no longer a concern provided PPE is used.

*Comment:* The registrant Hartz Mountain submitted comments during phase 5 on the Revised Risk Assessments. Hartz did not agree with the risk assessment and its limited use of exposure data provided by the registrant in June 1999. Consequently, they compiled a listing of the issues that were of concern to the Agency noting those areas that used conservative assumptions to derive estimates.

*Response:* Since the time that this comment was submitted, the risk assessment has been changed to reflect revisions to the Residential SOPs (1999). In addition, new exposure data were submitted to the Agency which enabled major refinement of the risks. Moreover, the toxicity endpoint was recalculated and this further improved the risk picture.

*Comments:* Relating to horses: Four citizens submitted comments concerning feed through uses of tetrachlorvinphos products on horses. Most of these comments were anecdotal reports of suspected adverse reactions, particularly those which caused reproductive problems in their horses. However, one commentor provided detailed information concerning the use of a feed through product containing tetrachlorvinphos, and its apparent reproductive effects on his horses.

The registrant Farnam Companies, Inc., submitted comments also. Farnam is a manufacturer and distributor of Equitrol®, which is a pelleted horse feed additive containing tetrachlorvinphos that is designed for fly control. Farnam wanted to address some of the citizens' comments focused on its product that were submitted during phase 5.

Additionally, a comment was submitted by William B. Ley, DVM, MS, Head of the Department of Veterinary Clinical Sciences, College of Veterinary Medicine, Oklahoma State University. Dr. Ley's comment focused on one comment that was submitted by a citizen during phase 5 of the public process. Dr. Ley stated that the data submitted by this citizen was not conclusive in showing a link between the use of Equitrol® and reproductive problems that occurred with exposed animals. He states that these problems could have been associated with an equine herpes virus.

*Response:* EPA has analyzed the available data regarding potential effects on horses resulting from use of tetrachlorvinphos products and information regarding cholinesterase inhibition from the use of tetrachlorvinphos and other organophosphate feed additives. EPA has data from multiple sources that show tetrachlorvinphos feed-through products decrease cholinesterase levels. EPA notes that other organophosphates mostly used as equine anthelmintics (intestinal wormers) are regulated by the Food and Drug Administration (FDA). Generally, FDA requires reproductive toxicity studies for equine anthelmintics. However, in the absence of such data, products should carry statements such as, "This product has not been tested in breeding horses."

## **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 organophosphate. The assessment is for this individual organophosphate, and does not reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with the cholinesterase enzyme. The Agency is in the process of considering the cumulative risk posed by the entire class of organophosphates.

EPA has determined that risk from exposure to tetrachlorvinphos is within its own "risk cup." In other words, if tetrachlorvinphos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for tetrachlorvinphos 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 the chronic and acute food exposure. An

aggregate assessment was conducted for exposures through food and residential uses. Based on the supported use pattern for tetrachlorvinphos, no exposure is expected to occur through consumption of drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to “fit” within the individual risk cup. Therefore, the tetrachlorvinphos tolerances remain in effect with modifications as summarized in Table 10 below, until a full reassessment of the cumulative risk from all organophosphates is considered.

#### **b. Tolerance Summary**

In the individual assessment, tolerances for residues of tetrachlorvinphos in/on plant commodities [40 CFR §180.252] are presently expressed in terms of 2-Chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate. All registered uses of tetrachlorvinphos on food or feed plant commodities, including alfalfa, were canceled in 1987. Therefore, EPA will propose to revoke the alfalfa tolerance. In the 1995 RED, EPA recommended revoking the tolerances for sheep fat because there were no registered uses associated with this commodity. Likewise, for the purposes of this TRED, EPA is recommending that the tolerances for goat fat be revoked because no registered uses are associated with this commodity.

At this time, tetrachlorvinphos tolerances for milk fat and the fat of cattle, hogs, and poultry are codified in 40 CFR 180.252. Due to inadequate studies (not reflecting dosing rates representing the maximum expected combined exposures or lacking other data) concerning residues of tetrachlorvinphos found in eggs, milk, poultry, and meat (excludes horses), EPA currently has insufficient data to reassess existing tolerances for milk fat and the fat of cattle, hogs, and poultry as permanent tolerances or for the Agency to provide recommendations in order to establish permanent tolerances for additional cattle, swine, and poultry commodities. However, based on metabolism studies in cattle, poultry, and swine, EPA has developed estimates of tolerances for tetrachlorvinphos in these commodities. Therefore, except for tolerances recommended for revocation, the additional tolerances that should be established and the existing tolerances in 40 CFR 180.252 should be made time-limited for a period of 18 months (should expire and be revoked on a given date at the end of the 18 month period) to permit sufficient time for the registrant to submit required residue studies.

Also, because current labels prohibit the use of tetrachlorvinphos products for horses destined for slaughter, the tolerance for horse fat in 40 CFR 180.252(a)(1) and the tolerance exemption for horse in 40 CFR 252(a)(2) should be revoked because they are no longer needed.

A feed additive regulation has been established for tetrachlorvinphos for use as an additive in the feed of beef cattle, dairy cattle, horses, and swine at the rates of 0.00015 lb per 100 lb body weight per day for cattle and horses, and 0.00011 lb per 100 lb body weight per day for swine. These exemptions should be deleted when time-limited tolerances for meat and milk are established. In addition, the exemption should be deleted for horses because feed through products are not to be used on horses destined for slaughter.

**Table 7. Tolerance Summary for Tetrachlorvinphos.**

Commodity	Current Tolerance, ppm	Time-Limited Tolerance <sup>a</sup> Reassessment*, ppm	Comment/ [Correct Commodity Definition]
<b>Tolerances Listed Under 40 CFR §180.252</b>			
<b>Alfalfa</b>	110.0	Revoke	No registered uses exist.
<b>Cattle, fat</b>	1.5	0.2	Additional data are required. New magnitude of residue studies with cattle and poultry are required because submitted studies do not reflect dosing rates representing the maximum expected combined exposures and do not contain data for all residues of concern.
<b>Cattle, kidney</b>	None	1	
<b>Cattle, liver</b>	None	0.5	
<b>Cattle, meat</b>	None	2	
<b>Cattle, meat by-products<sup>b</sup></b>	None	1	
<b>Eggs</b>	0.1	0.2	
<b>Goat, Fat</b>	0.5	Revoke	No registered uses exist.
<b>Hog, Fat</b>	1.5	0.2	Additional data are required. New magnitude of residue studies with hogs are required because submitted studies do not reflect dosing rates representing the maximum expected combined exposures and do not contain data for all residues of concern.
<b>Hog, meat</b>	None	2	
<b>Hog, meat by-products<sup>c</sup></b>	None	1	
<b>Hog, liver</b>	None	0.5	
<b>Hog, kidney</b>	None	1	
<b>Horse, fat</b>	0.5	Revoke	Current labels prohibit treatment of horses destined for slaughter.
<b>Milk, fat</b>	0.5	0.05	Reflecting negligible residues in whole milk.
<b>Poultry, fat</b>	0.75	7	Additional data are required. New magnitude of residue studies with poultry are required because submitted studies do not contain data for all residues of concern.
<b>Poultry, meat</b>	None	3	
<b>Poultry, liver</b>	None	2	
<b>Poultry, meat by-products<sup>d</sup></b>	None	2	
<b>Sheep, fat</b>	0.5	Revoke	No registered uses exist.
<b>Exempted Tolerances (Feed Additive Regulation)</b>			
<b>Beef Cattle</b>	Exempted	Revoke	These exemptions should be revoked when time-limited tolerances for meat and milk are established.
<b>Dairy Cattle</b>	Exempted	Revoke	
<b>Swine</b>	Exempted	Revoke	
<b>Horses</b>	Exempted	Revoke	This exemption should be revoked since current labels prohibit the treatment of horses for slaughter.

<sup>a</sup> Permanent tolerance(s) cannot be made at this time because additional data are required .

<sup>b</sup> Excludes kidney and liver

<sup>c</sup> Excludes kidney and liver

<sup>d</sup> Excludes kidney

For Cattle and Swine Commodities

For liver, 0.5 ppm (of which no more than 0.05 is tetrachlorvinphos per se)

For kidney, 1 ppm (of which no more than 0.05 is tetrachlorvinphos per se)

For muscle, 2 ppm (of which no more than 2 is tetrachlorvinphos per se)

For fat, 0.2 ppm (of which no more than 0.1 is tetrachlorvinphos per se)

For milk, 0.05 ppm ( of which no more than 0.05 is tetrachlorvinphos per se)

For Poultry Commodities

For liver, 2 ppm (of which no more than 0.05 is tetrachlorvinphos per se)

For muscle, 3 ppm (of which no more than 3 is tetrachlorvinphos per se)

For fat, 7 ppm (of which no more than 7 is tetrachlorvinphos per se)

For eggs, 0.2 ppm (of which no more than 0.05 is tetrachlorvinphos per se)

**\* The term “reassessed” here is not meant to imply that the tolerance has been reassessed as required by FQPA, since this tolerance may be reassessed only upon consideration of the cumulative risk assessment of all organophosphates, as required by this law. Rather, it provides a tolerance level for this single chemical, if no cumulative assessment was required, that is supported by all of the submitted residue data.**

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

## **3. Label Modifications**

Currently, worker risks are of concern at the maximum level of protection for mixers, loaders, and applicators in poultry egg production operations applying wettable powder formulations with a low-pressure handwand and paint-on application of the EC formulation. Further, additional Personal Protective Equipment (PPE) is needed for several occupational scenarios. In addition, EPA is concerned with tetrachlorvinphos feed-through products for horses. For residential concerns, risk were below the level of concern for both handler and post-application scenarios. However, EPA has concern over the potential for over-application of powder products by consumers. Therefore, label

changes to address this concern are necessary. The following label modifications are needed:

### Workers

- Restrict the use of low pressure handwands for wettable powder (WP) applications to spot treatment in poultry facilities.
- Remove the paint-on use with emulsifiable concentrate (EC) formulations.
- Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment to apply WP formulation as dusts; single layer and gloves for loaders and others handling dust bags.
- Single layer clothing and gloves for mixers, loaders, and applicators engaging in groundboom activities using the EC and WP formulations.
- Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators engaging in low pressure handwand activities using the WP formulations in egg and broiler facilities.
- Single layer clothing and gloves for mixers, loaders, and applicators engaging in low pressure handwand activities using the EC formulations in poultry facilities.
- Single layer clothing and gloves for mixers, loaders, and applicators engaging in backpack spraying activities.
- Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators engaging in paint-on activities using WP formulations.
- Single layer clothing and gloves for workers when handling ear tags.
- Single layer clothing and gloves for workers when handling mineral blocks.
- Single layer clothing and gloves for workers when handling pellets (oral larvicide feed-through products).
- Double layer clothing and gloves for workers when handling backrubber devices.

### Residential

- Use 1/3 oz. of powder per every 10 pounds of body weight of your cat or dog.
- Restrict outdoor premise uses to spot treatments, one time a year, and along woody borders of kennels, yards, campgrounds, recreational parks, and footpaths and roadways leading to such areas.

- Prohibit the use of outdoor premise treatments by homeowners.

### Other Concerns

For feed through products used on horses:

- This product contains tetrachlorvinphos, which is a cholinesterase inhibitor. The most frequently reported clinical signs of cholinesterase inhibition in the horse are abdominal pain, lethargy, sweating, tearing and excessive salivation. If these signs are seen in horses, consult your veterinarian immediately. Do not use this product simultaneously or within a week before or after treatment with cholinesterase inhibiting drugs, pesticides or chemicals. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals.
- This product has not been tested in breeding horses.

## **E. Regulatory Rationale**

### **1. Dietary (Food) Risk Mitigation**

Based on analyses of both acute and chronic dietary risk, the Agency has determined that the risk estimates are not of concern; therefore, no mitigation measures are necessary at this time.

### **2. Drinking Water Mitigation**

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

### **3. Occupational Risk Mitigation**

The Agency is concerned about exposures resulting to handlers using low pressure handwand WP in egg production facilities and paint-on EC scenarios. MOEs at maximum PPE for short and intermediate term exposures for mixers, loaders, and applicators, are 80 for low pressure handwand scenarios; MOEs at maximum PPE for short and intermediate term exposures for mixers, loaders, and applicators are 55 for paint-on scenarios.

To address these concerns, the registrant needs to limit the use of low pressure handwands WP to “spot treatment” only and delete the use of the EC products for paint-on applications. After consultation from USDA and poultry specialists in various states, EPA concluded that low-pressure handwand use is critical for treating the northern fowl mite, darkling beetle, and flies on birds and in poultry premises. Poultry specialists also concurred that low pressure handwands are not used to treat large areas in poultry facilities. Use is confined to areas where pest infestation is the heaviest.



For paint-on scenarios, poultry specialists indicated that WP paint-on methods are preferable to the EC paint-on methods to treat for the darkling beetle that destroys the wood of poultry houses because they have greater residual efficacy. Since EPA believes risks of concern can be mitigated for the paint-on WP scenario, despite the lack of data that are representative of the use, this is a suitable alternative to the EC paint-on use. However, EPA is requiring confirmatory data to estimate the actual exposures to workers using this scenario.

Worker risks exceeded the Agency's level of concern with baseline PPE for handlers engaging in backpack, using dust equipment, groundboom, and low pressure handwand activities. To mitigate these exposures to workers handling tetrachlorvinphos products, the following PPE is needed: single layer clothing, gloves, and no respirator.

In addition, the Agency is concerned about workers handling ear tags, mineral blocks, and pellets when these items are put into place. These scenarios were not assessed because the Agency does not have data for these scenarios, however the Agency has concluded that basic protective gloves will mitigate potential concerns which result from dermal contact.

Although risks were acceptable for dusting and paint-on WP mixing and loading scenarios, the Agency does not have data to assess what the actual exposure would be for applicators. For workers using dusting equipment, because there are no data for the application phase, when the greatest potential for exposure exists, EPA cannot with confidence predict risks. Therefore, a mixer/loader/applicator study is needed to confirm that PPE will adequately protect workers using dusting equipment or paint-on methods. Until those data are available, workers applying dusts need to wear double layers of clothing, gloves, and a dust/mist respirator.

#### **4. Residential Risk Mitigation**

The revised exposure and risk estimates are significantly below the level of concern for residential handlers and post application exposure for toddlers based on the new data submitted by Hartz. However, the Agency has concern over the potential for over-application of powder products. Due to vague directions regarding the use rates, labels need to be modified to specify how much product to apply to treat pets of different sizes. Therefore, the pet labels should be modified to include the use rate of 1/3 oz. of powder per every 10 pounds of body weight for a cat or dog. By guiding the user with a recommended rate, the potential for over-application will be reduced.

Three products registered for use on livestock and poultry also include directions for limited outdoor use as premise sprays for fleas, ticks, chiggers, and mites, around kennels, yards, campgrounds, and parks, and along foot paths and roadways leading to such areas. Two of these are restricted-use products. Labeling directions are intended to limit applications to spot treatments in border areas, potentially frequented by people, as opposed to broadcast use over large areas. As such, EPA believes there is minimal potential for contamination of drinking water sources or for significant residential exposure; therefore, drinking water and outdoor residential risk assessments have not been conducted.

Based on discussions with stakeholders, EPA is concerned that some users could broadly interpret directions for use on these labels and has decided that labels must clearly limit applications in these areas to only spot treatments, one time per year, along woody borders of kennels, yards, campgrounds, recreational parks, and footpaths and roadways leading to such areas. Further, while these products are all intended for professional use by certified applicators, to ensure applications are made only by professional handlers, labels must prohibit use by homeowners. If any party in the future is interested in expanding the use of tetrachlorvinphos to include broadcast outdoor uses, EPA will evaluate the potential risks associated with that use and additional data may be required.

## **5. Other Concerns**

EPA is concerned with tetrachlorvinphos feed-through products used in horses. EPA has data from multiple sources that show tetrachlorvinphos feed-through products decrease cholinesterase levels. EPA is therefore requesting the registrants add label statements to horse oral larvicides which state that the product is a cholinesterase inhibitor, describe signs of cholinesterase inhibition in horses, caution users against the use with other cholinesterase inhibiting compounds, and direct horse owners to consult a veterinarian before using products containing tetrachlorvinphos on debilitated, aged, pregnant or nursing animals. Also, since no controlled studies have been conducted with breeding horses, labels must state, “this product has not been tested in breeding horses.”

## **II. What Registrants Need to Do**

### **A. Manufacturing Use Products**

#### **1. Additional Generic Data Requirements**

The generic data base supporting the reregistration of tetrachlorvinphos for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain:

860.1340	Residue Analytical Method
860.1360	Storage Stability Data
860.1650	Analytical Reference Standards
860.1480	Magnitude of Residue - Meat/Milk/Poultry/Eggs
870.1200	Acute Dermal Toxicity
875.1100	Dermal Exposure (Indoor) for paint-on WP and Dust uses
875.1300	Inhalation Exposure (Indoor) for paint-on WP and Dust uses

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies. The technical registrants of tetrachlorvinphos, Boehringer Ingelhiem and Hartz Mountain requested a generic data waiver for to the developmental neurotoxicity study, and the Agency denied the requests in letters dated February 6, 2001, and July 31, 2000, respectively. The registrants intend to support the registration of tetrachlorvinphos and have committed to submit the required developmental neurotoxicity study.

## **2. Labeling for Manufacturing Use Products**

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

All registrants need to submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all label amendments outlined in Table 11 of this document incorporated, and a description on the application, such as, “Responding to the Tolerance Reassessment Eligibility Decision” document. All amended labels need to be submitted within 90 days of signature of this document. The Registration Division contact is George Larocca (703) 305-6100.

### **B. End-Use Products**

#### **1. Additional Product-Specific Data Requirements**

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

A product-specific data call-in, outlining specific data requirements, accompanies this interim TRED.

#### **2. Labeling for End-Use Products**

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Table 8 at the end of this section. Registrants need to submit applications for amended registration. This application should include the following items: EPA application form 8570-1 (filled in), five copies of the draft label with all label amendments outlined in Table 9 of this document incorporated, and a description on the application, such as, “Responding to the Tolerance Reassessment Eligibility Decision” document. All amended labels need to be submitted within 90 days of signature of this document. The Registration Division contact is George Larocca (703) 305-6100.

### **C. Existing Stocks**

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this interim TRED. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this interim TRED. However, existing stocks time frames will be established case-by-case, depending on the

number of products involved, the number of label changes, and other factors. Refer to “Existing Stocks of Pesticide Products; Statement of Policy”; *Federal Register*, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell tetrachlorvinphos products bearing old labels/labeling for 26 months from the date of issuance of this interim TRED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this interim TRED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

#### **D. Labeling Changes Summary Table**

In order to be eligible for reregistration, it is necessary to amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

E. Required Labeling Changes Summary Table

Table 12: Summary of Required Labeling Changes for Tetrachlorvinphos		
Description	Required Labeling (Addendum to the 1995 RED Labeling Requirements)	Placement on Label
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	“Only for formulation into an <i>insecticide</i> for the following use(s)” <i>[fill blank only with those uses that are being supported by MP registrant]</i> .	Directions for Use
	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
Environmental Hazards Statements Required by the TRED and Agency Label Policies.	<p><b>“Environmental Hazards”</b></p> <p>"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your Water Board or Regional Office of the EPA."</p>	Precautionary Statements

Description	Required Labeling (Addendum to the 1995 RED Labeling Requirements)	Placement on Label
End Use Products Intended for Occupational Use		
<p>Handler PPE requirements (all formulations)</p>	<p>Note the following information when preparing labeling for all end use products:</p> <p>For <b>sole-active-ingredient</b> end-use products that contain tetrachlorvinphos, the product label must be revised to adopt the handler personal protective equipment (PPE)/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current label must be removed.</p> <p>For <b>multiple-active-ingredient</b> end-use products that contain tetrachlorvinphos, the handler PPE/engineering control requirements set forth in this section must be compared with the requirements on the current label, and the more protective language must be retained. For guidance on which requirements are considered to be more protective, see PR Notice 93-7.</p> <p>PPE that was established on the basis of Acute Toxicity testing and currently appears on end-use product labels must be compared with the active ingredient PPE specified below by the TREAD. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.</p>	<p>Handler PPE Statements</p>

Description	Required Labeling (Addendum to the 1995 RED Labeling Requirements)	Placement on Label
<p>PPE Requirements Established by the TRED for Wettable Powder Formulations applied as Sprays only.</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators and other handlers supporting or using low-pressure handwand equipment or applying by paint brush must wear:</p> <ul style="list-style-type: none"> <li>- Coveralls over long-sleeved shirt and long pants</li> <li>- Chemical resistant footwear plus socks</li> <li>- Chemical resistant gloves</li> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p>All other mixers, loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants</li> <li>- socks and shoes</li> <li>- chemical resistant gloves for mixers and loaders supporting ground boom applications and all handlers supporting or using backpack spray equipment.</li> </ul> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>

Description	Required Labeling (Addendum to the 1995 RED Labeling Requirements)	Placement on Label
<p>PPE Requirements Established by the TRED for Wettable Powder Formulations applied as Dusts only.</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] on an EPA chemical-resistance category selection chart.”</p> <p>Loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- Coveralls over long-sleeved shirt and long pants</li> <li>- Chemical resistant footwear plus socks</li> <li>- Chemical resistant gloves</li> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p>Loaders and others handling dust bags must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants</li> <li>- socks and shoes</li> <li>- chemical resistant gloves.</li> </ul> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	<p>Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals</p>



Description	Required Labeling (Addendum to the 1995 RED Labeling Requirements)	Placement on Label
<p>PPE Requirements Established by the TRED for Wettable Powder Formulations applied as either as a Sprays or as a Dust</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers, loaders, applicators and other handlers supporting dusting applications, low-pressure handwand applications or applications by paint brush must wear:</p> <ul style="list-style-type: none"> <li>- Coveralls over long-sleeved shirt and long pants</li> <li>- Chemical resistant footwear plus socks</li> <li>- Chemical resistant gloves</li> <li>- A NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C <i>or</i> a NIOSH-approved respirator with any N, R, P, or HE filter.”</li> </ul> <p>All other mixers, loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants</li> <li>- socks and shoes</li> <li>- chemical resistant gloves for mixers and loaders supporting ground boom applications and all handlers supporting or using backpack spray equipment.</li> </ul> <p><i>Note to Registrant: If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” filter designation must be dropped from the above respirator statement.</i></p>	

Description	Required Labeling (Addendum to the 1995 RED Labeling Requirements)	Placement on Label
PPE Requirements Established by the TRED for EC Formulations	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Mixers loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants,</li> <li>- shoes plus socks</li> <li>- chemical resistant gloves for mixers and loaders supporting ground boom applications and all handlers supporting or using backpack or low pressure spray applications.</li> </ul>	Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals
PPE Requirements Established by the TRED for Ear Tags, Mineral Blocks or Feed Pellets.	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“Loaders, applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants,</li> <li>- shoes plus socks</li> <li>- chemical resistant gloves”</li> </ul>	Precautionary Statements: Immediately following/below Hazards to Humans and Domestic Animals

Description	Required Labeling (Addendum to the 1995 RED Labeling Requirements)	Placement on Label
User Safety Requirements	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.</p> <p>Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p> <p><i>(The above phrase “Discard clothing....” is only required for WP formulations applied as sprays or dusts. It is not required for EC formulations.)</i></p>	Precautionary Statements: Immediately following the PPE requirements
User Safety Recommendations	<p><b>“User Safety Recommendations”</b></p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	Precautionary Statements: Immediately following Engineering Controls)  Must be placed in a box
Environmental Hazards	<p><b>“Environmental Hazards”</b></p> <p>Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wastewater or rinsate.</p>	Precautionary Statements: Immediately following the User Safety Recommendations

<b>Description</b>	<b>Required Labeling (Addendum to the 1995 RED Labeling Requirements)</b>	<b>Placement on Label</b>
Entry Restrictions for products applied as sprays.	“Do not enter or allow others to enter until sprays have dried”	Directions for Use in the Non-Agricultural Use Requirements Box.
Entry Restrictions for products applied as dusts.	“Do not enter or allow others to enter until dusts have settled”	Directions for Use in the Non-Agricultural Use Requirements Box.
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Directions for Use

Description	Required Labeling (Addendum to the 1995 RED Labeling Requirements)	Placement on Label
Other Risk Mitigation Restrictions	<p><b>EC Formulations:</b> Remove paint-on use on EC formulations and add the following statement: “This product may not be applied by paint brush”.</p> <p><b>Wettable Powder Formulations Applied as Sprays:</b>  “When using a low-pressure handwand, this product may only be used for spot treatments.”</p> <p><b>Feed Through Products (Mineral Blocks or Pellets):</b>  This product contains tetrachlorvinphos, which is a cholinesterase inhibitor.</p> <p>The most frequently reported clinical signs of cholinesterase inhibition in the horse are abdominal pain, lethargy, sweating, tearing and excessive salivation. If these signs are seen in horses, consult your veterinarian immediately.</p> <p>Do not use this product simultaneously or within a week before or after treatment with cholinesterase inhibiting drugs, pesticides or chemicals.</p> <p>Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals.</p> <p>This product has not been tested in breeding horses.</p>	Directions for Use

Description	Required Labeling (Addendum to the 1995 RED Labeling Requirements)	Placement on Label
Other Risk Mitigation Restrictions	<p><b>For Pet Powder Uses:</b></p> <p>Use 1/3 oz. of powder per every 10 pounds of body weight of your cat or dog.</p> <p><b>For Outdoor Premise Uses:</b></p> <p>Restrict uses to only spot treatments.</p> <p>The product should be applied only one time per year.</p> <p>The product is to be used along woody borders of kennels, yards, campgrounds, recreational parks, and footpaths and roadways leading to such areas.</p>	

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

<sup>2</sup> If the product contains oil or bears instructions that will allow application with an oil-containing material, the “N” designation must be dropped.

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

Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

## VI. Related Documents and How to Access Them

This interim Reregistration Eligibility Document 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 *[date]*. 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 *[date]*.

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. Table of Use Patterns Eligible for Reregistration

Site Application Type Application Equipment	Formulation [EPA Reg No.]	Maximum Single Application Rate <sup>1</sup>	Use Limitations
Beef/Range/Feeder Cattle (Meat) & Dairy Cattle (Lactating or Unspecified)			
Animal Treatment (Backrubber)	24% Emulsifiable Concentrate [4691-132]	2 lb ai/ 25 gallons (25 and 50 gallons of charge solution considered).	Double layer clothing and gloves for workers when handling backrubber devices.
Animal Treatment -Dust (Dust Bag)	3% Dust [4691-131]	NS <sup>2</sup>	Single layer and gloves for loaders and others handling dust bags.
Animal Treatment - Dust (Hand Held Duster) (Rotary Duster)	3% Dust [4691-131]	0.0375 lb ai/animal	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Treatment (Shaker Can)	3% Dust [4691-131]	0.0375 lb ai/animal	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Treatment (Backpack Sprayer) (Power Sprayer)	24% Emulsifiable Concentrate [4691-132]	0.001295 lb ai/animal	
Enclosed Premise Treatment (Backpack Sprayer) (Power Sprayer)	24% Emulsifiable Concentrate [4691-132]	.2129 lb 1K sq. ft	
Enclosed Premise Treatment (Backpack Sprayer) (Power Sprayer)	50% Wettable Powder [4691-128]	.3333 lb 1K sq. ft	.
Animal Treatment (Feed Through Use)	97.3 % Granular [4691-135]	0.00015 lb per 100 lb body weight per day	Single layer clothing and gloves for workers when handling pellets (oral larvicide feed- through products).
Animal Treatment (Cattle Ear Tag)	13.7% Ear Tag [56493-50]	NS	Single layer clothing and gloves for workers when handling ear tags.
Hog/Pig/Swine (Meat)			
Animal Bedding/Litter Treatment (Hand Held Duster)	3% Dust [4691-131]	.2 lb 1K sq.ft	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Bedding/Litter Treatment (Power Duster)	3% Dust [4691-131]	2 lb 1K sq.ft	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Bedding/Litter Treatment (Rotary Duster)	3% Dust [4691-131]	2 lb 1K sq.ft	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.



Site Application Type Application Equipment	Formulation [EPA Reg No.]	Maximum Single Application Rate <sup>1</sup>	Use Limitations
Animal Bedding/Litter Treatment (Shaker Can)	3% Dust [4691-131]	2 lb 1K sq.ft	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Treatment (Hand Held Duster)	3% Dust [4691-131]	0.075 lb ai/animal	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Treatment (Power Duster)	3% Dust [4691-131]	0.075 lb ai/animal	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Treatment (Backpack Sprayer) (Power Sprayer)	24% Emulsifiable Concentrate [4691-132]	0.1575 lb ai/animal	
Animal Treatment (Backpack Sprayer) (Power Sprayer)	50% Wettable Powder [4691-128]	.02038 lb ai/animal	
Animal Treatment (Feed Through)	97.3 % Granular [4691-135]	0.00015 lb per 100 lb body weight per day	Single layer clothing and gloves for workers when handling pellets (oral larvicide feed-through products).
Enclosed Premise Treatment (Backpack Sprayer) (Power Sprayer)	24% Emulsifiable Concentrate [4691-132]	.2129 lb 1K sq.ft	
Enclosed Premise Treatment (Backpack Sprayer) (Power Sprayer)	50% Wettable Powder [4691-128]	.3333 lb 1K sq.ft	
Poultry (Egg)			
Animal Bedding/Litter Treatment (Backpack Sprayer) (Power Sprayer)	24% Emulsifiable Concentrate [4691-132]	0.0436 lb ai/100 ft <sup>2</sup>	Single layer clothing and gloves for mixers, loaders, and applicators engaging in low pressure handwand and backpack spraying activities.
Animal Bedding/Litter Treatment (Backpack Sprayer) (Power Sprayer)	50% Wettable Powder [4691-128]	0.0417 lb ai/100 ft <sup>2</sup>	Restrict the use of low pressure handwands for wettable powder applications to spot treatment in poultry facilities and require double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators engaging in low pressure handwand activities using the WP formulations in egg facilities.
Animal Bedding/Litter Treatment (Rotary Duster)	3% Dust [4691-131]	0.078 lb ai/100 ft <sup>2</sup>	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.

Site Application Type Application Equipment	Formulation [EPA Reg No.]	Maximum Single Application Rate <sup>1</sup>	Use Limitations
Animal Bedding/Litter Treatment (Shaker Can)	3% Dust [4691-131]	0.078 lb ai/100 ft <sup>2</sup>	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Treatment (Dust Box)	3% Dust [4691-131]	0.078 lb ai/animal	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Treatment (Rotary Duster)	3% Dust [4691-131]	0.078 lb ai/animal	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Treatment (Shaker Can)	3% Dust [4691-131]	0.078 lb ai/animal	Double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators using dusting equipment.
Animal Treatment (Backpack Sprayer) (Power Sprayer)	24% Emulsifiable Concentrate [4691-132]	0.0436 lb ai/animal	Single layer clothing and gloves for mixers, loaders, and applicators engaging in low pressure handwand and backpack spraying activities.
Animal Treatment (Backpack Sprayer) (Power Sprayer)	50% Wettable Powder [4691-128]	0.0436 lb ai/animal	Restrict the use of low pressure handwands for wettable powder applications to spot treatment in poultry facilities and require double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators engaging in low pressure handwand activities using the WP formulations in egg facilities.
Poultry (Broiler)			
Animal Premise/Litter Treatment (Backpack Sprayer) (Power Sprayer)	24% Emulsifiable Concentrate [4691-132]	0.6996 lb ai/animal	Single layer clothing and gloves for mixers, loaders, and applicators engaging in low pressure handwand and backpack spraying activities.
Animal Premise/Litter Treatment (Backpack Sprayer) (Power Sprayer)	50% Wettable Powder [4691-128]	0.6996 lb ai/animal	Restrict the use of low pressure handwands for wettable powder applications to spot treatment in poultry facilities and require double layer clothing, gloves, and dust/mist respirator for mixers, loaders, and applicators engaging in low pressure handwand activities using the WP formulations in broiler facilities.
Animal Premise/Litter Treatment (Groundboom Sprayer)	24% Emulsifiable Concentrate [4691-132]	0.6996 lb ai/animal	Single layer clothing and gloves for mixers, loaders, and applicators engaging in groundboom activities.
Animal Premise/Litter Treatment (Groundboom Sprayer)	50% Wettable Powder [4691-128]	0.6996 lb ai/animal	Single layer clothing and gloves for mixers, loaders, and applicators engaging in groundboom activities.

Site Application Type Application Equipment	Formulation [EPA Reg No.]	Maximum Single Application Rate <sup>1</sup>	Use Limitations
Animal Bedding/Litter Treatment (Aerosol, Pump Spray)	1.08 % Spray [2596-140]	Repeat once a week.	
Animal Bedding/Litter Treatment	3.3 % Powder [2596-78]	Repeat at weekly intervals if necessary	
Animal Treatment	13.7 % Collar [4691-151]	Replace collar every four months.	
Animal Treatment	3.06 % Dip [2596-119]	Dilute 2 ounces of Dip with 1 gallon of water. Dip animal into solution, or sponge solution on, making sure hair is thoroughly wet to skin. Repeat as necessary for control.	
Animal Treatment	3.3 % Powder [2596-78]	1/3 oz for every 10 lb animal	
Animal Treatment (Aerosol, Pump Spray)	1.08 % Spray [2596-126]	Direct spray towards pet and spray entire coat pressing dispenser with quick short strokes. Move bottle to get even coverage of coat (until tips of hair are moist). Repeat once a week.	
Pets (Dogs)			
Animal Bedding/Litter Treatment (Aerosol, Pump Spray)	1.08 % Spray [2596-140]	Repeat once a week.	
Animal Bedding/Litter Treatment	3.3 % Powder [2596-79]	Repeat at weekly intervals if necessary	
Animal Treatment	13.7% Collar [4691-150]	Replace collar every five months.	
Animal Treatment	3.06 % Dip [2596-119]	Dilute 2 ounces of Dip with 1 gallon of water. Dip animal into solution, or sponge solution on, making sure hair is thoroughly wet to skin. Repeat as necessary for control.	
Animal Treatment	3.3 % Powder [2596-79]	1/3 oz for every 10 lb animal	

Site Application Type Application Equipment	Formulation [EPA Reg No.]	Maximum Single Application Rate <sup>1</sup>	Use Limitations
Animal Treatment (Aerosol, Pump Spray)	1.08 % Spray [2596-125]	Direct spray towards pet and spray entire coat pressing dispenser with quick short strokes. Move bottle to get even coverage of coat (until tips of hair are moist). Repeat once a week.	
Horses			
Feed Through	97.3 % Granular [4691-135]	0.00015 lb per 100 lb body weight per day	This product is a cholinesterase inhibitor. It should not be used with other cholinesterase inhibitors. Horse owners should consult a veterinarian before using products containing tetrachlorvinphos on debilitated, aged, breeding, pregnant or nursing animals
Non-Food Outdoor Residential			
Outdoor Premise Treatment (Kennels, Campgrounds, Picnic Areas)	50% Wettable Powder <sup>3</sup> [4691-128]	Restrict usage to spot treatment only. Usage should not exceed one time a year.	Only use along woody borders of kennels, yards, campgrounds, and recreational parks. Prohibit the use of outdoor premise treatment by homeowners.
Outdoor Premise Treatment (Fence Rows, Hedgerows, Foot Paths)	50% Wettable Powder [4691-128]	Restrict usage to spot treatment only. Usage should not exceed one time a year.	Only use along woody borders of footpaths and roadways leading to such areas. Prohibit the use of outdoor premise treatment by homeowners.

1. Maximum Rates are based on the Label Usage Information System (LUIS) report and the risk management decision
2. Not stated on the label
3. Typically used in conventional power or low pressure backpack sprayers

# APPENDIX B

## Data Supporting Guideline Requirements for the Reregistration of Tetrachlorvinphos

REQUIREMENT		USE PATTERN	CITATION(S)
<b><u>PRODUCT CHEMISTRY</u></b>			
New Guideline Number	Old Guideline Number		
830.1550	61-1	Product Identity and Composition	All 41222501, 41222502, 43160601
830.1600	61-2A	Start. Mat. & Mnfg. Process	All 41222501, 42013001
830.1670	61-2B	Formation of Impurities	All 40491301, 41222501, 42013001
830.1700	62-1	Preliminary Analysis	All 40924701, 41222502, 43160601, 43160602
830.1750	62-2	Certification of limits	All 41222502
830.1800	62-3	Analytical Method	All 41222502, 42013002, 42275201, 42679201, 43160601
830.6302	63-2	Color	All 41222503
830.6303	63-3	Physical State	All 41222503
830.6304	63-4	Odor	All 41222503
830.7200	63-5	Melting Point	All 41222503
830.7220	63-6	Boiling Point	All NOT APPLICABLE
830.7300	63-7	Density	All 41222503
830.7840 830.7860	63-8	Solubility	All 41222503
830.7950	63-9	Vapor Pressure	All 41222503
830.7370	63-10	Dissociation Constant	All NOT APPLICABLE
830.7550	63-11	Octanol/Water Partition Coefficient	All 41222503
830.7000	63-12	pH	All 41222503
830.6313	63-13	Stability	All 41222503
830.6314	63-14	Oxidizing/Reducing Action	All NOT APPLICABLE
830.6315	63-15	Flammability	All NOT APPLICABLE
830.6316	63-16	Explosibility	All NOT APPLICABLE
830.6317	63-17	Storage Stability	All 41222503, 42013003, 4207801
830.7100	63-18	Viscosity	All NOT APPLICABLE
830.6319	63-19	Miscibility	All NOT APPLICABLE
830.6320	63-20	Corrosion characteristics	All 41222503, 42013003
<b><u>ECOLOGICAL EFFECTS</u></b>			
850.2100	71-1A	Avian Acute Oral Toxicity	B, C, K 00160000
850.2200	71-2A	Avian Dietary Toxicity - Quail	B, C, K 00022923
850.2200	71-2B	Avian Dietary Toxicity - Duck	B, C, K 00022923
850.1075	72-1A	Fish Toxicity Bluegill	B, C, K 40098001
850.1075	72-1C	Fish Toxicity Rainbow Trout	 40098001

850.1010	72-2A	Invertebrate Toxicity	B, C, K	41257101
None	72-3A	Estuarine/Marine Toxicity - Fish		40228401
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk		40228401
850.1035	72-3C	Estuarine/Marine Toxicity - Shrimp		40228401
850.3020	141-1	Honey Bee Acute Contact		00036935
850.3030	141-2	Honey Bee Residue on Foliage		05000837

### **TOXICOLOGY**

870.1100	81-1	Acute Oral Toxicity-Rat	ALL	41222504
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	ALL	41222505
870.1300	81-3	Acute Inhalation Toxicity-Rat	ALL	00138933
870.2400	81-4	Primary Eye Irritation-Rabbit	ALL	41222506
870.2500	81-5	Primary Skin Irritation	ALL	41222507
870.2600	81-6	Dermal Sensitization	ALL	41377902, 42981001
870.6100	81-7	Acute Delayed Neurotoxicity - Hen		00079791, 41905901
870.6200	81-8	Acute Neurotoxicity Screen		42912501
870.3100	82-1A	Subchronic Oral Toxicity Test (90-Day Feeding - Rodent)	B, L	43371201
870.3250	82-3	90-day Subchronic Dermal Toxicity Test, Rat		41342001
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	B, L	00112525, 42980901
870.4100	83-1B	Chronic Feeding Toxicity -Non-Rodent	B, L	00077819, 42679401
870.4200	83-2A	Oncogenicity - Rat	B, L	00117443, 42980901
870.4200	83-2B	Oncogenicity - Mouse	B, L	00117443, 00126039
870.3700	83-3A	Developmental Toxicity - Rat	B, L	40152701, 4250101
870.3700	83-3B	Developmental Toxicity - Rabbit	B, L	00127831
870.3800	83-4	2-Generation Reproduction - Rat	B, L	00077802, 42054301
870.5140	84-2A	Gene Mutation (Ames Test)	B, C, K, L, M	41222508
870.5375	84-2B	Structural Chromosomal Aberration	B, C, K, L, M	41312901
None	84-4	Other Genotoxic Effects	B, C, K, L, M	42156401
870.7485	85-1	General Metabolism	B, L	41988401
870.7600	85-2	Dermal Penetration		42111501
870.7200	86-1	Domestic (Companion) Animal Safety		40436601, 41810101, 41810102

### **OCCUPATIONAL/RESIDENTIAL EXPOSURE**

875.1200	233	Estimation of Dermal Exposure, Indoor Sites		45519601, 45528801
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875.1400	234	Estimation of Inhalation Exposure, Indoor Sites		45519601, 45528801
875.2400	133-3	Dermal Passive Dosimetry Exposure		42622301, 45485501
875.2500	133-4	Inhalation Passive Dosimetry Exposure		42622301

### **ENVIRONMENTAL FATE**

None	160-5	Chemical Identity	ALL	41222501, 41222502, 43160601
835.2120	161-1	Hydrolysis	ALL	41929101
835.4100	162-1	Aerobic Soil Metabolism	B, C, K	00077821, 42082401
835.1240	163-1	Leaching/Adsorption/Desorption	B, C, K	41681301
None	164-A-SS	Dissipation of Residues in Excrement		42848501

### **RESIDUE CHEMISTRY**

860.1300	171-4B	Nature of Residue - Livestock	B	00116020, 00117354, 00120147, 00120204, 42828801, 42828802, 42828803
860.1340	171-4C	Residue Analytical Method - Plants	B	00038458, 00077812, 00077814, 00077816, 00115939, 00116020, 00116553, 00117329, 00117340, 00117351, 00117354, 00117389, 00118265, 00120147, 00120200, 00120205, 00120206, 00120229, 00130705, 00133913, 05004211
860.1340	171-4D	Residue Analytical Method - Animals	B	00038458, 00077812, 00077814, 00077816, 00115939, 00116020, 00116553, 00117329, 00117340, 00117351, 00117354, 00117389, 00118265, 00120147, 00120200, 00120205, 00120206, 00120229, 00130705, 00133913, 05004211
860.1380	171-4E	Storage Stability	B	00117329, 00117354, 00117361, 00117389, 00133913

860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg	B	00038458, 00084189, 00115939, 00117298, 00117298, 00117339, 00117340, 00117354, 00117389, 00118265, 00120200, 00120206, 00120225, 00120227, 05006630
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## **Appendix C. Technical Support Documents**

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

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[www.epa.gov/pesticides/op](http://www.epa.gov/pesticides/op)

These documents include:

### **HED Documents**

Boyle, Kathryn (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. The Revised HED Chapter of the Reregistration Eligibility Decision (RED) Document. April 1, 1998.

Swartz, Christina (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Acute and Chronic Dietary Exposure and Risk Analyses. September 28, 1998.

Swartz, Christina (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Addendum to HED Human Health Risk Assessment and RED Chapter dated 4/1/98. November 2, 1998.

Hanley, Susan (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Occupational and Residential Exposure and Risk Assessment. November 3, 1998.

Hanley, Susan (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Occupational and Residential Exposure and Risk Assessment. January 7, 1999.

Hanley, Susan (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. HED Response to 30 day comments submitted by Hartz Mountain Corporation: Occupational and Residential Exposure Assessment. January 7, 1999.

Hanley, Susan (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Revised Occupational and Residential Exposure and Risk Assessment. June 2, 1999

Hazel, William (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Revised HED Human Health Risk Assessment. June 16, 1999.

Olinger, Christine (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Revised Anticipated Residue Estimates. June 16, 1999.

Swartz, Christina (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Revised Acute and Chronic

Dietary Exposure and Risk Analyses for the HED Human Health Risk Assessment. June 16, 1999.

Hanley, Susan (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Revised Occupational and Residential Exposure and Risk Assessment for the Health Effects Division RED. October 25, 1999.

Swartz, Christina (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Revised HED Human Health Risk Assessment. December 8, 1999.

Dobozy, Virginia (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Incident Report of Equine Reproduction Problems. March 15, 2000.

Dobozy, Virginia (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Review of Registrants May 26, 2000 Submission Concerning Equitrol®. October 19, 2000.

Dawson, Jeffery (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Addenda to previous occupational and residential risk assessment. February 15, 2001.

Hanley, Susan (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Addendum for Residential Exposure using updated Standard Operating Procedures for Residential Exposure. June 8, 2001.

Dobozy, Virginia (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Review of Literature References on Organophosphate Toxicity in Pregnant Horses. November 26, 2001.

Hanley, Susan (USEPA/OPPTS/OPP/HED) Addendum to the Tetrachlorvinphos Occupational and Residential Exposure Risk Revision for the Reregistration Evaluation Decision. February 4, 2002.

Dawson, Jeffery (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Further revisions to occupational risk assessment for uses in poultry and cattle production industries. March 28, 2002.

Hanley, Susan (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Summary of Revised Residential Handler and Postapplication Toddler Exposure Risk. April 1, 2002.

Swartz, Christina (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Addendum to the HED Human Health Risk Assessment for the Interim Reregistration Eligibility Decision (IRED). April 5, 2002.

Dobozy, Virginia (USEPA/OPPTS/OPP/HED) Tetrachlorvinphos. Review of Cholinesterase Data in Horses Treated with Equitrol®. July 2, 2002.

### **Other Related Documents**

Fuller, Demson (USEPA/OPPTS/OPP/SRRD) Letter sent to SRA International. Responding to their comments on the Preliminary Human Health Risk Assessment.

Wilhite, Mark (USEPA/OPPTS/OPP/SRRD) Letter sent to SRA International. Transmitting the

Addendum to the Preliminary Human Health Risk Assessment.

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## **Appendix D. Citations Considered to be Part of the Data Base Supporting the Tolerance Reassessment Decision (Bibliography)**

### **GUIDE TO APPENDIX D**

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
  - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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