Tetrachlorvinphos (TCVP)

Interim Registration Review Decision
Case Number 0321

April 2024

Approved by: _____

Timothy Kiely
Acting Director
Pesticide Re-evaluation Division

Date: April 22, 2024

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for tetrachlorvinphos (TCVP) (PC Codes: 083701 and 083702, case 0321). Tetrachlorvinphos [(Z)-2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate] is a member of the organophosphate (OP) class of insecticides. TCVP was first registered in 1966. TCVP technical grade active ingredient registrations are registered by the Hartz Mountain Corporation (Hartz) and Elanco Animal Health (Elanco). All crop uses for TCVP were cancelled by 1987. TCVP inhibits acetylcholinesterase (AChE) through phosphorylation of the serine residue on the enzyme leading to accumulation of acetylcholine and ultimately cholinergic neurotoxicity. Products containing TCVP are registered for use as an animal treatment to mink, poultry, and livestock (i.e., cattle, swine, and horses) and livestock premises to control mites, beetles, lice, and flies. TCVP is also registered for use in kennels (including outdoor runways and along woody borders of kennels), recreational areas, garbage piles, livestock and poultry manure, and as a flea and tick treatment on cats and dogs.

The Federal Insecticide, Fungicide, Rodenticide Act (FIFRA)[1] mandates a periodic review of existing pesticide registrations every 15 years, referred to as registration review.[2] During registration review, the Agency ultimately determines whether a currently registered pesticide continues to meet FIFRA's registration standard.[3] Where appropriate, the Agency may issue an Interim Registration Review Decision (ID) before completing a final registration review decision.[4] However, issuance of an ID is not a decision on whether a pesticide's registrations continue to satisfy the FIFRA standard for registration.[5] Rather, the ID may include mitigation measures and changes to labeling that EPA has determined would address risks of concern, identify data or information needed to complete registration review, and include schedules for submitting such data, conducting the new risk assessment, and completing the registration review.[6] The Agency is issuing this ID for TCVP to identify risk mitigation that EPA has determined would address risks of concern for TCVP, as presented in Section IV and Appendices A and B.

EPA has not yet fully evaluated TCVP's effects on federally threatened and endangered (referred to as "listed") species or their designated critical habitats. However, consistent with its

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 *et seq*.
[2] For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.
[3] FIFRA § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57; *see also* FIFRA § 3(c)(5).
[4] 40 C.F.R. §§ 155.56, 155.58. Consistent with 40 C.F.R. § 155.58, EPA must first issue and take comment on a PID before issuing an ID.
[5] At the end of the registration review process, EPA will decide whether a pesticide registration "continues to satisfy the FIFRA standard for registration." 40 C.F.R. §§ 155.40(a), 155.57; FIFRA § 3(g), 7 U.S.C. § 136a(g); *see also* FIFRA § 3(c)(5), 7 U.S.C. § 136a(c)(5) (FIFRA registration standard); FIFRA § 2(bb), 7 U.S.C. § 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA's risk-benefit standard] and "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]"). This document is not a "registration review decision" within the meaning of FIFRA Section 3(g) and 40 C.F.R. § 155.57.
[6] 40 C.F.R. § 155.56.

obligations under the Endangered Species Act (ESA),[7] EPA expects to complete effects determinations and any necessary consultation with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively, "the Services") before completing the TCVP registration review and issuing a final registration review decision. For more information on EPA's ESA obligations during registration review, see Appendix C.

EPA continues to work with the Services to improve the consultation process for pesticides in registration review. In April 2022, EPA released its ESA Workplan, which outlines strategies and actions for the Agency to meet its ESA obligations for FIFRA actions.[8] Consistent with the ESA Workplan, EPA is focused on steps it will take during registration review to reduce exposure for listed species as it moves toward fulfilling its ESA obligations and making final registration review decisions. In November 2022, EPA released its first ESA Workplan Update.[9] As part of this update, EPA announced that, going forward, EPA may include a variety of FIFRA Interim Ecological Mitigation (IEM) measures in its registration review decisions that seek to reduce exposures for non-target organisms based on its FIFRA ecological risk assessment(s). EPA expects that this mitigation may also reduce pesticide exposures for listed species.

As part of this ID, EPA has considered a variety of FIFRA IEM measures based on the risks and benefits of TCVP to reduce exposures to non-target organisms, including listed species, while the Agency works toward a final registration review decision. While these mitigation measures do not satisfy EPA's ESA obligations, EPA has determined that early mitigation may shorten the consultation process and improve protections for listed species from currently registered pesticide products. EPA also believes that the FIFRA IEM measures that the Agency is implementing for TCVP in this ID would also fulfill EPA's obligations under Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022). Among other things, Section 711 requires EPA to "include, where applicable, measures to reduce the effect of the applicable pesticide on" listed species and designated critical habitats in any ID noticed in the *Federal Register* between December 29, 2022, and October 1, 2026 for which EPA has not "made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)]."

Between October 2009 and February 2010, EPA issued EDSP Tier 1 test orders/data call-ins for a group of 67 chemicals, which contains 58 pesticide active ingredients and nine inert ingredients. The Agency has prepared initial reviews of all the assay data received for the chemicals and the conclusions of those initial reviews are available in the chemical-specific public dockets (https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-tier-1-screening-determinations-and). Tier 1 data were submitted for TCVP (Gardona; *cis* isomer). In 2015, EPA published the *EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals* which provided review conclusions for TCVP **(**available in the TCVP public docket; see EPA-HQ-OPP-2008-0316). See Appendix D and the *Tetrachlorvinphos (Gardona): Data Evaluation Records (DERs) for EDSP Tier 1 Assays* for additional information.

[7] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[8] *Balancing Wildlife Protections and Responsible Pesticide Use* (Apr. 2022), https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf.
[9] *ESA Workplan Update: Non-target Species Mitigation for Registration Review and Other FIFRA Actions* (Nov. 2022), https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf.

This document is organized in five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments);
- *Use and Usage* (discussing how TCVP may legally be used and how TCVP is actually used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Interim Registration Review Decision* (presenting EPA's interim decision, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete registration review).

A. Updates Since the Proposed Interim Decision was Issued

In September 2023, EPA published the Proposed Interim Decision (PID) for TCVP. EPA received comments regarding several proposed mitigation measures that were included in the TCVP PID. EPA has reconsidered the mitigation necessary to address either human health or ecological risks of concerns from certain application methods based on these comments.

Non-cancer risks of concern were identified for occupational handlers filling poultry dust boxes using shaker cans and plunger dusters. With the use of personal protective equipment (PPE) (as directed) on the current labels margins of exposure (MOEs) were below the level of concern (LOC) of 300 with a range of 97-270. The Agency initially proposed to require respirators with an assigned protection factor of at least 50 (APF50) for applicators applying TCVP formulations to poultry dust boxes using shaker cans and APF10 respirators for filling poultry dust boxes with plunger dusters. Comments from United States Department of Agriculture (USDA) and Elanco stated that APF50 respirators may pose heat stress concerns for workers in poultry houses. The comments also stated that poultry dust boxes are not likely to be filled with shaker cans, and TCVP dust or wettable powder is likely to be poured or scooped directly into dust boxes. Therefore, EPA is prohibiting filling poultry dust boxes with shaker cans or plunger dusters. Poultry dust boxes are likely filled by mixers/loaders scooping or pouring TCVP product from the source container. The MOEs for filling poultry dust boxes by scooping or pouring range from 19,000 to 51,000 without a respirator and are not a risk of concern. Since EPA is only allowing poultry dust boxes to be filled directly from the source container, the Agency is not requiring use of a respirator for filling poultry dust boxes.

To limit runoff, EPA also proposed to require that outdoor garbage and manure piles be covered after treatment with TCVP. Comments from USDA, Elanco, and National Association of State Departments of Agriculture (NASDA) indicated that there may be situations where immediately covering garbage piles could impact actions taken to manage disease outbreak in livestock operations. EPA is therefore implementing advisory language to help users limit ecological exposure while allowing flexibility when applying TCVP to these use sites. This language guides users to cover garbage piles as soon as possible or move garbage indoors to reduce runoff.

The Agency reconsidered the proposed pollinator advisory language for TCVP following receipt of comments from USDA and Elanco. Given the use pattern for TCVP, insect pollinators are

more likely to be exposed to TCVP from residues on the ground or from runoff than from other application methods (e.g., spray applications). TCVP is not used on any crops, so exposure to insects that are actively pollinating plants is considered negligible. As such, EPA considers ground nesting bees to be of greater concern for exposure to TCVP than other insect pollinators. Therefore, EPA is reducing some of the FIFRA IEM and best management practices (BMPs) previously considered in the PID as they were specific to foliar applications. EPA is also adding advisory language specific to ground nesting bees. See Section IV. A. for more information.

The Agency also proposed limiting TCVP use to concentrated animal feeding operations (CAFOs) with National Pollutant Discharge Elimination System (NPDES) permits and Nutrient Management Plans (NMPs). The Agency reviewed this proposed mitigation following comments from USDA, Elanco, and NASDA. Based on these comments and additional discussion with USDA, EPA is no longer limiting use of TCVP to CAFOs with NPDES permits and NMPs. EPA finds that livestock operations that do not have NPDES permits and NMPs do not present significant risk to aquatic organisms from manure runoff. These operations are typically grazing operations on pasture or grassland and have livestock population densities that are well below that of CAFOs. These factors diminish the amount of manure that could potentially reach waters of the U.S. and therefore do not present significant risk to aquatic organisms. As a result, the Agency will continue to allow TCVP to be used at these facilities. The Agency is requiring mitigation measures for use of dusts on livestock operations to account for potential exposure from these applications when rain is expected. See EPA's response to comments in Section I.C. and IV.A. of this document for additional details. EPA is also updating the EPA registration numbers for 61483-43, now 11556-156, and 61483-50, now 11556-162. The EPA registration numbers for these products were updated after 2012 when Bayer (EPA company number 11556) acquired animal health products from KMG Chemicals (EPA company number 61483).[10] EPA is requiring specific label updates for these registrations as well as EPA Reg. No. 47000-126, which is also applied as a direct animal spray to cattle.

The Agency also identified additional ecological and environmental fate data needs. These data needs have been identified in Section III. B. EPA also found that following terrestrial invertebrate studies were no longer needed based in part of TCVP's registered uses and use patterns:

- Tier 1
    - Honey bee toxicity of residues on foliage (OCSPP 850.3030)
    - Honey bee larvae acute oral toxicity, Non-Guideline (OECD TG 237)
- Tier 2
    - Field trial of residues in pollen and nectar, Non-Guideline
    - Semi-field testing for pollinators (OECD GD 75)
- Tier 3
    - Full-Field testing for pollinators, OCSPP 850.3040.

These studies have been removed in this ID. Finally, there are minor updates to the Bulletins Live! Two (BLT) language to include the BLT website in Section IV.A. EPA is also including

[10] https://www.prnewswire.com/news-releases/bayer-to-acquire-animal-health-business-from-kmg-chemicals-inc-139434528.html

ecological incident reporting language as part of the Agency's FIFRA IEM measures for TCVP. In addition, EPA has included information in this ID regarding its work on several ESA strategies such as the Vulnerable Species Pilot[11] and the Herbicide Strategy[12] as well as Pesticide Use Limitation Areas (PULAs).

B. Summary of TCVP Registration Review

On June 25, 2008, the Agency formally initiated registration review for TCVP with the opening of the registration review docket for the case.[13,14] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of TCVP:

- June 2008 – EPA posted the *Tetrachlorvinphos: Registration Review Summary Document* (June 11, 2008), which included the Preliminary Work Plan (PWP), *Tetrachlorvinphos. Human Health Assessment Scoping Document in Support of Registration Review* (May 9, 2008), and *Preliminary Problem Formulation for the Ecological Risk Assessment of Tetrachlorvinphos* (June 5, 2008) to the public docket for a 60-day public comment period.

- December 2008 – EPA posted the *Tetrachlorvinphos Final Work Plan* (FWP) *for Registration Review* (November 26, 2008) to the public docket. The Agency received comments from three sources on the PWP and *Preliminary Problem Formulation for the Ecological Risk Assessment of Tetrachlorvinphos*. These comments did not change the data and risk assessment needs, or the timeline detailed in the PWP of the Summary Document.

- February 5, 2009 – EPA posted *Tetrachlorvinphos. Animal Incident Summary.*

- April 24, 2009 – EPA received a petition from the Natural Resources Defense Council (NRDC) to cancel all pet uses for TCVP.[15]

- December 2009 – EPA issued two identical generic data call-ins (GDCIs) for TCVP to obtain data needed to conduct the registration review risk assessments (GDCI-083702-0845 and GDCI-083702-1011). The data requirements were the same for each GDCI. The registrants submitted all required data from these generic data call-ins.

- August 2015 – The Agency completed its weight of evidence review of the Tier I assays required under the Endocrine Disruptors Screening Program in *Tetrachlorvinphos (Gardona): Data Evaluation Records (DERs) for EDSP Tier 1 Assays* (June 29, 2015).

[11] https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0327
[12] https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0365
[13] 40 C.F.R. § 155.50
[14] https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0316
[15] https://www.regulations.gov/docket/EPA-HQ-OPP-2009-0308

- January 2016 – EPA posted the *Tetrachlorvinphos (TCVP) Human Health Draft Risk Assessment* (December 21, 2015) and *Registration Review: Preliminary Environmental Fate and Ecological Risk Assessment [and] Endangered Species Effects Determination for Tetrachlorvinphos* (September 22, 2015) for a 60-day public comment period. The Agency received comments from seven commenters. The data and risk assessment needs changed based on information provided by NRDC in their August 2015 Opening Brief. The Agency has summarized and responded to these comments in the September 2023 TCVP PID.

- April 2016 – EPA posted the *Proposal to Rely on Data from Human Research on TCVP Exposure from Flea Control Collars: Tetrachlorvinphos* to the public docket for a 60-day public comment period. The Agency received three comments from three different commenters. The Agency has summarized and responded to these comments in the September 2023 TCVP PID.

- December 2016 – EPA posted the *Tetrachlorvinphos (TCVP) Health Effect Division Response to Comments on the December 21, 2015 Draft Human Health Risk Assessment for TCVP Registration Review* and the *Tetrachlorvinphos (TCVP) Revised Human Health Risk Assessment for Registration Review*. The Agency received one comment on the Revised Human Health Assessment. EPA summarized and responded to this comment in the September 2023 TCVP PID. EPA also posted the following documents for a 60-day public comment period:
  - *Tetrachlorvinphos: Final Occupational and Residential Exposure Assessment for Registration Review*

  EPA did not receive any comments on this document.

- May 2017 – EPA posted the following documents:
  - *Response to Comments on the Preliminary Ecological Risk Assessment for Tetrachlorvinphos (TCVP)*
  - *Tetrachlorvinphos (TCVP): Revised Acute, Steady State, and Cancer Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessment for the Registration Review Human Health Assessment*
  - *Office of Pesticide Programs' Framework for Incorporating Human Epidemiological & Incident Data in Risk Assessments for Pesticides*
  - *Summary Reviews from September 2015 Epidemiological Literature Review for Organophosphates*
  - *Organophosphates: Response to Endocrine Disruptor Screening Program (EDSP) Comments on the Preliminary Organophosphate Human Health Risk Assessments*
  - *Summary Reviews for Additional Epidemiological Literature Studies on Organophosphates*
  - *Organophosphates: Response to Occupational and Residential Exposure-Related Comments on the Preliminary Organophosphate Human Health Risk Assessments*
  - *Organophosphates: Response to Dietary Related Comments on the Preliminary Organophosphate Human Health Risk Assessments*
  - *Summary Review for Additional Epidemiological Literature Studies March 2016*

  - *Response to Comments for Public Comments Related to Applying the FQPA 10X Safety Factor for the Organophosphate Pesticides*
  - *Updated Literature Review on Neurodevelopmental Effects and FQPA Safety Factor Determination for the Organophosphate Pesticides*

- October 2017 – EPA published a request to voluntarily cancel certain TCVP pesticide registrations.

- August 2019 – EPA issued the TCVP Generic Data Call-In Notice GDCI-083702-1791 for composition of pet collar products.

- September 2019 – The Agency posted the following documents:
  - *EPA Letter to NRDC re: Petition Requesting Cancellation of All Pet Uses of TCVP (March 21, 2017)*
  - *TCVP Summary of Pet Collar Risk Estimates (February 22, 2010)*
  - *Residential Exposure Assessment in Response to NRDC Petition to Cancel All Pet Uses for TCVP (November 5, 2014)*
  - *TCVP: Responses to Arguments Presented in the NRDC's August 5, 2015 Opening Brief in NRDC vs. EPA, Case No. 15-70025 (9th Cir.) (December 21, 2015)*

- February 2020 – The Agency posted the *Data Evaluation Record for the Study Determination of TCVP and DCA Residues Released from Hartz Flea and Tick Collars by Torsion Stressing* and the *TCVP Review of Residue Transfer Studies*.

- July 2020 –EPA posted the *Agency Response to the Natural Resources Defense Council's (NRDC) April 2009 Tetrachlorvinphos Petition* in addition to the following documents:
  - *Alternatives Assessment for Tetrachlorvinphos (TCVP) Impregnated Flea and Tick Collars on Dogs and Cats.*
  - *Tetrachlorvinphos: Revised Residential Exposure and Risk Assessment for the Registered Pet Product Uses*
  - *Tetrachlorvinphos Addendum to the Revised Residential Exposure and Risk Assessment for the Registered Pet Product Uses*

- August 2020 - EPA published a request to voluntarily cancel certain TCVP pesticide registrations and amend TCVP registrations to terminate certain uses.

- December 2020 – EPA posted the *EPA Meeting with the National Toxicology Program (NTP) and Relevant Pesticide Chemical Technical Registrants to Discuss the Upcoming NTP Testing of Various Organophosphate (OP) and Oxon Compounds* and the *Product Cancellation Order for Certain Pesticide Registrations of Tetrachlorvinphos.*

- January 2021 – EPA published the *Tetrachlorvinphos (TCVP); Order to Voluntarily Terminate a Certain Use.*

- December 2021 – EPA posted the *Tetrachlorvinphos (TCVP): Tier I Review of Human Incidents for Draft Risk Assessment (May 21, 2015)* and the *Tetrachlorvinphos TCVP: Review of Domestic Animal Incidents for Response to Comments (May 6, 2015).*

- September 2022 – EPA posted *Meetings Between EPA and Hartz on Tetrachlorvinphos (TCVP) Petition Response and Data.*

- October 2022 – Following a judicial vacatur and remand of EPA's July 2020 response to NRDC's Petition, EPA posted the *Agency Response to the Natural Resources Defence Council's (NRDC) April 2009 Tetrachlorvinphos Petition* to the docket for *NRDC Petition Requesting Cancellation of all Tetrachlorvinphos (TCVP) Pet Uses* at https://www.regulations.gov/docket/EPA-HQ-OPP-2009-0308. EPA also posted the following documents:
    - *Tetrachlorvinphos (TCVP). Third Revision: Human Health Risk Assessment for Registration Review (October 6, 2022)*
    - *TCVP: Addendum to Review and Summary of Residue Transfer Studies Submitted (October 5, 2022)*
    - *TCVP: Addendum to the Data Evaluation Record for the Study "Determination of TCVP and DCA Residues Released from Hartz Flea and Tick Collars by Torsion Stressing (October 5, 2022)*
    - *Tetrachlorvinphos (TCVP). Revised Acute and Cancer Dietary (Food and Drinking Water) Exposure and Risk Assessments and Chronic (Average) Exposure Assessment for the Registration Review Human Health Risk Assessment (October 5, 2022)*
    - *Pet Collar Trimming Factor for Use in Exposure and Risk Assessments: A Refinement of the Treated Pet SOP (October 6, 2022)*
    - *Tetrachlorvinphos (TCVP): Second Revision – Occupational and Residential Exposure Assessment for Registration Review (October 6, 2022)*
    - *Tetrachlorvinphos (TCVP). Third Revision: Human Health Draft Risk Assessment for Registration Review*

- December 2022 – EPA posted the following:
    - *Tetrachlorvinphos (TCVP). Second Revision: Human Health Risk Assessment for Registration Review (January 26, 2022)*
    - *Revised Pet Collar Trimming Factor for Use in Exposure and Risk Assessments: A Refinement of the Treat Pet SOP (October 25, 2022)* and *Meeting Between EPA and Natural Resources Defense Council (NRDC) on Tetrachlorvinphos (TCVP) Registration Review (October 18, 2022)*

- May 2023: EPA posted the data evaluation records for the following studies:
    - *On Animal Collar Release Over Time* (MRID 52062502)
    - *Pet Collar Revised Torsion Protocol CPD-2022-3 – Final Report* (MRIDs 52101703 and 52062503)
    - *The in Vitro Percutaneous Absorption of Radiolabeled Tetrachlorvinphos (TCVP) at Three Concentrations in Aqueous and Lipid Vehicles through Human and Rat Split-Thickness Skin* (MRID 51890001)

- September 2023 – EPA completed the PID for TCVP and made it available in the public docket for a 60-day public comment period. EPA also opened a 60-day comment period for the *Tetrachlorvinphos (TCVP). Fourth Revision: Human Health Draft Risk Assessment for Registration Review* (HH DRA). Along with the PID and revised HH DRA, EPA posted the following documents to the public docket:

    - *Tetrachlorvinphos (TCVP): Third Revision - Occupational and Residential Exposure Assessment for Registration Review (September 7, 2023)*
    - *Tetrachlorvinphos (TCVP): Revised Data Evaluation Record for the Study "On Animal Collar Release over Time" (September 7, 2023)*
    - *Tetrachlorvinphos Data Evaluation Records (DERs) (September 5, 2023)*
    - *Tetrachlorvinphos (TCVP): Tier I Updated Review of Domestic Animal Incidents for the Proposed Interim Decision (PID) (May 2, 2023)*
    - *Approach for Evaluating Developmental Neurotoxicity Potential for the Organophosphate Pesticides (April 10, 2023)*
    - *Tetrachlorvinphos (TCVP): Revised Occupational and Residential Exposure Assessment for Registration Review (January 26, 2022)*
    - *Tetrachlorvinphos (TCVP): Revised Acute, Steady State, and Cancer Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Registration Review Human Health Risk Assessment (January 26, 2022)*
    - *Tetrachlorvinphos (TCVP): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment (July 27, 2021)*
    - *Tetrachlorvinphos (TCVP): Addendum to Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment (DP Barcode: D462910) (September 9, 2021)*
    - *Tetrachlorvinphos (TCVP): Summary of the Joint Hazard and Science Policy Council (HASPOC) and Cancer Assessment Review Committee (CARC)(October 4, 2022)*
    - *Tetrachlorvinphos (TCVP) (083701) Use in Animal Production: Percent of Animals Treated Data (April 14, 2021)*
    - *Tetrachlorvinphos (TCVP) Drinking Water Assessment for Registration Review (November 6, 2014)*
    - *Assessment of the Use, Usage, and Benefits of Tetrachlorvinphos (TCVP) (PC #083701) and Impacts of Potential Mitigation Measures Related to Poultry and Livestock Production (August 16, 2023)*
    - *Tetrachlorvinphos (TCVP) Revisit of Mutagenicity Studies (May 1, 2020)*

- April 2024: EPA is completing the ID and will announce its availability in the registration review docket.

C. Summary of Public Comments on the Draft Risk Assessments

During the 60-day comment period (opened on September 19, 2023, and extended to December 4, 2023, in response to a request from Elanco), the Agency received comments from six commenters on the 2023 PID. Comments were submitted by Elanco, USDA, NASDA, the

American Veterinary Medical Association (AVMA), an anonymous commenter attributing their comments to WhoPoo App, and a private citizen. The Agency has summarized and responded to all substantive comments below. The Agency thanks all commenters for participating and has considered all comments in developing this ID.

Comments on the Agency's proposed mitigation for limiting TCVP use to CAFOs with NMPs and NPDES permits

NASDA, USDA, and Elanco provided comments expressing concern about the impacts of limiting TCVP use to CAFOs with NMPs and NPDES permits. These commenters also provided supplemental information regarding livestock operations.

Comments about the impact of proposed mitigation and risk from livestock on pastureland

(EPA-HQ-OPP-2008-0316-0127) USDA stated that the proposed mitigation will be most impactful on non-CAFO producers that pose less of a relative risk than CAFOs. USDA expressed concern that smaller producers in the Western U.S. may not be covered under documentable NMPs. USDA "supports verbiage that is more inclusive of all NMPs, not just from the NPDES." USDA also commented that, "residual manure runoff in pastures would only be of concern when high stocking densities are utilized (i.e., 1,000 animal pounds or more per acre), as would be seen in cattle stocker or backgrounder operations areas and times with ample rain that provides lush pasture resources." USDA also stated that, "the most likely areas for potential manure accumulation outside of CAFOs would be in areas where animals are intentionally congregated, particularly for loading of livestock for sale."

(EPA-HQ-OPP-2008-0316-0128) Elanco commented that the Agency consider the "stark difference in stocking density between, for example, a feedlot and a pasture-managed herd." Elanco's comments state that animal stocking densities for beef calves on pasture range from 2 to 5 acre/animal, and, in some cases as high as 20 acre/animal. Elanco also commented that the impacts of the proposed restriction may be substantial. NASDA's comments (EPA-HQ-OPP-2008-0316-0127) encourage the Agency "to consider recommendations outlined by USDA OPMP to accommodate smaller producers."

Comments about current regulations for animal feeding operations

Elanco commented that EPA should consider protections built-in at the state level (EPA-HQ-OPP-2008-0316-0128). NASDA's comments state that the linkage to NPDES requirements for CAFOs ignores the presence of robust NMPs that other Animal Feeding Operations (AFOs) may have in place on their operations (e.g., state-level NMPs) (EPA-HQ-OPP-2008-0316-0127). NASDA further states that while requirements vary from state to state, the Agency would be remiss not to consider these existing mitigations when developing updated label language. NASDA commented that 48 states have mandatory NMP requirements, and several states have enacted application restriction and applicator certification laws of their own. NASDA also noted that EPA will be able to effectively address runoff concerns by accounting for NMPs beyond NPDES permits. USDA also finds that many poultry and livestock operations are expected to

comply with NMPs and that these NMPs provide sufficient mitigation (EPA-HQ-OPP-2008-0316-0126).

Comments on alternative options for TCVP and alternatives to EPA's proposed mitigation

(EPA-HQ-OPP-2008-0316-0126) USDA's comments stated that prohibiting TCVP use in certain livestock operations would likely lead to increased reliance on a small number of registered alternatives. USDA also stated that restriction of TCVP would exacerbate pyrethroid resistance issues. USDA commented that TCVP and dichlorvos (DDVP) represent the only OP insecticide options for manure fly treatment. USDA also proposed alternative mitigation language in lieu of prohibiting TCVP use for operations that do not fall under these regulations.

EPA Response: After review of comments and discussions with USDA, EPA acknowledges that the runoff risks posed using TCVP in animal agricultural operations can differ substantially depending on operation density, manure management, and vegetation. EPA concludes that the risks of TCVP runoff from manure are low from operations which are not classified as CAFOs and, therefore, concludes that the risks of TCVP can be managed without restricting the use of TCVP to only CAFOs with NPDES permits and NMPs. EPA agrees that restricting the use of TCVP to livestock and poultry operations with NPDES permits and NMPs could have a high impact on operations with pastured or grazing animals. The Agency also agrees that, depending on the concentration of animals per acre and the proximity to naturally occurring water bodies, these livestock producers may pose minimal risk to aquatic invertebrates. Vegetation provided for pastured cattle can also act as a buffer to any residues deposited in the manure and soil. EPA acknowledges that there are current state and local regulations in place to manage manure runoff from livestock operations, although the standards between individual regulations could vary.

Based on these comments and discussions with USDA, the Agency is no longer proposing to limit use of TCVP to CAFOs with NMPs and NPDES permits. The Agency recognizes TCVP as a critical tool for pest control in livestock operations and finds that current regulations account for potential exposure of TCVP to aquatic organisms via manure runoff. However, runoff from self-application devices such as dustbags and face/backrubbers may still result in exposure to non-target organisms. As a result, EPA is implementing mitigation to reduce runoff from self-application devices used at livestock operations. EPA is requiring measures to minimize runoff from dustbags and face/backrubbers when the National Oceanic and Atmospheric Administration (NOAA)/ National Weather Service predict a total rainfall of 1 inch or greater is within 48 hours only when, at any point during the 48-hour period, the precipitation potential is 50% or greater. See Section IV. A. for additional information. EPA thanks USDA, NASDA, and Elanco for their comments.

Comments on the Agency's proposed requirement for APF50 respirators

Comment: USDA and Elanco provided comments expressing concern for EPA's proposal to require APF50 respirators while filling poultry dust boxes with shaker cans. USDA commented that APF50 respirators may post problematic heat stress concerns for workers in poultry houses. Elanco commented that a full-face APF50 respirator may cause undue strain on the applicator including heat stress (EPA-HQ-OPP-2008-0316-0126 and EPA-HQ-OPP-2008-0316-0128).

USDA also stated that shaker cans are not used to load TCVP product into poultry dust boxes. USDA commented that wettable powder products are loaded directly from the product container to the poultry dust box by scooping or pouring. Elanco commented that updating directions for use to those methods with greater MOEs (e.g., application of wettable powders to dust boxes via scooping or pouring vs. via shaker can) may more appropriately address EPA's concerns than the full-face APF50 respirator where proposed. Elanco requests consideration for alternatives to the full-face respirator (e.g., appropriately fitted canister respirator or N95 mask).

EPA Response: The Agency agrees that poultry dust boxes are likely to be filled more efficiently by scooping or pouring TCVP product directly into the boxes. Given the additional burden imposed on producers and occupational handlers with the use of respirators for this application method, EPA is updating the directions to prohibit filling poultry boxes by any other means other than by directly pouring or scooping dust product into the dust boxes. See Section IV. A. for additional mitigation details.

Comments on the Agency's proposed mitigation for covering garbage piles

Comment: USDA and NASDA provided comments with concerns about EPA's proposed mitigation to require users to cover garbage and/or manure piles after treatment with TCVP (EPA-HQ-OPP-2008-0316-0126 and EPA-HQ-OPP-2008-0316-0127). USDA's comments stated that "it is not always reasonable or practical to require covering of piles or to maintain full compliance with NMPs in a time-sensitive situation where public health and animal biosecurity is at stake." USDA requested that the Agency maintain an exception to the covering requirements for treatment of garbage piles.

NASDA similarly commented that, "time-sensitive and rapid fly management must be an overwhelming priority and the prohibition of TCVP endangers both animal and human health." NASDA requested the EPA defer to USDA's Animal and Plant Health Inspection Service, state departments of agriculture and state animal health officials on management of garbage piles.

EPA Response: EPA acknowledges that covering garbage piles immediately may not be feasible during certain livestock management procedures. However, EPA also recognizes that covering garbage may prohibit flies from proliferating by reducing access to a site that attracts pests. Further, residues from runoff from garbage and manure piles may pose a concern for non-target organisms. Therefore, EPA is requiring an advisory statement for covering garbage piles as soon as possible following treatment with TCVP.

Comment regarding use of other active ingredients (EPA-HQ-OPP-2008-0316-0128)

Comment: Elanco expressed concern about the future impact of EPA's proposal to prohibit application via electrostatic dusters on other dust use patterns (e.g., hand-dusting, dustbags, dust boxes, application via hand wand/handgun). Elanco commented that organophosphate dust applications, including coumaphos and TCVP, provide an efficacious option as a rotational pesticide. Elanco further commented that these applications enable the producer to treat individual animals with a ready-to-use product that can be applied during cold weather months. Elanco claims that the removal of these products would adversely affect the ability of producers on small farms to control pests like flies, grubs, and lice on individual animals. Elanco requests

inclusion in conversations around the path forward should the assessment change adversely with respect to these use patterns in the future.

EPA Response: EPA considers the impact of proposed mitigation, including the availability of alternative application methods for TCVP and alternative control tools. EPA considered the impacts of proposed mitigations in the *Assessment of the Use, Usage, and Benefits of TCVP and Impacts of Potential Mitigation for Poultry and Livestock Production* (September 2023). In making its regulatory decision for TCVP, EPA weighed the risks of the use of TCVP against these benefits and proposed a decision accounting for this information (see regulatory rationale section). EPA thanks Elanco for their comments.

Comments on the Agency's proposed pollinator advisory language (EPA-HQ-OPP-2008-0316-0126): USDA commented that EPA's proposed statements for pollinators are "not appropriate or practical for products only applied to animals or animal premises…" USDA disagreed with EPA's proposal to add directions for users to advise beekeepers of applications, the directions to apply TCVP at night, or directly advising managed pollinator protection plans (MP3s) for application Best Management Practices (BMPs) because "these statements were more clearly intended to inform insecticide uses on crops." USDA requested that EPA consider shortening the proposed verbiage to the following:

> *"Following best management practices (BMPs) can help reduce risk to pollinators… For additional resources on pollinator BMPs and Pollinator Protection Plans, visit https://www.epa.gov/pollinator-protection/tools-and-strategies-pollinator-protection."*

EPA Response: EPA's proposed mitigation was based on TCVP's classification as an organophosphate insecticide, a class of pesticides that are known to be toxic to pollinator species. The proposed mitigation was also based on uncertainties due to a lack of pollinator toxicity data for TCVP. The Agency acknowledges that some of the initially proposed FIFRA IEM measures are applicable to pesticides with foliar applications but are not as relevant for all uses on livestock and livestock premises. Therefore, the Agency is removing advisory language related to bees foraging and beekeeping. However, EPA is requiring advisory language for MP3s, BMPs and integrated pest management (IPM) as this content may be of use for certain applications of TCVP. EPA will be calling in pollinator data as listed in Section III. B. 3.

Comments about the World Health Organization's International Agency for Research on Cancer's Assessment on Five Organophosphate Pesticides (EPA-HQ-OPP-2008-0316-0125)
Comment: An anonymous commenter submitted comments regarding the classification of TCVP as carcinogenic and the registration status of TCVP in other nations. The comment stated that TCVP was classified as *possibly carcinogenic to humans* and is banned in the European Union. The comment also stated that "TCVP should also be banned in the United States as it is banned by the WHO (World Health Organization)." The comment was accompanied by the *International Agency for Research on Cancer (IARC) Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides.*

EPA Response: In the most recent TCVP human health risk assessment (HH DRA; Lowe *et al*., D467076; 09/07/23), TCVP was classified as a Group C, possible human carcinogen, based on

statistically significant increases in combined hepatocellular adenomas/carcinomas (primarily carcinomas) in female mice, and suggestive evidence of thyroid c-cell adenomas and adrenal pheochromocytomas in male rats (Backus, B.T., TXR#0011438, 03/06/1995). A cancer potency factor (Q_1^*) of 1.83 x 10^{-3} $(mg/kg/day)^{-1}$ was estimated based on the liver tumor rates in female mice (Fisher, B., TXR#0012766, 01/11/1995) and was used to quantify cancer risk in the 2023 human health risk assessment.

The 2023 HH DRA assessed both non-cancer and cancer exposure and risk from all currently registered uses of TCVP and found no aggregate risks of concern (dietary plus residential). While some occupational risks of concern were identified, these can be mitigated through various actions (e.g., addition of personal protective equipment, or cancellation of specific products).

D. Tetrachlorvinphos Litigation

Concurrently with the ongoing registration review of TCVP, the Natural Resource Defense Council (NRDC) filed a Petition with EPA under the Administrative Procedure Act (APA) on April 23, 2009, requesting that EPA cancel all pet uses for TCVP under FIFRA. Due to uncertainty around the physical form of TCVP present in impregnated TCVP pet collars, the Agency sent NRDC a letter in 2017 stating that EPA intended to mitigate any risk as part of registration review. During this time, EPA continued negotiations with the registrant, Hartz, to determine how to confirm the physical form for TCVP in the impregnated pet collars.

Between 2009 and 2022, the Agency responded to several legal actions and issued revised human health assessments. On October 6, 2022, EPA granted NRDC's petition to cancel all six remaining pet collars containing TCVP and denied NRDC's petition to cancel the remainder of the registered TCVP pet uses (three pump/trigger sprays) that were not associated with risks of concern. At the time, the October 2022 HH DRA identified risks of concern for all remaining pet collar products. Therefore, EPA's October 6, 2022 petition response stated that EPA would move to draft a proposed Notice of Intent to Cancel (NOIC) for the pet collar products, which would include evaluating then-anticipated new data if the data were received in a timeframe that allowed for such evaluation. EPA also stated that it would not further pursue a NOIC if that data demonstrated that there was no longer a risk concern for any pet collars containing TCVP. Since the October 2022 assessment, Hartz submitted additional data related to the collar uses and the physical form of TCVP present in pet collars to address this remaining uncertainty.

These studies have been reviewed, deemed acceptable for risk assessment, and have been incorporated into the *Tetrachlorvinphos (TCVP) Fourth Revision: Human Health Draft Risk Assessment for Registration Review*. Using the available chemical-specific data, residential non-cancer handler inhalation risks are not of concern for adults and post-application incidental oral risks are not of concern for children 1 to <2 years old. Residential handler (adult dermal plus inhalation) and post-application cancer risks (adult dermal only) estimated for TCVP pet collars, using chemical-specific data, are also not of concern. Therefore, based on these new data, the Agency issued a *Determination Not to Further Pursue Cancellation of TCVP Pet Collars*

(September 2023).[16] These data are discussed below, in the data evaluation records (DERs) for these studies, and in the most recent HH DRA (September 2023). The DERs and the most recent HH DRA can be found in the public docket at EPA-HQ-OPP-2008-0316.

E. Uncertainty Factors

The registration review of the OP insecticides, which includes TCVP, has presented EPA with numerous scientific issues. Most notable of these issues is the potential for neurodevelopmental effects on the young (pre-natal, infants and children) that the Agency has taken to multiple FIFRA Scientific Advisory Panel (SAP) meetings since the completion of reregistration.[17] Reregistration for TCVP was completed in 2006. The Agency completed a weight-of-the-evidence (WOE) analysis for neurodevelopmental effects using the *Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment.*[18] The WOE analysis integrated quantitative and qualitative findings from experimental toxicology studies, epidemiology studies, and physiologically based pharmacokinetic-pharmacodynamic (PBPK-PD) modeling.[19] Despite several years of research, the science addressing neurodevelopmental effects remains unresolved. Due to the uncertainty in the human dose-response relationship for neurodevelopmental effects, the 10X Food Quality Protection Act (FQPA) Safety Factor was retained for TCVP for infants, children, youths, and women of childbearing age for all exposure scenarios. EPA has similarly applied a 10X database uncertainty factor (UF_{DB}) in its assessment of TCVP occupational risks as women of childbearing age may also work as occupational handlers.

Recognizing the uncertainty in the human dose-response relationship for neurodevelopmental outcomes, EPA has pursued the development of approaches to facilitate quantitative or semi-quantitative comparisons between doses which elicit AChE inhibition and those which are associated with potential neurodevelopmental outcomes. Since the previous WOE analysis for neurodevelopmental effects, high quality data on underlying biological processes of neurodevelopment have become available as a result of an international effort to develop new approach methodologies (NAMs) for developmental neurotoxicity (DNT). This international effort led to the development of a battery of *in vitro* assays (referred to hereafter as DNT NAM battery) that assess processes critical to development of the nervous system and provide chemical-specific evaluation of DNT potential.

In 2020, EPA convened a FIFRA SAP to review the DNT NAM battery with the OPs as a case study.[20] Overall, the SAP agreed that the current DNT NAM battery reflects, if not directly models, critical processes for neurodevelopment and that data from the battery can be used as

[16] https://www.regulations.gov/document/EPA-HQ-OPP-2009-0308-0032
[17] https://www.epa.gov/sap/fifra-scientific-advisory-panel-meetings
[18] U.S. Environmental Protection Agency. 2016. Framework for Incorporating Human Epidemiologic and Incident Data in Health Risk Assessment, December 28, 2016. Available at https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf.
[19] The PBPK-PD model was used to derive toxicological points of departure (PoDs) and to determine the appropriate intra-species and inter-species uncertainty factors. https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0941.
[20] https://www.regulations.gov/document/EPA-HQ-OPP-2020-0263-0006

part of a WOE evaluation. Furthermore, based on DNT NAM battery data for numerous OP compounds, OPP has determined based on the best available science that DNT potential of OPs should be evaluated on a chemical-by-chemical basis, rather than as a group (M. Perron, TXR 0058584, D467385, April 10, 2023).

In the case of TCVP, a WOE evaluation of DNT potential using chemical-specific data has not been performed because data for all assays in the DNT NAM battery are not available for review at this time. Therefore, the FQPA 10X Safety Factor/UF_{DB} will continue to be retained for TCVP at this time for the population subgroups that include infants, children, youths, and women of childbearing age for all exposure scenarios.

II. USE AND USAGE

TCVP is a broad-spectrum organophosphate insecticide (Group 1B with the Insecticide Resistance Action Committee [IRAC]). TCVP is registered for use as a direct application to poultry and livestock (i.e., cattle, swine, horses) and their premises (i.e., poultry houses, poultry dust boxes, barns, under feed troughs, livestock facility garbage piles, other livestock buildings, and swine bedding), oral feedthrough application to livestock and mink, and broadcast and spot treatments to poultry litter and livestock manure. One end-use product registered for use on cattle, poultry, poultry litter, manure, and livestock areas is co-formulated with another organophosphate active ingredient, dichlorvos (EPA Reg. 11556-162). TCVP is also registered for direct applications to pets, pet bedding, and other pet areas, and for spot treatments in and around kennels, yards, and recreational areas (including campgrounds, footpaths, and roads).

TCVP products registered for livestock and poultry uses are available as dusts, liquids, wettable powders (WP), solid and liquid feed supplements (i.e., feed throughs), and feed blocks. Some dust formulations can be used to create a slurry when mixed with water to treat poultry premises. In addition, some WP formulations are applied directly to poultry areas as a powder. Liquid and wettable power formulations of TCVP may be applied to livestock as a direct spray with various sprayers (including backpack sprayers, mechanically pressurized handguns, manually pressurized handwands, airless sprayers, or high- and low-pressure sprayers) and face/backrubbers. These handheld application methods can also be used to apply TCVP to livestock premises, garbage piles, and manure. TVCP may be applied to livestock and poultry as a dust via dustbags, plunger duster (poultry only), rotary duster, power duster, shaker can, or manually (e.g., via spoon). In addition, horses can be treated with dust with a hand duster, grooming brush, or dust mitt; and poultry houses, floors, litter, and walls may be treated with an electrostatic duster. Garbage piles and manure can be treated with various sprayers, dusters (e.g., plunger, rotary, mechanical), shaker cans, and manually (e.g., via spoon).

TCVP pet use formulations include impregnated collars and pump and trigger sprays that can be applied directly to pets, pet bedding, and other pet areas. Spot treatments in and around kennels, yards, and recreational areas may be made with low pressure handwand sprayers only.

<u>Poultry and Livestock Usage</u>

Limited insecticide usage data for poultry and livestock production are available as product-level sales measured in dollars. While product sales data do not provide an estimate of usage in terms of amount of active ingredient applied per area or animal in a specific sector or year, these data can provide characterization of the role of TCVP in pest management in the poultry and livestock markets. Recent data on expenditures for fly and ectoparasite control among poultry and livestock indicate that TCVP is not a market leader, in sales, for these uses.[21,22] Among the registered formulations of TCVP for use in cattle, an average of nearly 95% of sales in beef cattle and 80% of sales in dairy cattle in 2017 and 2021 were for feedthrough products.[2121,2222] Alternatively, in the swine and poultry markets, premise sprays/foggers dominated sales of TCVP during this time, representing virtually all sales captured for these segments.

In 2021, EPA used available sales data from 2012 to 2017 to calculate a conservative upper-bound estimate of the percentage of beef cattle, dairy cattle, and poultry in the U.S. treated with TCVP each year. The most recent sales data[22] reinforce the usage estimates provided in *Tetrachlorvinphos (TCVP) (083701) Use in Animal Production: Percent of Animals Treated Data.*[23] The percentage of poultry and cattle treated with TCVP are presented in Table 1. Reliable information on swine usage is not available from the data provider and data regarding pesticide usage among equestrian operations are not collected.

Table 1. Tetrachlorvinphos (TCVP) Usage: Percent of U.S. Animals Treated (2012, 2015, 2017)[23]

Animal Type	Average # U.S. Animals	Average # Animals Treated with TCVP*	Average % of Animals Treated with TCVP**	Maximum % of Animals Treated with TCVP**
Beef Cattle	56,100,000	2,400,000	5	10
Dairy Cattle	17,600,000	800,000	5	10
Poultry***	2,146,000,000	610,800,000	30	45

Values are rounded up to the next increment of five

* The number of animals treated is derived from private market research data on the quantity of products available from sales and the number of animals treated at the minimum application rates listed on the product labels; these result in a higher number of animals treated.

** The average percent of animals treated estimates are calculated based on the ratio of the average number of animals treated with TCVP to the average herd size in the U.S. during this period, expressed as a percentage. The maximum percent of animals treated estimate is the single maximum average value reported across all years.

*** Poultry includes layers, broilers, pullets, and turkeys.

[21] Kline and Company. 2018. Pest Control in Production Animal Health 2017: U.S. Market Analysis and Opportunities. Accessed 06/2022.

[22] Nonagricultural Market Research Data (NMRD). 2022. Study of Production Animal Health in 2021. Accessed 01/2023.

[23] https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0316

Pet Insecticide Usage

Table 2 provides information on the sales of consumer market pet insecticides in 2011 and 2016. Based on available private market research, sales of all surveyed consumer market pet insecticides in 2016 were approximately $1.5 billion, a 25% increase over sales in 2011 of $1.2 billion, unadjusted for inflation.[24] In 2016, the top pet insecticide formulations, in terms of sales, were liquid products, which represented more than 80% of the market, followed by tablets for veterinary use with 12.7% of sales.[24] As a proportion of sales, collars have remained similar over time. As discussed in the *Benefits* section below, collars tend to be cheaper and provide longer-lasting control than liquid sprays, dusts, and powders. Therefore, the proportion of sales does not represent the proportion of usage. Expenditures on dust and powder formulations declined in nominal terms from 2011 to 2016, which likely indicates a decrease in usage.

Table 2. Sales of Pet Products by formulation[24,25]

Product Form	2011		2016	
	Million USD ($)	Percent	Million USD ($)	Percent
Liquids[a]	949.7	78.0	1,188.9	80.7
Tablets[b]	182.6	15.0	187.1	12.7
Collars	60.9	5.0	98.7	4.6
Dusts and Powders	12.2	1.0	7.3	0.5
Other (aerosols, foggers, soaps, combs, & traps)	12.2	1.0	21.5	1.5
Total	1,217.5	100	1,473.4	100

[a] Includes shampoos, dips, and topical spot-ons.
[b] Veterinary supplied oral treatments.

Based on preliminary private market research of sales of brands carrying the TCVP flea collars, sales were estimated to be slightly more than 50% of the total pet collar sales in the U.S. in 2018.[26] Hartz voluntarily cancelled its TCVP dust products, including flea powder, in 2020.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency has summarized the 2023 HH DRA below. EPA used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of TCVP. For additional details on the 2023 HH DRA, see the *Tetrachlorvinphos (TCVP). Fourth Revision: Human Health Draft Risk Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2008-0316).

[24] Kline and Company. 2017. Consumer Markets for Pesticides and Fertilizers 2016: U.S. Market Analysis and Opportunities - Volume 1. [Accessed June 2020.]
[25] Kline and Company. 2012. Consumer Markets for Pesticides and Fertilizers 2011. [Accessed June 2020.]
[26] Business Confidential Attachment to Email from Kline and Company to Cynthia Doucoure (Retired), EPA/OPP/BEAD/SIAB, June 11, 2020.

Acetylcholinesterase (AChE) inhibition is the initiating event in the adverse outcome pathway/mode of action for organophosphates, including TCVP. This can lead to a buildup of acetylcholine and neurotoxicity in the central and/or peripheral nervous system. TCVP does not require metabolic activation to an oxon to inhibit AChE. Therefore, the parent compound is the active form inhibiting AChE.

As with other OPs, TCVP exhibits a phenomenon known as steady state AChE inhibition. Following repeated exposure at the same level, the degree of inhibition reaches equilibrium with production of new, uninhibited enzyme and the amount of AChE inhibition in a given dose remains consistent across exposure duration. It generally takes approximately 2 to 3 weeks for organophosphates to reach steady state (U.S. EPA, 2002); however, this timeframe can vary between chemicals. For TCVP, the steady state is reached after a single day of exposure.

The acute and steady state points of departure (PODs) selected for oral exposure risk assessment are based on red blood cell (RBC) AChE inhibition in the postnatal day 11 (PND 11) and postnatal day 21 (PND 21) pups in the acute comparative cholinesterase study (CCA). Although the steady state dietary POD was also selected from an acute CCA, the acute study is considered health protective and appropriate for longer-term durations since AChE data across the TCVP database demonstrate that there is no increased severity or progression of AChE inhibition with repeated daily exposures, and steady state inhibition occurs essentially after a single dose. The steady state inhalation POD was selected from a 4-week inhalation toxicity study (MRID 48803501) in rats, based on an increase in RBC AChE inhibition in both sexes. The PODs selected based on RBC AChE provide the most robust dose-responses and are protective of all life stages as well as AChE inhibition in the brain. EPA is using a total uncertainty factor of 1000X for residential incidental oral exposures: 10X for interspecies extrapolation, 10X for intraspecies variation, and 10X Food Quality Protection Act (FQPA) Safety Factor (SF). EPA is using a total uncertainty factor of 300X to assess exposures from inhalation: 3X for interspecies extrapolation, 10X for intraspecies variation, and 10X FQPA SF for residential assessments (or a 10X database uncertainty factor for occupational assessments to protect pregnant female workers). EPA applied the 10X FQPA SF to dietary and residential assessments and the 10X database uncertainty factor is applied to occupational assessments. The standard interspecies extrapolation uncertainty factor for the inhalation route can be reduced from 10X to 3X due to the human equivalent concentration (HEC) calculation accounting for pharmacokinetic (not pharmacodynamic) interspecies differences between rats and humans.

AChE data for the dermal and inhalation routes are available and allow for route-specific evaluation. Inhibition of RBC AChE was observed in both sexes in the inhalation study (brain AChE was not assessed), while no inhibition of RBC or brain AChE was observed up to the limit dose in the dermal study. TCVP is classified as a Group C possible human carcinogen. Although a non-cancer dermal assessment is not required for TCVP, a cancer dermal assessment is required based on this classification. Based on human *in vitro* dermal absorption data submitted in April of 2022 (MRID 51890001), a dermal absorption factor of 3% was applied to the TCVP cancer dermal assessment since only oral AChE data can be used for the POD for this assessment. A non-cancer dermal risk assessment is not warranted since no AChE inhibition was observed from dermal exposure; the dermal route of exposure is not a concern.

1. Risk Summary and Characterization

Based on the most recent 2023 HH DRA, there are no non-cancer or cancer dietary risks of concern for TCVP.

EPA identified occupational risks of concern from application by electrostatic duster (using misters and foggers data as a surrogate) and filling poultry dust boxes by using a shaker can or plunger duster. There are also occupational risks of concern at various rates for multiple handheld application methods unless a respirator with an assigned protection factor of 10 (APF10) is used. It is noted that only four TCVP labels currently require a respirator of any kind: (1) two dust products (EPA Reg. No 11556-158, 11556-182) and (2) two wettable powder products (EPA Reg. No 11556-156, 47000-126). Occupational post-application exposure is not a concern given the registered use patterns for TCVP.

In the 2023 HH DRA, there are no residential handler or post-application risks of concern for the registered pet products. There had been residential incidental oral post-application risks of concern for pet collars identified in the October 2022 HH DRA, which resulted in EPA granting the NRDC petition to cancel pet collars containing TCVP. However, in granting the petition for the pet collars, EPA noted that new data were expected to be submitted for the pet collars and indicated that it would not pursue a NOIC if the new data demonstrated that there are no risk concerns for any TCVP pet collars. EPA received and reviewed the additional data from Hartz in 2023, and based on these new data, the Agency found that there are no risks of concern from incidental oral exposure resulting from pet collar use. Please see the *Tetrachlorvinphos (TCVP). Fourth Revision: Human Health Draft Risk Assessment for Registration Review* and the *Determination Not to Further Pursue Cancellation of TCVP Pet Collars* for detailed discussions of the new data and these risk estimates.

Dietary (Food + Water) Risks

TCVP is used to treat poultry and livestock and their premises. As a result, human exposure to TCVP in food may occur from consuming residues in animal commodities (e.g., milk, meat, eggs, and poultry). Animal commodities were the only foods included in the analyses since TCVP is not registered for use on crops grown for food. Exposure may also occur from drinking water that may contain TCVP residues because of some outdoor use patterns. EPA also conducted a review of available groundwater monitoring data for TCVP. An analysis of EPA's Pesticides in Ground Water Database (USEPA, 1992) indicates TCVP was not detected in well water. The dietary (food and drinking water) exposure analyses for TCVP are refined and retain the 10X FQPA SF for infants, children, youths, and women of childbearing age resulting in a total uncertainty factor of 1000X. The 10X FQPA SF is not retained for adults 50-99 years of age; therefore, the total dietary uncertainty factor for that population is 100X.

The parent compound, TCVP, is the residue of concern for the acute and steady state non-cancer dietary assessments. The acute dietary risk for the highest exposed population subgroup, all infants (<1 year), was 16% and was 4.8% for the general U.S. population at the 99.9th percentile of exposure. Since TCVP reaches steady state after a single day of exposure, the steady state dietary risk assessment is equivalent to the acute dietary risk assessment and is not of concern.

No non-cancer dietary risks of concern from TCVP were identified. The refined dietary cancer assessment included TCVP in addition to its metabolites containing the 2,4,5 trichlorobenzene moiety (the residues of concern for cancer). Drinking water is the major contributor to the cancer dietary risk estimate. The refined cancer dietary assessment resulted in an estimated exposure to the highest exposed adult population subgroup (adults 20-49) to TCVP and its metabolites containing the 2,4,5-trichlorobenzene moiety of 0.000459 mg/kg/day. With the linear low-dose approach for quantification of risk, an oral slope factor (Q_1*) of 1.83 x 10^{-3} $(mg/kg/day)^{-1}$ is used to assess cancer risk. The dietary cancer risk estimate is 8 x 10^{-7} and is not considered to be a risk of concern.

Residential Risks

Residential exposures (handler and post-application) are anticipated from the use of TCVP pet products for dogs and cats including collars and pump/trigger sprays. Exposures are expected for adults who apply TCVP products to their pets and/or bedding and from post-application exposures for adults and children who may contact previously treated pets. Residential TCVP handler exposures are expected to be short-term (1 to 30 days), and post-application exposures are anticipated to be short- (1 to 30 days), intermediate- (1 to 6 months – *for pet collar scenarios only*) and long-term (>6 months - *for pet collar scenarios only*). Due to the nature of organophosphates inducing steady state AChE inhibition, steady state exposures were assessed and presented for residential exposures to TCVP pet products. This is typically 21 days and longer for most organophosphates, but steady state is induced after only one day of TCVP exposure.

As stated previously, Hartz submitted a new torsion study (MRID 52062503), and a new on-animal fur clipping study (MRIDs 52062502 and 52185901) after EPA issued the October 2022 revised HH DRA and petition response. The new torsion study provides data for assessing TCVP exposure to pet collars during the opening of the package, stretching the collar and placing it on the cat or dog. The on-animal fur clipping studies provide data for assessing TCVP post-application exposure (e.g., petting) while the collar is on the cat or dog.

Since there is no non-cancer dermal hazard for TCVP (no adverse inhibition of RBC or brain AChE observed in the dermal route specific study up to the limit dose and no quantitative susceptibility observed for juvenile or gestational lifestages), neither a quantitative non-cancer residential handler nor a residential post-application dermal exposure assessment was performed for adults or children. For the purposes of the cancer assessment, where both dermal and inhalation exposures and doses are quantified, a dermal absorption factor of 3% was used for TCVP based on human *in vitro* dermal absorption data submitted in April 2022 (MRID 51890001).

Residential Handler: Non-cancer inhalation risks were assessed for residential handler exposure for all TCVP pet products (pump/trigger sprays and pet collars). Handler unit exposure (UE) data was not available for pet collars. Therefore, to evaluate handler exposure to pet collars, EPA used surrogate data for liquid and dust formulation pet products.

Based on the new December 2022 torsion study, a factor of 4.7% TCVP released from the pet collar after stretch activation and torsion activity was used in the exposure calculations, with the released TCVP having a dust to liquid ratio of 8% dust to 92% liquid.[27] All MOEs for handlers were above the inhalation risk LOC of 300 with a range of 510,000 to 1,200,000. Therefore, no non-cancer inhalation risks of concern were identified for residential handlers applying pet collars to cats or dogs. Residential handler cancer risks (combined dermal and inhalation) estimated for TCVP pet collars range from 10^{-9} to 10^{-10} and are not of concern.

Handler UE data for trigger pump sprays are provided in the Standard Operating Procedures for Residential Pesticide Exposure Assessment ("2012 Residential SOPs"). EPA did not identify risks of concern from residential application of pump/trigger sprays containing TCVP. Inhalation MOEs for residential handlers using pump/trigger sprays were well above the inhalation LOC of 300 with a range from 8,900 to 120,000. Residential handler cancer risk estimates for TCVP pump/trigger sprays range from 10^{-8} to 10^{-9} and are not risks of concern.

Residential Post-Application: A quantitative residential post-application inhalation exposure assessment was not performed as inhalation exposure is expected to be negligible from applications to pets. Therefore, the quantitative exposure/risk assessment for residential post-application exposures is based on the following scenario: post-application incidental oral (hand-to-mouth) exposure (children 1 to < 2 years old only) from contacting cats and dogs treated with TCVP.

Post-application exposure is dependent on the amount of residue available for transfer (i.e., transferable residue), post-application exposure data (i.e., transfer coefficients), and the duration of exposure. For both pump/trigger spray formulations and pet collars, EPA used chemical-specific transfer data from submitted studies. For pet collars, EPA also used the 2023 on-animal fur clipping studies to obtain estimates of dust versus liquid TCVP residues on animal fur while wearing TCVP-impregnated flea and tick collars. The data evaluation records (DERs) for these studies are available in the public docket (EPA-HQ-OPP-2008-0316).

For the registered pet collar uses, all residential non-cancer post-application incidental oral risk estimates were above the LOC of 1,000 and are not of concern; MOEs for children 1 to <2 years old range from 1,300 to 110,000. Residential post-application cancer risk estimates (adult dermal only) range from 10^{-7} to 10^{-8} and are also not of concern.

No residential post-application risks of concern for children were identified from use of pump/trigger sprays with TCVP. The residential steady-state non-cancer incidental oral MOEs for children (1 to <2 years old) exposed to pets treated with TCVP pump/trigger sprays are above the LOC of 1000 (1,600 to 15,000). Residential handler cancer risk estimates for TCVP pump/trigger sprays range from 10^{-7} to 10^{-8} and are not of concern.

[27] https://www.regulations.gov/document/EPA-HQ-OPP-2008-0316-0103

Non-Cancer Aggregate Risks

EPA considers the route and duration of exposure when assessing aggregate risks. Both acute and steady-state aggregate risks were assessed for TCVP. Acute aggregate risk estimates for TCVP are equivalent to the acute dietary risk estimates (food and drinking water) and are not of concern. The steady-state aggregate assessment takes into account the combined pesticide exposures and risks from the chronic (average) dietary (food and drinking water) and steady-state residential exposures. The Agency calculated the exposures from these sources and compared the aggregate risk to quantitative estimates of hazard. For adults, an aggregate risk index (ARI) has been calculated as the LOCs for the routes of exposure [dietary (oral) and inhalation] have different LOCs (inhalation = 300 and oral = 1000). The aggregated routes for children, which include dietary (oral) and incidental oral, have the same LOCs. However, for consistency, an ARI has also been calculated for this lifestage. The steady-state ARI for adults is 27.3 and for children (1 to <2 years old) is 1.3, both of which are above the LOC of 1 and are not of concern.

Cancer Aggregate Risks

The cancer aggregate risk assessment combines residential and dietary expected lifetime exposures for adults. EPA performed a cancer aggregate assessment for adult post-application activities related to residential use of TCVP pet products. The aggregate cancer risk estimate for adults is 1×10^{-6} and is not of concern.

Previously, EPA considered requiring a mouse micronucleus assay (OPPTS 870.5395) and an additional study to investigate possible genotoxic activity in the liver (target organ). These studies were initially recommended to determine if a mutagenic mode of action (MOA) analysis should be pursued. EPA conducted an updated literature search that identified an additional study (MRID 51926104) that examined the mutagenic potential of TCVP. This new study and all previously available mutagenicity data were evaluated concurrently to determine if the above-mentioned mutagenicity studies were still needed. The evaluation revealed that there is low concern for mutagenicity, so based on a weight-of-evidence approach, the Hazard and Science Policy Council (HASPOC) recommended that the additional data were no longer needed at this time. Therefore, the previously required mutagenicity studies need not be conducted at this time (J. Wozniak, TXR# 0058377, 10/04/2022). Given the low concern for mutagenicity, a mutagenic MOA analysis will not be pursed for TCVP and the toxicity database is considered complete.

Cumulative Risks

Tetrachlorvinphos is a member of the OP class of pesticides. Organophosphates share the ability to inhibit AChE through phosphorylation of the serine residue on the enzyme leading to accumulation of acetylcholine and ultimately cholinergic neurotoxicity. This shared MOA/adverse outcome pathway (AOP) is the basis for the OP common mechanism grouping per OPP's *Guidance for Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999). The Agency first completed a cumulative risk assessment for the organophosphates in 2001, a revised cumulative risk assessment for the organophosphates was completed in 2002, and an updated organophosphates cumulative risk

assessment was completed in 2006.[28,29] The cumulative effects of exposure to multiple organophosphates, including TCVP, are evaluated in those documents. Prior to the completion of registration review, the Agency will update the organophosphate cumulative risk assessment on AChE inhibition to incorporate any toxicity and exposure information available since 2006.

Occupational Handler Risks

Occupational handlers working with pets may be exposed to TCVP using pump/trigger spray products or via application of impregnated collars. TCVP is no longer available as a dip or dust/powder application for companion animals. TCVP is also applied to poultry and livestock such as swine, horses, cattle, and their premises using wettable powder, dust, and liquid formulations applied as a roost paint (using brush/roller and airless sprayers), groundboom, face/backrubbers, handheld applications (e.g., shaker can, duster, backpack sprayer, manually pressurized handwands, and mechanically pressurized handguns), as a feedthrough, and in feedblocks. The use of TCVP in/on livestock, livestock premises, kennels, yards, recreational areas, and on pets is expected to result in exposures to occupational handlers. Non-cancer and cancer exposures and risks were calculated for occupational handlers of TCVP. A total uncertainty factor of 300X was selected for all inhalation exposures: 3X for interspecies extrapolation, 10X for intraspecies variation, and 10X database uncertainty factor for occupational assessments to protect pregnant female workers. Occupational handler and post-application non-cancer dermal risks have not been quantitatively assessed due to the finding of no dermal hazard for TCVP.

EPA identified risk estimates of concern for several application scenarios for poultry, livestock or livestock premises including:

- Application of dust via electrostatic duster for poultry litter;
- Filling of dust boxes for poultry treatment using shaker cans or plunger dusters;
- Application of wettable powders and liquids via mechanically-pressurized handgun at certain rates in poultry houses, barn/feedlots and direct application to poultry and livestock (beef cattle/swine);
- Application of wettable powders and liquids via backpack sprayer at certain rates in poultry houses;
- Application of wettable powders and liquids via manually-pressurized handwand at certain rates in poultry houses; and
- Direct application of dust via shaker can to swine beddings, beef cattle, and dairy cattle.

[28] US EPA, 2002. https://nepis.epa.gov/Exe/ZyNET.exe/9100BFLL.TXT?ZyActionD=ZyDocument&Client=EPA&Index=2000+Thru+2005&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C00thru05%5CTxt%5C00000023%5C9100BFLL.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL

[29] US EPA, 2006. https://www.regulations.gov/document?D=EPA-HQ-OPP-2006-0618-0002

- Application of roost (made from slurries of liquid and/or dust formulations) paint via airless sprayers;

Electrostatic Duster Applications

Occupational handler exposure from application of TVCP to poultry litter with electrostatic dusters was assessed using handheld and stationary foggers/mister data without reentry restrictions as a surrogate. EPA assumed a treatment area of 100,000 square feet with rates of 0.00023 to 0.00078 lbs. active ingredient (a.i.)/ square foot. All inhalation MOEs were below the LOC of 300 (estimates ranging from 0.39 without a respirator to 66 with use of an APF50 respirator) and are of concern.

Dust Applications (Shaker Can and Duster)

Dust boxes to treat poultry can be filled with either dust or wettable powder formulations using shaker cans or plunger dusters. The inhalation MOEs for loaders and applicators filling poultry dust boxes range from 10 to 270 with no respirator, which are below the LOC of 300 and are of concern. With the addition of an APF10 respirator, inhalation MOEs for loaders/applicators using plunger dusters are no longer of concern; however, MOEs for those using shaker cans are still of concern. With the use of an APF50 respirator, inhalation MOEs for loading poultry dust boxes with a shaker can are 490 to 1,300 and are no longer of concern.

As noted above in Section I.A., EPA received comments regarding the use of shaker cans to fill poultry dust boxes and the Agency's proposed requirement for occupational handlers to wear APF50 respirators during this process. Based on these comments, poultry dust boxes are likely to be filled by pouring or scooping dust/powder formulations into the dust boxes. MOEs for scooping or pouring TCVP from the source container directly into poultry boxes are 19,000 – 51,000 without a respirator and are not of concern.

Application of dust via shaker can directly to beef/dairy cattle, horses, swine, swine bedding, poultry, and poultry housing resulted in inhalation risk estimates of concern without a respirator; inhalation MOEs ranging from 69 to 160 (LOC = 300). Some dust products, but not all, require minimal inhalation protection (a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P,[30] or HE filter). With the addition of an APF10 respirator, inhalation MOEs for direct application of dusts are not of concern; inhalation MOEs range from 690 to 1,600 (LOC = 300).

For direct applications of dust formulations via dusters to cattle, swine, or horses, inhalation MOEs were not of concern. MOEs for treating livestock other than poultry ranged from 720 to 1,600 without the use of a respirator.

[30] N, R, and P refer to a filter's ability to resist oil. See https://www.ehss.vt.edu/uploaded_docs/201402031829220.NRP%20Designations.pdf

Handheld Application Methods for Liquid and Wettable Powder Formulations.

Handheld application methods may be used to spray poultry houses, barns, feedlots, or to directly apply TCVP to cattle, swine, and poultry using various sprayers, including backpack sprayers, airless sprayers, manually pressurized handwands (MPHW) and mechanically pressurized handguns (MPHG).

Mixing/loading/applying wettable powder (WP) formulations using a MPHG to treat poultry premises and dairy barns and directly to livestock result in occupational risks of concern at rates equal to or greater than 7 lbs a.i./Acre or 0.042 lb a.i./gallon or more. Mixing/loading/applying WP formulations for the treatment of poultry premises, barns, and directly to cattle with MPHG results in inhalation MOEs of 36 to 710 without the use of a respirator. Mixing/loading/applying liquid formulations with MPHG results in inhalation MOEs ranging from 42 to 1,200, with risks of concern identified at rates equal to or greater than 6.5 lbs a.i./Acre or 0.026 a.i./gallon or more without use of a respirator (MOEs = 220 and 230, respectively).

Non-cancer risks of concern were identified for mixer/loaders/applicators using backpack sprayers to apply liquid and WP formulations to poultry house floors, poultry droppings, manure piles, garbage piles, under feed troughs, dairy barns, and other animal buildings. Without a respirator, mixing/loading/applying WP formulations by backpack sprayer at rates equal to or greater than 14.4 lbs a.i./Acre resulted in inhalation MOEs ranging from 90 to 230. For liquid formulations, the inhalation MOE for mixers/loaders/applicators using a backpack sprayer without a respirator was 98 at a rate of 33.5 lbs a.i./Acre to poultry houses, poultry facilities, livestock facilities, and for litter management.

Without a respirator, some non-cancer inhalation risk estimates were below the LOC of 300 for mixer/loader/applicators using MPHW to apply liquid or wettable powder formulations to poultry houses. At rates of 14.4 lbs a.i./Acre or higher, mixing/loading/applying WP formulations without a respirator resulted in MOEs from 110 – 270 and are of concern. For liquid formulations, the inhalation risk estimate for use of MPHW was also below the LOC of 300 at a rate of 33.5 lb a.i./Acre without the use of a respirator (inhalation MOE = 110).

Airless Sprayer Applications of Liquid and Dust Formulations

Some dust formulations can be mixed with water to create a slurry, and applied as a roost paint, used to treat poultry premises. There are no risks of concern from mixing and loading liquid, WP or dust formulations to make a roost paint for applications via brush/rollers or airless sprayers with MOEs all greater than or equal to 4,100. However, EPA identified risks of concern to occupational handlers applying roost paint (made from slurries of liquid and/or dust formulations) containing TCVP via airless sprayers. Applications of roost paint (made from slurries of liquid and/or dust formulations) to facilities via airless sprayer without a respirator result in inhalation MOEs below the LOC of 300 with a range of 120 to 130.

Other Application Methods

Occupational handler inhalation MOEs were above the LOC of 300 for the following uses without use of a respirator. Therefore, EPA did not identify occupational risks of concern for the following:

- Liquid trigger-spray bottle applications (veterinary and grooming cats and dogs)
- Pet collar applications
- Liquids and wettable powders for ground boom applications
- Liquids for face/backrubbers
- Application of dust via spoon to livestock
- Application of dust via dustbag to livestock
- Application of roost paint (made from slurries of liquid and/or dust formulations) with a brush/roller
- Solid or liquid feed additives (feed-through applications)

Due to the formulation and the requirement for gloves on product labels, dermal and inhalation exposures from the application of feed blocks (salt or mineral) in livestock (typically, 5 – 15 per head of cattle or horses) are assumed to be negligible when placing the blocks.

Occupational Cancer Risks

For occupational cancer risks, EPA's target is for risk estimates to be less than 1×10^{-4}. Cancer risk estimates for application of wettable powder via electrostatic duster at 0.00078 lb a.i./square foot exceed the LOC of 1×10^{-4} without a respirator with an estimate of 2×10^{-4} and are of concern. With a respirator, cancer risk estimates are 2×10^{-5} or less. Although labels for application with electrostatic duster require gloves and an APF10 respirator, non-cancer risks of concern remain. All labels require occupational handlers to wear gloves, which mitigate cancer risks of concern for all other application methods. However, the respirator requirements are not consistent from label to label.

Occupational Post-Application Risks

While there may be activities that include interaction with livestock and/or their premises after TCVP treatments, occupational post-application exposures are not anticipated for TCVP. There are no foliar use sites and post-application contact is expected to be negligible. Labels do not include restricted entry intervals (REIs) as the registered uses (i.e., livestock and companion animals, in or around animal premises, garbage and manure piles, kennels, yards, and recreational areas) are not covered by the Worker Protection Standard (WPS). There is the potential for TCVP residues after application. However, the use of TCVP is not expected to result in occupational post-application exposure as reentry activities related to crop production (e.g., scouting, harvesting) are not anticipated for TCVP's registered use patterns. Occupational post-application exposure is expected to be negligible from TCVP's use sites. In addition, the use of TCVP pet products by veterinarians and groomers is not expected to result in occupational post-application exposure, as those individuals are not expected to have contact with the animals after application.

2. Human Incidents and Epidemiology

In 2015, EPA reviewed TCVP incidents reported to EPA's Incident Data System (IDS) and the Center for Disease Control's National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides. There were a moderate number of TCVP human incidents reported to Main and Aggregate IDS (n=374) and SENSOR-Pesticides (n=61) and most of these incidents were classified as low severity. The effects experienced were generally minimally traumatic and resolved rapidly and usually involved skin, eye, or respiratory irritation. Most of the reported incidents were due to handling and applying TCVP products to pets.

EPA conducted a new analysis for incidents reported from January 1, 2015 to June 30, 2021. This analysis identified 50 TCVP incidents reported to Main IDS. Of these, 48 incidents were classified as moderate severity and two incidents were classified as having no or unknown severity. During this time, 201 minor severity incidents involving TCVP were reported to Aggregate IDS. A query of SENSOR-Pesticides 2012-2017 identified 27 cases involving TCVP.

For incidents reported to both Main and Aggregate IDS, spray products were associated with the most incidents (51%), followed by collars (34%) and powders (11%).[31] Individuals who report incidents following the use of spray products are most often exposed through direct dermal contact either by accidental exposure during spraying, using their bare hands to apply the product which requires being "rubbed into the animal's coat," or by using the product on themselves. Similarly, most TCVP cases reported to SENSOR-Pesticides were residential and involved pet owners who were 1) applying a product onto their pet, or 2) were in contact with the treated pet post application, when the exposure occurred.

The Agency conducted a search of the Agricultural Health Study (AHS) publications and the available open literature (PubMED, PubMED Central, and Science Direct) in June and July 2021 and identified five epidemiological publications that reported on the potential association between TCVP exposure and health effects. Two AHS publications investigated and reported risk estimates on the association between TCVP exposure and non-carcinogenic health effects including central and peripheral nervous system function among the AHS participants. Two publications from the open literature investigated and reported risk estimates on the association between TCVP exposure and carcinogenic health effects including non-Hodgkin's lymphoma (NHL). One publication found in the open literature, (Brown *et al*., 1990), investigated the potential association between several pesticides, including TCVP, and leukemia in pesticide applicators in Iowa and Minnesota. These studies are summarized in the *Tetrachlorvinphos (TCVP): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment* and the *Addendum to Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment (DP Barcode: D462910)*.[32]

In both the *Tetrachlorvinphos (TCVP): Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment* and the *Tetrachlorvinphos (TCVP): Addendum to Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment (DP Barcode:*

[31] Reg. Numbers: 2596-125, 2596-126, and 2596-140
[32] https://www.regulations.gov/docket/EPA-HQ-OPP-2008-0316.

D462910), EPA concluded that there is insufficient evidence to determine a clear associative or causal relationship between TCVP and any of the health outcomes investigated.

Based on the continued low severity of TCVP incidents reported to both IDS and SENSOR-Pesticides identified between 2015 and 2021, there does not appear to be a concern at this time. The Agency will continue to monitor the incident and epidemiology data and, if a concern is triggered, additional analysis will be conducted.

3. Tolerances

Tolerances for residues of TCVP are established under 40 CFR §180.252 for livestock commodities (cattle, swine, and poultry). The residues of concern for tolerance enforcement are:

- Tetrachlorvinphos (TCVP)
- *des*-O-methyl tetrachlorvinphos (TCVPdeme)
- 1-(2,4,5-trichlorophenyl)ethanol (TCPEol, free and conjugated forms),
- 2,4,5-trichloroacetophenone (TCPEone)
- and 1-(2,4,5-trichlorophenyl)ethanediol (TCPEdiol)

The current tolerance expression under 40 CFR §180.252 includes all these residues except TCVPdeme; this metabolite must be included in the tolerance expression. There are no Codex maximum residue limits (MRLs) established or proposed for residues of TCVP. Canada has established MRLs for plant (apple and grape) and livestock commodities. The differences in U.S. and Canadian residue definitions prevent harmonization. EPA is updating the current tolerance levels in the 40 CFR. See Section IV.C below for more information.

4. Human Health Data Needs

The human health database for TCVP is considered complete.

B. Ecological Risks

The Agency has summarized the 2015 Draft Ecological Risk Assessment (2015 Eco DRA) below. The Agency used the most current science policies and risk assessment methodologies at the time to prepare a risk assessment in support of the registration review of TCVP. For additional details on the 2015 Eco DRA, see *Preliminary Environmental Fate and Ecological Risk Assessment Endangered Species Effects Determination for Tetrachlorvinphos* in EPA's public docket (EPA-HQ-OPP-2008-0316). The 2015 Eco DRA focuses on risks to non-listed species and does not assess potential risks to individual listed species. EPA is currently working with its federal partners and other stakeholders to improve the consultation process for federally listed species and their designated critical habitats and to implement a Revised Method (EPA-HQ-OPP-2019-0185-0054) for assessing potential risk to listed species and their designated critical habitats. The Agency has not yet fully evaluated TCVP's risks to listed species. However, EPA will complete its listed-species assessment once EPA has completed listed species' effects determinations and any necessary consultation with the Services before completing the TCVP registration review. See Appendix C for more details.

Exposure of terrestrial and aquatic organisms to TCVP are possible from use of the compound on livestock, livestock premises, and pets. Formulations of TCVP include collar (pet use only), liquid sprays, dusts, wettable powders, feed additives, and feed blocks. Larvicides with TCVP may pass through a treated animal in manure and be applied to agricultural lands as a soil amendment with TCVP residues. Residues from application to livestock, livestock premises, and application of TCVP-containing manure to areas may result in exposure to plants and terrestrial and semi-aquatic wildlife. TCVP is not registered for use on crops and spray applications are expected to be limited to spot treatments or manure amendment applications. Therefore, spray drift is not expected to be a significant route of exposure. Runoff is expected to be the primary route of pesticide loading to non-target areas.

The 2015 Eco DRA assessed the potential risk from exposure of non-target organisms to TCVP products, including down-the-drain exposure from pet dips containing TCVP. All pet dip products containing TCVP have since been cancelled, and registered TCVP pet products are limited to pump/trigger sprays and collars. Therefore, the initial risk assessed from untreated municipal wastewater discharge from pet dips is significantly reduced and the slow release of TCVP from pet collars is not expected to be a significant contributor to exposure for non-target organisms.

Environmental Fate and Transport

The ecological risk assessment focused on TCVP parent alone, specifically the *Z*-isomer (PC code 083702). Most of the submitted environmental fate studies were conducted on the TCVP *cis*:*trans* isomers (i.e., racemic mixture). Bridging between the biodegradation data for the racemic mixture and the *Z*-isomer has not been performed; however, EPA assumes that the racemic data are representative of the Z-isomer based on an aerobic soil metabolism study which showed degradation rates for the Z-isomer TGAI were similar to those in earlier studies on the racemic mixture. Results from the Agency's Ecological Structure Activity Relationships (ECOSAR) predictive model indicate the degradates are as toxic or less toxic than TCVP.[33]

Available data indicate that TCVP is slightly to moderately mobile in soil and is not stable in terrestrial or aquatic environments, as it is readily biodegraded in soil and hydrolyzes in water. TCVP is not expected to volatilize significantly; therefore, inhalation is not considered to be an exposure pathway of concern for either avian or mammalian species. Applications of TCVP are assumed to have minimal spray drift as it is applied to animals or animal premises and not applied by broadcast methods, with the exception of groundboom applications to indoor poultry facilities where the likelihood of drift outside such premises is low. No bioconcentration factor (BCF) studies have been submitted for TCVP and although TCVP has a log octanol-water partition coefficient (log K_{ow}) of 3.53, results from the K_{ow} (based) Aquatic BioAccumulation Model (KABAM) model suggest that the potential for bioaccumulation of TCVP is low.[34]

[33] https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model
[34] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/kabam-version-10-users-guide-and-technical

1. Risk Summary and Characterization

No risk estimates of concern were identified for freshwater fish (and aquatic-phase amphibians, for which freshwater fish serve as surrogates), aquatic plants, or terrestrial plants. No acute risks of concern were identified for estuarine/marine fish and invertebrates. However, chronic risk estimates could not be determined for estuarine/marine taxa since there are no chronic toxicity data available for estuarine/marine taxa. EPA identified risks of concern to freshwater invertebrates, birds (and reptiles and terrestrial-phase amphibians, for which birds serve as surrogates), and mammals. Uses resulting in risks of concern include treatment of kennels (spot treatment), residual surfaces (e.g., barns, farm buildings) poultry droppings, manure and garbage piles, and treatment as a manure and/or soil amendment.

Terrestrial Risks

Mammals

TCVP is characterized as slightly toxic to mammals on an acute oral exposure basis. Most acute dose-based risk quotient (RQ) values exceed the LOC of 0.5 for risk to non-listed mammalian herbivores, omnivores, and insectivores from TCVP uses on barns and farm buildings, and from uses on poultry droppings, garbage piles, and manure piles (RQs range: <0.1 to 9.2). These applications also resulted in chronic dietary-based RQ values (RQ range: 0.05 – 8.35) which exceed the chronic risk LOC of 1 for most feeding strategies. However, these chronic risk estimates are based on a no-observed adverse effect concentration (NOAEC) of 1,000 mg/kg diet at which there were no adverse effects on growth, survival or reproduction detected in a rat two-generation reproduction study at the highest dietary concentration tested (i.e., 1,000 mg/kg diet). The highest risk estimates are also based on highest application rate (i.e., 34.8 lbs a.i./Acre) for spot treatment on poultry droppings. Additionally, since the available data do not provide an estimate of chronic exposure levels which result in an adverse effect which can be quantified (i.e., a lowest observable adverse effect concentration (LOAEC)) it is not possible to determine how much higher the dietary exposure concentration would have to be above the NOAEC before adverse effects on growth, reproduction or survival would become apparent. Therefore, impacts to mammals from TCVP exposure is considered unlikely.

Birds, Reptiles, and Terrestrial-Phase Amphibians

TCVP technical grade active ingredient is categorized as practically non-toxic to birds, reptiles, and terrestrial-phase amphibians on an acute oral exposure basis. No mortalities were observed in the avian acute oral toxicity study up to the limit dose of 2,000 mg/kg bw (i.e., the lethal dose to 50% of the birds tested [LD_{50}] is greater than 2,000 mg/kg bw) and acute dose-based RQs were not calculated. While estimated exposure values based on the maximum extrapolated application rate of 34.8 lbs ai/Acre exceed the non-definitive LD_{50} value, no mortalities were observed at the limit dose and there is no indication, based on available data, that TCVP is acutely toxic to birds and by extension to reptiles and terrestrial-phase amphibians.

Nearly all chronic avian RQ values exceeded the chronic risk LOC of 1.0 with a range from 0.5 to 87 with risks of concern from most uses and feeding strategies. Drinking water exposure by

itself was determined to be a potential pathway of concern for avian species on a chronic exposure basis. On a chronic exposure basis, adult female mallard ducks *(Anas platyrhynchos*) that consumed diet containing TCVP had lower body weight gain relative to controls. Bobwhite quail (*Colinus virginianus*) fed diets containing TCVP had fewer live embryos per egg set and reduced eggshell thickness relative to controls. Mortality was not observed in any of the acute or chronic toxicity studies with birds. The highest RQ values for birds are based on an extrapolated rate equivalent to 34.8 lbs a.i./Acre from what are supposed to be spot treatments to areas of 1000 ft^2. Based on the lowest treatment rate (3.3 lbs a.i./Acre) for kennels and recreational areas and using mean food consumption numbers coupled with a NOAEC of 290 mg a.i./kg diet, the maximum chronic RQ for birds is 0.97 and drops below the chronic risk LOC. Since TCVP is used to treat poultry directly without apparent adverse effects, the likelihood of chronic effects in birds is considered low; however, it is unknown whether passerine species may be more sensitive to TCVP exposure than other species, such as the mallard duck. As noted, available toxicity data indicate that TCVP is practically non-toxic to birds on an acute oral exposure basis with no mortalities up to the limit dose of 2000 mg a.i./kg of body weight and there are no apparent adverse effects from the use of the compound in and around poultry. Accordingly, the study was not requested in registration review. The likelihood of acute or chronic mortality from the currently registered uses of TCVP is considered low for birds as well as the other taxa for which they serve as surrogates (i.e., reptiles and terrestrial-phase amphibians).

Terrestrial Invertebrates

TCVP is an insecticide and categorized as highly toxic to adult honey bees (*Apis mellifera*), which serve as a surrogate for both *Apis* and non-*Apis* bees, on an acute contact exposure basis. The likelihood of TCVP exposure to honey bees is considered limited given the current registered uses; however, no data are available for honey bees other than for adult acute contact toxicity (MRID 00036935, Atkins *et. al*.,1975). Consequently, there is uncertainty regarding the effect of treated manure on fields where ground-nesting solitary and social non-*Apis* bees may be located. Risks for terrestrial invertebrates were not quantified. EPA has determined that contact exposure to adult honey bees may present a risk of concern. However, EPA cannot determine whether TCVP presents risks of concern to larval or to adult honey bees through oral exposure as the Agency does not have larval or adult bee acute and chronic oral toxicity studies for TCVP. In the absence of other data, EPA relies on honey bee toxicity data as a surrogate for terrestrial invertebrate species. Based on the available data, EPA has determined that TCVP uses may present risks of concern to bees and other beneficial insects.

Aquatic Risks

TCVP is expected to be slightly to moderately mobile in the environment, and its primary route of degradation is expected to be aerobic soil metabolism and alkaline hydrolysis. TCVP is not volatile but is likely to move off-site through runoff and leaching. TCVP entering surface waters is expected to degrade via hydrolysis at a pH-dependent rate with a more rapid rate of hydrolysis in alkaline water. Significant partitioning of TCVP to benthic sediments in most aquatic habitats is not expected. Instead, TCVP is expected to remain primarily in the water column, where dilution and degradation are expected to reduce concentrations over time.

Freshwater Fish and Aquatic-Phase Amphibians

All acute and chronic RQs were below the Agency's LOCs (acute LOC = 0.5; chronic LOC = 1.0) for freshwater fish, which serve as surrogates for aquatic-phase amphibians. Acute RQs were between 0.001 and 0.003 and chronic RQs were between 0.008 and 0.01. Although TCVP is categorized as highly toxic to freshwater fish on an acute exposure basis, the likelihood of adverse effects to freshwater fish and aquatic-phase amphibians from the registered uses of TCVP is considered low.

Estuarine/Marine Fish

Based on available data, EPA estimates that there are no acute risks of concern to estuarine/marine fish from exposure to TCVP. TCVP is classified as moderately toxic to estuarine/marine fish on an acute exposure basis. Although the acute toxicity endpoint for estuarine/marine spot is non-definitive (i.e., LC_{50}>1000 mg a.i./L), the compound is categorized as moderately toxic to estuarine/marine fish on an acute exposure basis. Because of the non-definitive toxicity endpoint, acute RQs are non-definitive (<) values and potential acute risk to marine/estuarine fish from exposure to TCVP in surface water is considered low. No chronic toxicity data are available for estuarine/marine fish; therefore, chronic RQ values could not be estimated. Although chronic toxicity data are not available for estuarine/marine fish, based on available data for freshwater fish, there is no indication at this time that chronic exposure of fish to TCVP would represent a risk of concern.

Freshwater Invertebrates

TCVP is categorized as very highly toxic to freshwater invertebrates on an acute exposure basis. EPA identified acute risks of concern for freshwater invertebrates from exposure to TCVP. Applications to residual surfaces, poultry droppings, and manure and garbage piles exceed acute risk LOC of 0.5 with a RQ of 0.88. Chronic exposure resulted in a NOAEC of 0.125 µg a.i./L for the freshwater invertebrate waterflea *Daphnia magna* based on a reduction in the total number of offspring at the LOAEC of 250 µg a.i./L, and the Eco DRA identifies both acute and chronic risks of concern. Chronic RQ values for the same uses as those exceeding the acute risk LOC also exceed the chronic risk LOC of 1 (RQ = 9). Use of TCVP on manure used as a soil amendment results in an acute RQ of 0.34, which is below the acute risk LOC, but the chronic RQ for this use is 5, which exceeds the chronic risk LOC. Chronic exposure resulted in a NOAEC of 0.125 µg a.i./L for the freshwater invertebrate waterflea *Daphnia magna* based on a reduction in the total number of offspring and the Eco DRA identifies both acute and chronic risks of concern.

Estuarine/Marine Invertebrates

EPA did not identify acute risks of concern for estuarine/marine invertebrates. Although TCVP is categorized as highly toxic to estuarine/marine invertebrates on an acute exposure basis, the estuarine/marine mysid shrimp (*Americamysis bahia*) is roughly 147 times less sensitive to TCVP than the freshwater invertebrate *D. magna*. Chronic toxicity data were not available for marine/estuarine invertebrates, and chronic RQ values were not estimated for marine/estuarine invertebrates.

EPA compared the highest peak surface water EEC (1.68 µg a.i./L) to the acute toxicity endpoint for mysid (EC_{50}=280 µg a.i./L) which resulted in an RQ of 0.006. The RQ is below the acute risk LOC of 0.5; therefore, EPA has concluded that the likelihood of acute mortality for estuarine/marine invertebrates from the use of TCVP is low. There is uncertainty though in the potential for adverse effects on estuarine/marine invertebrates from chronic exposure. However, if an acute-to-chronic ratio (ACR) based on studies with freshwater invertebrates (daphnid acute-to-chronic ratio=15.2) were applied to the acute mysid EC_{50} of 280 µg a.i./L, it would result in an estimated NOAEC of 18.4 µg a.i./L for mysids. Based on the highest 21-day EEC of 1.11 of µg a.i./L and a NOAEC of 18.4 µg a.i./L, the chronic RQ value would be 0.06 and would fall below the chronic risk LOC of 1.0. Therefore, based on available information, the likelihood of adverse effects on estuarine/marine invertebrates from chronic exposure to TCVP is considered low.

Terrestrial and Aquatic Plants

With a non-definitive EC_{50} value of >4,625 µg a.i./L for aquatic vascular plants and an EC_{50} of 3,200 µg a.i./L for aquatic non-vascular plants, the aquatic plants are several orders of magnitude less sensitive than the most sensitive aquatic invertebrate (*D. magna* EC_{50} of 1.9 µg a.i./L). Based on a peak estimated environmental concentration of 1.68 µg a.i./L, RQ values for both vascular and non-vascular aquatic plants fall below the LOC of 1.0; therefore, there are no risks of concern for aquatic plants.

In both seedling emergence and vegetative vigor studies with terrestrial plants, the 25% effect concentration (EC_{25}) exceeded the highest application rate tested (6.09 lbs ai/Acre); therefore, no risks of concern have been identified for terrestrial plants. While there is some uncertainty as extrapolated application rates go up to 34.8 lbs a.i./Acre, as noted earlier, these rates are based on spot treatments and may overestimate exposure for plants.

2. Ecological Incidents

EPA reviewed TCVP incidents included in the Incident Data System [(IDS); formerly the Ecological Incident Information System (EIIS)]. One incident was reported as of EPA's search on July 1, 2014. This report indicated adverse effects to a red-tailed hawk (*Buteo jamaicensis*) that was linked to the use of TCVP. While this incident was considered highly probable, as the bird died after a TCVP feather treatment, it should be noted that TCVP dust products have never been registered for use on wild birds such as hawks. TCVP is used to treat poultry directly without any apparent adverse effects; however, it is unknown whether wild species may be more sensitive to TCVP exposure than other species. TCVP is considered safe for species identified on the label (i.e., poultry) when used according to label directions. On July 27, 2023, the IDS aggregate incident database was searched and resulted in no additional incident reports involving wildlife (minor), plant damage (minor), "other non-targets," or "plant lawn" related to TCVP. However, a lack of reported incidents does not necessarily mean that incidents have not occurred. In addition, incident reports for non-target plants and animals typically provide information on mortality events only. Reports for other adverse effects, such as reduced growth or impaired reproduction, are rarely received. The Agency will continue monitoring ecological incidents for TCVP and will conduct additional analyses if necessary.

3. Ecological Effects and Environmental Fate and Effects Data Needs

The ecological effects and environmental fate database for TCVP is not considered complete. The Agency has identified the following environmental fate and effect studies as data gaps for TCVP:

Table 3: Ecological Effects and Environmental Fate Data Requirements

Guideline #	Study
835.2240	Photodegradation in water
835.4300	Aerobic aquatic metabolism
835.4400	Anaerobic aquatic metabolism
850.6100	Terrestrial field dissipation[1]
850.1025	Oyster acute toxicity

[1]Environmental chemistry methods (ECM) and independent laboratory validation (ILV) for soil/sediment and water.

The need for these studies is triggered because TCVP has use patterns that fall under the terrestrial outdoor use category. However, the potential for TCVP to reach soil and water is significantly limited compared to that of other pesticides since TCVP is not used on any crops and has no registered agricultural uses.

Pollinator Data Gaps

TCVP is classified as highly toxic to honey bees on an acute contact exposure basis. Pollinator data were not included in GDCI-083702-845. Acute and chronic risks to adult honey bees and chronic risks to larval bees from oral exposure have not been defined at this time based on current information. However, as TCVP is an insecticide, risks to terrestrial invertebrates are expected. Additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators, based on the *Guidance for Assessing Pesticide Risks to Bees* (June 2014).[35]

Given the uncertainties surrounding potential risks to terrestrial invertebrates, EPA has determined that additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. Although EPA identified the need for certain data to evaluate potential effects to pollinators when initially scoping the registration review for TCVP, the problem formulation and registration review DCI for TCVP were both issued prior to EPA's release of the June 2014 *Guidance for Assessing Pesticide Risks to Bees.*[36] This 2014 guidance lists additional pollinator studies that were not included in the TCVP registration review DCI. Therefore, EPA finds that additional pollinator data are needed for TCVP. The pollinator studies that could be required are listed in Table 4. EPA has an acute contact toxicity study for adult honey bees (MRID 00036935; Atkins *et al*. 1975) which satisfies Guideline 850.3020. As noted

[35]https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf
[36] https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

in Section I. A., EPA is no longer considering calling in two of the Tier 1 pollinator studies and is no longer considering calling in Tier 2 or Tier 3 pollinator studies for TCVP.

Table 4: Potential Pollinator Data Requirements

Guideline #	Study
Tier 1	
Non-Guideline (OECD TG 213)	Honey bee adult acute oral toxicity
Non-Guideline (OECD TG 245)	Honey bee adult chronic oral toxicity
Non-Guideline OECD GD 239)	Honey bee larvae chronic oral toxicity

GD=guidance document; OECD=Organization for Economic Cooperation and Development; TG=test guideline

C. Pet Incidents

In response to comments from the Humane Society of the United States, EPA reviewed domestic animal incidents reported to the Aggregate Incident Data System (IDS). EPA reviewed domestic animal incidents in 2015 and again in 2023. A query for TCVP's PC Codes 083701 and 083702 resulted in 9,964 incidents between 1998 and 2013.[37] Many of these incidents (3,286) were classified as minor severity which means the animal exhibited symptoms that were minimally bothersome and resolved rapidly. Another 3,040 incidents were classified as unknown or "moderate, minor, or unspecified."

As of EPA's latest assessment, a query of IDS for TCVP (PC codes: 083701, 083702) domestic animal incidents from 2014 to 2022 (Table 5), found 2,294 reported incidents. Fifty-three percent of these incidents were classified as minor severity which means the animal exhibited symptoms that were minimally bothersome and resolved rapidly. The number of reported incidents has declined in recent years with a slight increase in 2019 (n=410) and 2020 (n=360) then decreasing in 2021 (n=198) and 2022 (n=122) (Figure 1). The number of TCVP domestic animal incidents reported to IDS has decreased 88% from its peak of 1,051 incidents in 2005 to 122 incidents reported in 2022 (Figure 1).

In EPA's efforts to protect pets under FIFRA, the Agency is requiring enhanced incident reporting and sales data for pet products akin to what is already submitted for spot-on products.[38] These data would allow the Agency to conduct a comparative assessment of pet incidents across registered pet products based on sales data to better determine whether any changes to the pet product registrations and labels are necessary.

[37] *Tetrachlorvinphos (TCVP): Review of Domestic Animal Incidents for Response to Comments* (May 6, 2015) https://www.regulations.gov/document/EPA-HQ-OPP-2008-0316-0091

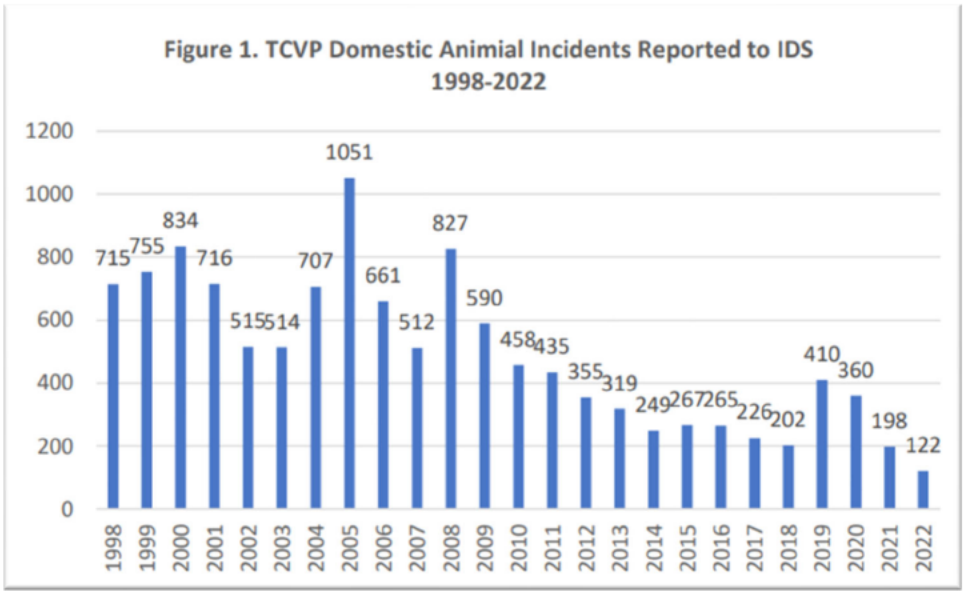
[38] https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects.

Table 5. Tetrachlorvinphos Domestic Animal Incidents in Incident Data System (IDS; Main and Aggregate) from 2014 - 2022

Severity	Main IDS Individual Cases	Aggregate Summary Module	Total
Death	5	180	185
Major	4	30	34
Moderate	28	566	594
Minor	44	1186	1230
Unknown	0	5	5
Mod, Minor, Unspecified	0	246	246
Subtotal	81*	2213	2294

* Some incidents involved more than one domestic animal.

Figure 1 shows the annual number of TCVP domestic animal incidents that were reported to the OPP through the IDS from 1998 to 2022 (including incidents from both the Main and Aggregate IDS Modules) by year.



See the *Tetrachlorvinphos (TCVP): Tier I Updated Review of Domestic Animal Incidents for the Proposed Interim Decision (PID)* for additional information.

D. Benefits Assessment

Benefits of TCVP for direct applications to poultry and indoor poultry premises for mite and lice control were deemed high due to resistance issues with some of the identified alternatives, including some pyrethroids and carbaryl. Due to a limited number of control options for these use sites and target pests, TCVP also plays an important role in adult fly knockdown and darkling beetle control in poultry premises when birds are present. High benefits from TCVP

use in cattle (beef and dairy), swine, and equine facilities were also identified for feed throughs because of limited alternatives for fly larva control on manure via oral treatment.[39]

TCVP pet collars are effective at controlling fleas and ticks on cats and dogs.[40] Pet collars impregnated with TCVP tend to be less expensive and provide longer-lasting control compared to other formulations of liquids, sprays, and powders and many other collars. TCVP is also available as a spray for a quick knockdown of target pests when applied directly to pets as well as their bedding/kennel.

Benefits are unknown for other registered uses. Additional information on the Benefits of TCVP can be found in the *Assessment of the Use, Usage, and Benefits of Tetrachlorvinphos (TCVP) (PC #083701) and Impacts of Potential Mitigation Measures Related to Poultry and Livestock Production*

IV. INTERIM REGISTRATION REVIEW DECISION

The Agency is issuing this ID in accordance with 40 CFR § 155.58. Based on the Agency's review of TCVP at this time in the registration review process, EPA is implementing certain changes to the affected registrations and their labeling. EPA determined that the mitigations identified in Sections IV.A–B and Appendices A and B would address specific risks of concern identified at this point in the ongoing registration review process.

At the end of the registration review process, EPA will decide whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[41] However, what is specified in this ID may not be sufficient for EPA to determine that TCVP registrations continue to satisfy the FIFRA standard for registration. EPA may determine that additional mitigations or other measures are necessary in subsequent interim determinations or its final registration review decision. The Agency has reviewed the risks and benefits associated with the registered uses of TCVP in developing this Interim Decision. EPA determined that changes are needed to address risks as discussed in Section III of this document. EPA has identified in this ID additional information that is needed to complete registration review for TCVP and will issue a data call-in for that information, as discussed in Section IV.E.

The Agency has not made ESA effects determinations for TCVP registrations. However, EPA has determined that the mitigation in this ID will reduce environmental exposure to TCVP and may reduce effects on listed species whose range or designated critical habitat co-occur with the use of TCVP. Additionally, EPA has added FIFRA IEM measures in Section IV.B of this ID, which are intended to reduce effects to non-target organisms, including listed species. EPA also

[39] https://www.regulations.gov/document/EPA-HQ-OPP-2008-0316-0114
[40] https://www.regulations.gov/document/EPA-HQ-OPP-2008-0316-0087
[41] 40 C.F.R. §§ 155.40(a), 155.57; 7 U.S.C. § 136a(g); *see also* 7 U.S.C. §§ 136a(c)(5) (FIFRA registration standard), 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" – FIFRA's risk-benefit standard – and "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]").

believes that the FIFRA IEM measures discussed in Section IV.B would fulfill EPA's obligations under Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022). Section 711 requires EPA to "include, where applicable, measures to reduce the effect of the applicable pesticide on" listed species and designated critical habitats in any ID noticed in the Federal Register between December 29, 2022 and October 1, 2026 for which EPA has not "made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)]." Section 711 also requires EPA to "take into account the input" of the Secretary of Agriculture and other members of the Interagency Working Group (IWG), established under FIFRA Section 3(c)(11), in developing such measures. EPA has considered input from USDA and other members of the IWG in developing the FIFRA IEM measures. EPA has previously requested public input on the FIFRA IEM measures described in this ID. The Agency will complete effects determinations and any necessary ESA Section 7 consultation with the Services before issuing a final registration review decision for TCVP. For more information, see Appendix C.

A. Risk Mitigation and Regulatory Rationale

After considering the risks and the benefits of the use of TCVP, EPA determined that changes are needed in order to address risks as discussed in Section II of this document. Below, EPA summarizes the required mitigations.

EPA has determined that there are potential risks of concern to mixers, loaders, and applicators for the following scenarios:

- Application of dust via electrostatic duster for poultry litter;
- Filling of dust boxes for poultry treatment using shaker cans or plunger dusters;
- Application of wettable powders and liquids via mechanically-pressurized handgun at certain rates to treat poultry premises/houses (including litter management), dairy/swine barns, or other animal buildings (i.e., poultry and livestock facilities) and directly to cattle and swine;
- Application of wettable powders and liquids via manually-pressurized handwands at certain rates to treat poultry houses (including litter management) and livestock facilities;
- Application of wettable powders and liquids via backpack sprayer at certain rates to treat poultry houses (litter management), dairy/swine barns, or other animal buildings (i.e., poultry and livestock facilities);
- Application of roost paint (made from slurries of liquid and/or dust formulations) via airless sprayers; and
- Direct application of dust via shaker can to swine beddings, beef cattle, and dairy cattle.

The Agency has identified as necessary a prohibition of use of electrostatic dusters and a prohibition on filling poultry dust boxes with shaker cans and plunger dusters. EPA has also identified as necessary a requirement of additional PPE for occupational handlers.

EPA has also determined that there are risks of concern to freshwater invertebrates, birds, reptiles, terrestrial-phase amphibians, and mammals. While the likelihood of exposure to honey bees is low based on the TCVP use pattern, and exposure for other terrestrial invertebrates is limited since some of TCVP's uses are being restricted to indoor use only, the Agency's understanding of risk to other terrestrial invertebrates would benefit from additional data on bees

to assess exposure and risk to non-target insects. The Agency has identified as necessary a restriction of poultry and poultry premises applications to indoor uses only.

EPA has identified as necessary restrictions on dust applications for grazing animals, requiring runoff mitigation statements, effluent discharge statements, water protection statements, precautionary statements for down-the-drain exposure, mandatory non-target statements, advisory statements for covering garbage and manure piles, and resistance management language. EPA has also identified as necessary requiring FIFRA IEM measures (i.e., ecological incident reporting language and Bulletins Live! Two language on pesticide labels as appropriate) to reduce exposure of non-target species, including listed species and designated critical habitat, at this time based on the use patterns for TCVP. The use sites for many of TCVP's applications are restricted to indoor use only, such as poultry building sprays. These indoor uses would not be subject to FIFRA IEM measures. While EPA initially proposed to limit the use of TCVP to only CAFOs with NPDES permits and NMPs in order to limit manure runoff, the Agency has not identified this restriction as necessary.

Finally, in this ID, EPA has identified as necessary requiring updates to the Terms and Conditions for Registration for all TCVP pet product registrations, requiring enhanced pet incident reporting and sales data from registrants to better determine whether any additional changes to the pet product registrations and labels would be necessary.

The technical registrants are aware of the mitigation measures in the ID.

Manure and Litter Management

To limit the likelihood of TCVP runoff from animal manure, EPA initially considered restricting TCVP applications to CAFOs with NPDES permits and NMPs. Since issuing the PID, information on runoff from animal manure has been provided by USDA, NASDA, and Elanco and the Agency has further considered the risks from this exposure pathway. EPA has determined that the likelihood of TCVP exposure via runoff from animal manure is low due to the way livestock enterprises are regulated to control nutrient runoff, and therefore there is no need to further restrict the use of TCVP to only CAFOs with NPDES permits and NMPs.

Nutrients (e.g., nitrogen and phosphorus) from poultry and livestock manure can be significant sources of water pollution if not managed properly. Livestock operations vary in terms of stock density, from low-density grazing operations through stocker and backgrounder operations up to high-density confined animal feeding operations. The likelihood of runoff from manure containing excess nutrients and TCVP increases with stocking concentration and with proximity to water bodies. However, regulatory schemes, both under the Clean Water Act and from state regulations, are currently in place to address runoff of manure pollution from livestock. Large operations, and operations that discharge manure to surface water, allow animals into contact with surface water, or otherwise significantly contribute to water pollution, are classified as CAFOs and subject to the NPDES program and required to implement an NMP. Other operations do not pose a substantial risk of runoff of either nutrients or TCVP from manure.

EPA also recognizes the impact that flies and other insect pests can have on livestock and that TCVP offers an important means of treatment of these pests. EPA determined that feed throughs have high benefits in cattle, swine, and equine facilities due to the limited availability of alternatives for fly larva control on manure. Therefore, the Agency is not restricting use of TCVP to CAFOs with NPDES permits and NMPs.

1. Prohibit Electrostatic Duster Applications

The Agency has identified as necessary prohibiting application of TCVP by electrostatic dusters. TCVP can be applied as a wettable powder with electrostatic dusters for indoor treatment of poultry litter. Non-cancer occupational handler risks of concern were found for mixers/loaders/applicators using electrostatic dusters to apply TCVP. Labels currently require "a National Institute for Occupational Safety and Health (NIOSH)-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P, or HE (high efficiency) filter" which offers an assigned protection factor of 10 (APF10). However, the personal protective equipment (PPE) currently required by the label does not sufficiently mitigate the estimated risks of concern. This application method results in risks of concern to occupational handlers with MOEs up to 66 with the use of an APF50 respirator. Use of additional PPE does not fully mitigate risks of concern to occupational handlers as this is still well below the LOC of 300. Therefore, the Agency has identified as necessary prohibiting electrostatic duster applications across all TCVP labels.

Although this application method is primarily used to treat poultry litter, there are multiple alternative application methods for treating these use sites, including manual application using mechanically-pressurized handgun, manually-pressurized handwand, and backpack sprayer. With additional treatment methods available, no significant impact is expected with this restriction. Prohibiting this application method would fully mitigate occupational handler inhalation risks of concerns from electrostatic dusters.

2. Prohibit Filling Poultry Dust Boxes with Shaker Cans and Plungers Dusters

EPA previously identified risks of concern to occupational handlers filling poultry dust boxes with shaker cans and plunger dusters. The Agency received comments stating that poultry dust boxes are more likely to be filled manually by scooping or pouring dust products, which is more efficient. The MOEs from filling dust boxes with shaker cans and plunger dusters were of greater concern than from scooping or pouring dust into the boxes. EPA did not identify risks of concern from scooping and pouring TCVP dust or wettable powder directly into poultry dust boxes. An APF10 or APF50 respirator is needed to mitigate risks of concern from filling dust boxes with shaker cans and plunger dusters, which would be impractical and potentially costly. Therefore, the Agency has identified as necessary simply prohibiting filling poultry dust boxes with shaker cans and plunger dusters.

3. Personal Protective Equipment (PPE)

Glove Statement Revision

The Agency has identified as necessary requiring updates to the glove statements on current TCVP labels, consistent with Chapter 10 of the Label Review Manual.[42] In particular, EPA is requiring the removal any references to specific categories in EPA's chemical-resistance category selection chart and specifying the appropriate types of gloves. The clarification does not fundamentally change the PPE that workers currently must use.

APF10 Respirator Requirement for TCVP Handlers

The Agency has identified as necessary updating the respirator statement currently on TCVP labels.[43] The clarification does not fundamentally change the PPE that workers currently must use. The Agency has also identified as necessary requiring that APF10 respirators be worn when applying TCVP by mechanically-pressurized handguns (MPHG), manually pressurized handwands (MPHW), backpack sprayers, as a roost paint (made from slurries of liquid and/or dust formulations) via airless sprayers, and certain other application methods as the Agency has identified occupational risks of concern from these handheld application methods. The PPE found on TCVP labels varies among similar products. This additional PPE of an APF10 respirator is for consistency across products and to mitigate potential cancer and non-cancer (inhalation) exposure risks to occupational handlers (mixers, loaders and applicators) applying TCVP. Therefore, EPA is requiring an APF10 respirator for the following:

1. Applications using a mechanically pressurized handgun (MPHG) to treat poultry premises/houses, dairy/swine barns, or other animal buildings and directly to cattle and swine using wettable powder formulations at rates equal to or greater than 7 lbs a.i./Acre or 0.042 lb a.i./gallon.
2. Applications using a MPHG to treat poultry houses (litter management), poultry and livestock facilities and directly to cattle using liquid formulations at rates equal to or greater than 6.5 lbs a.i./Acre or 0.026 lb a.i./gallon.
3. Application using a backpack sprayer to treat poultry houses (litter management), dairy/swine barns, or other animal buildings using wettable powder formulations at rates equal to or greater than 14.4 lbs a.i./Acre.
4. Application using a backpack sprayer to treat poultry houses (litter management) and poultry and livestock facilities using liquid formulations at rates equal to or greater than 33.5 lbs a.i./Acre.
5. Applications using a manually pressurized handwand (MPHW) to treat poultry houses using wettable powder formulations at rates equal to or greater than 14.4 lbs a.i./Acre (for potential non-cancer and cancer risks of concern).
6. Applications using a MPHW to treat poultry houses (litter management) and poultry and livestock facilities using liquid formulations at rates equal to or greater than 33.5 lbs a.i./Acre.

[42] https://www.epa.gov/pesticide-registration/label-review-manual
[43] For specific label language, see Appendix B.

7. Applications of dusts via shaker cans to treat poultry and livestock (e.g., cattle, horses, and swine) and swine bedding.
8. Applications using airless sprayers to treat roost areas of facilities using slurries of liquid and/or dust formulations.

The addition of an APF10 respirator increases MOEs as illustrated in Table 6. The addition of an APF10 respirator will fully mitigate the risks of concern identified in Table 6 and Section III.

Table 6: Risk estimates with and without the use of APF10 respirator.[1]

Application method	Occupational Handler	Formulation	Rate	MOEs of concern with PPE required by the current labels	MOE with APF10 respirator and gloves
1. MPHG to poultry premises/houses, dairy/swine barns, or other animal buildings and directly to cattle and swine	Mixers/loaders/ applicators	Wettable powder	Rates equal to or greater than 7 lb a.i./Acre or 0.42 lb a.i/gallon	36 – 280	360 – 2,800
2. MPHG to treat poultry houses (litter management), poultry and livestock facilities and directly to cattle	Mixers/loaders/ applicators	Liquid formulations	Rates equal to or greater than 6.5 lbs a.i./Acre or 0.026 a.i./gallon	42 – 230	420 – 2,300
3. Backpack sprayer application to treat poultry houses (litter management), dairy/swine barns, or other animal buildings	Mixers/loaders/ applicators	Wettable powder	Rates equal to or greater than 14.4 lbs a.i./Acre	90 – 230	900 – 2,300
4. Backpack sprayer application to poultry houses (litter management) and poultry and livestock facilities	Mixers/loaders/ applicators	Liquid formulations	Rates equal to or greater than 33.5 lbs a.i./Acre	98	980
5. Application to poultry houses via MPHW	Mixers/loaders/ applicators	Wettable powder	Rates equal to or greater than 14.4 lb a.i./Acre	110 – 270	1,100 – 2,700
6. Application to poultry houses via MPHW	Mixers/loaders/ applicators	Liquid formulations	Rates equal to or greater than 33.5 lb a.i./Acre	110	1,100
7. Applications of dusts via shaker cans to treat poultry and livestock (e.g., cattle, horses, and swine) and swine bedding	Loaders and applicators	Dust	N/A	69 – 160	690 – 1,600
8. Applications using airless sprayers to treat	Loaders and applicators	Slurries from liquid and	N/A	120 – 130	1,200 – 1,300

Application method	Occupational Handler	Formulation	Rate	MOEs of concern with PPE required by the current labels	MOE with APF10 respirator and gloves
roost areas of facilities using slurries of liquid and/or dust formulations		dust formulations			

[1]LOC = 300.

To reduce risks to occupational handlers (i.e., mixers, loaders, and applicators) from TCVP use in poultry and livestock production, EPA has identified as necessary requiring use of an APF10 respirator for several use sites, formulations, and equipment types. Requiring use of a respirator may impose a cost on users for the respirator and fit test unless they already use a respirator for other chemicals. Respirator costs vary depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. APF10 respirators include N95 masks. Under the Worker Protection Standard, users of respirators are also required to have an annual fit test performed; BEAD found the cost of a respirator fit test to be about $350 per applicator per year; this includes fees and the time required to obtain the test (Smearman and Berwald, 2024).[44] In addition to the potential monetary costs, the use of a respirator can reduce productivity of workers due to the stress or discomfort of wearing a respirator (Johnson, 2016).[45] For example, handlers may take more frequent breaks which could increase the time required to make an application.

Alternatively, producers currently using TCVP could hire a commercial applicator, likely at some increase in cost. Finally, a grower could use a different insecticide that does not require use of an APF10 respirator, but alternatives are limited for many of the TCVP use sites, as discussed in *Assessment of the Use, Usage, and Benefits of Tetrachlorvinphos (TCVP) (PC #083701) and Impacts of Potential Mitigation Measures Related to Poultry and Livestock Production.*

4. Indoor use only for application to poultry, poultry premises, and litter

Based on the Agency's ecological assessment, EPA has determined that mitigation to address potential ecological risks of concern to freshwater invertebrates from the poultry applications of products containing TCVP are necessary. EPA has identified as necessary restricting TCVP applications to poultry and poultry premises to indoor use only. This measure may also ensure greater consistency across labels and reduce exposure to terrestrial invertebrates, including pollinators. Multiple labels already include language limiting poultry use directions to indoor use only and most applications are likely to take place in poultry houses. This mitigation will not likely effect large commercial operations but may require smaller pastured bird producers to switch from TCVP to a product that does not have an indoor use only restriction.

[44] Smearman, S., D. Berwald. 2024. Estimates by the Biological and Economic and Analysis Division, Office of Pesticide Programs, Environmental Protection Agency and available upon request.
[45] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4748517/pdf/13036_2016_Article_25.pd

5. Restrictions for Self-Application Devices

TCVP may be self-applied by livestock using a dustbag or face/backrubber. These self-application devices are often placed outside for livestock to pass against or under when bothered by insects. [46] Non-target organisms may be exposed to TCVP during rain events from runoff from these devices. Therefore, EPA has identified as necessary the following mitigation for grazing operations that apply TCVP with self-application devices:

- Dustbags or face/backrubbers must be covered or moved indoors if NOAA/National Weather Service predicts a total rainfall of 1 inch or greater within 48 hours, only when, at any point during the 48-hour period, the precipitation potential is 50% or greater. Detailed National Weather Service forecasts for local weather conditions should be obtained on-line at: www.weather.gov or by contacting your local National Weather Service Forecasting Office.

The impact from covering or moving dustbags and face/backrubbers when rain is expected within 48 hours is expected to be minimal.

EPA acknowledges that animals treated with TCVP formulated as liquids and dusts will have TCVP residues on their fur; and EPA acknowledges that if these animals are outdoors during a rain event, some TCVP could be washed off by rain. However, given the low amounts of TCVP likely to run off animals treated with dusts and sprays, and given the lower densities of animals that are kept outdoors (e.g., pastured animals), EPA concludes that this pathway is unlikely to result in substantial TCVP runoff and, therefore, poses minimal exposure risk to non-target organisms.

6. Effluent Discharge and Water Protection Statements

EPA has identified as necessary adding mandatory statements to limit exposure from both application of TCVP as well as exposure from materials to which TCVP has been applied. To reduce potential runoff to freshwater aquatic organisms, EPA has identified as necessary adding the following statements to TCVP labels:

> *"Do not spray the product into fish pools, ponds, stream, or lakes. Do not apply directly to sewers or storm drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur."*
>
> *"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA"*

[46] https://downloads.usda.library.cornell.edu/usda-esmis/files/jh343s28d/02870z74h/sb397c17p/AgriChemUsDairy-05-23-2007.pdf

Although these mandatory statements may not fully mitigate potential risks of concern to non-target invertebrates, this along with additional mitigation measures in this section are expected to reduce exposure to aquatic taxa. Considering that many livestock operations are subject to state and federal regulations for manure management, this mitigation is expected to primarily impact smaller livestock production operations.

7. Statements on Prohibiting Down-the-Drain Disposal

Applications of TCVP to treat livestock in certain areas may lead to leaching and potentially runoff. TCVP labels currently do not have any statements preventing TCVP from reaching drainage systems. As freshwater aquatic invertebrates are particularly susceptible to mortality from exposure to organophosphates, the Agency has determined that mitigation to address potential risks of concern from the indoor applications of products containing TCVP are necessary. EPA has identified as necessary requiring the following statements to minimize down-the-drain exposure:

> *"Do not allow to enter indoor or outdoor drains. Do not pour or dispose down the drain or sewer. Call your local solid waste agency for local disposal options."*

EPA has also identified as necessary requiring the addition of a pictogram prohibiting down-the-drain disposal to provide a visual warning to prevent products from ending up down the drain. The Agency does not expect that this mitigation would have an adverse impact to pesticide users. The directions are intended to promote proper disposal after use of the product.

8. Mandatory Non-target Organism Statement and Runoff Statement

Although some labels have an aquatic advisory statement for fish, TCVP labels currently do not have an aquatic advisory statement addressing other freshwater taxa. Risks of concern were identified from exposure to TCVP for freshwater invertebrates. EPA, therefore, has also identified as necessary requiring the following aquatic statement:

> *"This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of treated materials, including manure and litter, equipment washwaters or rinsate. Runoff may adversely affect aquatic invertebrates, and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."*

This statement, in combination with other mitigation, is expected to reduce exposure to aquatic invertebrates and, therefore, reduce the expected risk. The impact of this statement is expected to be minimal as the statement is similar to the current one for fish.

9. Advisory statement on covering outdoor garbage and manure piles

In the TCVP PID, EPA proposed that garbage and manure piles must be covered after treatment with TCVP. As noted earlier in this ID, EPA received multiple comments requesting exceptions to this requirement when garbage piles are generated as part of a disease outbreak where animals

may be culled to manage the spread of a contagion. EPA recognizes that events involving disease outbreaks in herds or flocks may result in activity where covering garbage piles in the process of animal depopulation may not be conducive to mitigating disease control until herd management measures are complete. Therefore, the Agency has identified as necessary the following advisory language:

> "*Covering outdoor garbage piles as soon as possible or moving garbage indoors after application will reduce runoff.*"

Covering manure piles may already be included as part of an operation's NMP. As stated above, operations without NMPs that treat manure with TCVP are expected to pose less risk of concern to non-target organisms based on the concentration of animals at the facility (e.g., pastured cattle), the proximity to water bodies, and having vegetation to buffer runoff from manure.

10. Resistance Management

EPA has determined that resistance-management labeling is necessary for livestock use products to provide pesticide users with easy access to important information to help maintain the effectiveness of pesticides. The Agency has identified as necessary adding resistance-management language to TCVP labels[47] to address pesticide resistance.[48] Adding this language will provide pesticide users with easy access to important information on maintaining the effectiveness of pesticides—including TCVP—thereby preserving the benefits of TCVP and other useful pesticides.[49] Consistent with EPA's Pesticide Registration Notice (PRN) on general pesticide resistance management,[50] EPA is requiring pesticide resistance measures for existing chemicals during registration review and for new chemicals and new uses at the time of registration. To combat pesticide resistance, resistance management experts recommend using pesticides with different chemical modes (or mechanisms) of action against the same target pest population as part of integrated pest management (IPM) programs. This approach may prevent or delay target pest populations from developing resistance to a particular mode (or mechanism) of action without resorting to increased rates and frequency of application, possibly prolonging the useful life of pesticides. EPA expects little or no impact from resistance management labeling.

11. Label Update for EPA Registration Number 7455-38

The label for R.O.L. PREMIX, EPA Registration Number 7455-38, currently reads: "Personal Protective Equipment (PPE) should be used with long sleeved shirt and long pants, shoes and socks and chemical resistant gloves." The use of certain words such as "should" may erroneously

[47] For specific label language, see Appendix B.
[48] Pesticide resistance is the ability of portions of a pest population to tolerate or survive otherwise lethal doses of a pesticide through genetic or behavioral changes. EPA considers increased pesticide resistance an adverse effect that can drive increased use of pesticides. For more details, see PRN 2017-1 and PRN 2017-2, available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.
[49] For a detailed discussion of TCVP's benefits, see Section III.C, above. Resistance-management language is already on some TCVP labels, but the label mitigation is most effective when all product labels reflect resistance-management best practices.
[50] PRN 2017-1, "Guidance for Pesticide Registrants on Pesticide Management Labeling" (Aug. 24, 2017), available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.

mislead the user to believe that use of personal protection equipment is optional. For clarity and consistency, EPA has identified as necessary requiring that the statement on PPE be revised to read: "Handlers must wear: long-sleeved shirt and long pants; shoes and socks; and chemical-resistant gloves."

12. Label Updates for Direct Animal Spray Applications

EPA has identified as necessary following label revisions based on the application methods and rates used in the TCVP magnitude of the residue studies, which were used to determine the tolerance levels in livestock commodities (GLN 860.1200 Directions for Use):

- Based on the magnitude of the residue study on cattle, EPA requires product labels with direct animal spray uses on cattle (EPA Reg. Nos. 11556-156 (formerly 61483-43) and 11556-162 (formerly 61483-50) and 47000-126) be amended to specify a maximum of three applications per year, with a minimum 14-day retreatment interval, and a maximum single application rate of 19 g a.i./animal (0.67 oz ai/animal).
- EPA requires that the product label for Ravap (EPA Reg. No. 11556-162) also be amended to provide conversion factors to allow calculation of direct animal spray treatment rate in terms of pounds a.i./animal.
- Based on the magnitude of the residue study on poultry, EPA is requiring product labels with direct animal spray uses on poultry (EPA Reg. Nos. 11556-156, 11556-162, and 47000-126) be amended to specify a maximum of seven applications per year, with a minimum two-week retreatment interval, and a maximum single application rate of 0.18 g a.i./bird (0.006 oz a.i). The label must specify the weight (in pounds) or volume (in fluid ounces or gallons) of the product to be applied.

These label updates will help to ensure that the residues found on commodities are below the established tolerance. However, the impact of restricting the number of applications per year for these registrations is uncertain. EPA did not receive comments on the TCVP PID about any impacts from these restrictions and therefore expects impacts to be negligible.

13. Updates to the Terms and Conditions of Registration

Consistent with EPA's commitment to improve the quality of pet product incident reporting data and sales data it receives from pesticide registrants, EPA has identified as necessary requiring updates to the terms and conditions of TCVP pet collar registrations to include the submission of enhanced incident reporting. Enhanced reporting requirements for pet products will allow the Agency to review pet incidents across the most used registered pet products to better determine whether any changes to the pet product registrations and labels are necessary.

The Agency has identified as necessary a requirement that the following updated terms and conditions for TCVP pet collar registrations:

> Registrants must submit annual enhanced incident reports and annual sales information in doses sold for these products in the EPA developed templates found at https://www.epa.gov/pesticides/use-standardized-templates-report-pet-spot-incidents-

conclusion-pilot-and-implementation. The data are to be provided no later than the end of the first quarter of the following fiscal year with the first submission expected by March 31, 2025.

B. FIFRA Interim Ecological Mitigation Measures

The ESA Workplan Update Appendix includes a menu of FIFRA IEM measures, some of which are included in this ID. EPA previously sought public comment on the full suite of FIFRA IEM measures, which is available in the ESA Workplan Docket (EPA-HQ-OPP-2022-0908-0002), at www.regulations.gov. EPA updated some of the FIFRA IEM measures after considering public comments on the ESA Workplan Update and additional EPA and interagency review of the mitigations. The FIFRA IEM measures described for TCVP in this ID reflect these revisions.

EPA developed the FIFRA IEM measures to reduce exposure to non-target organisms, including listed species, based on the risks and benefits of TCVP.[51] EPA has identified as necessary the following FIFRA Interim Ecological Mitigation measures for TCVP:

- Pollinator stewardship advisory label language
- Ecological incident reporting label language
- Bulletins Live! Two (BLT) labeling

The FIFRA Interim Ecological Mitigation measures in this ID are not designed to fully address EPA's ESA obligations for TCVP during registration review. Rather, they are initial steps under FIFRA that are designed to reduce exposure to all non-target organisms, including listed species, while EPA continues to work towards meeting its ESA obligations during registration review before issuing a final registration review decision. EPA may subsequently propose additional mitigation measures for TCVP during registration review, such as mitigations developed as part of its various ESA initiatives.[52] Additional measures may also be necessary when EPA conducts effects determinations and, if necessary, consults with the Service(s) on TCVP.

1. Ecological Incident Reporting Label Language

EPA has proposed and subsequently required ecological incident reporting language on some labels in the past, and ecological incident reporting has been included as a reasonable and prudent measure in Biological Opinions issued by the Services. The Agency anticipates the need to add incident reporting labeling as part of any necessary ESA consultation. EPA has identified as necessary additional incident reporting labeling to provide consistent information to pesticide users on how to report ecological incidents and in order to expedite any ESA necessary consultation. The incident reporting language is as follows:

"**REPORTING ECOLOGICAL INCIDENTS**: For guidance on reporting ecological incidents, including death, injury, or harm to plants and animals, including bees and other non-target

[51] See the *ESA Workplan Update: Non-target Species Mitigation for Registration Review and Other FIFRA Actions* (Nov. 2022), https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf.
[52] https://www.epa.gov/endangered-species/implementing-epas-workplan-protect-endangered-and-threatened-species-pesticides

insects, see EPA's Pesticide Incident Reporting website: https://www.epa.gov/pesticide-incidents or call (registrant phone number)."

2. Bulletins Live! Two Labeling

ESA mitigation can take the form of nationwide restrictions on the general pesticide product labeling or geographic-specific restrictions located in Endangered Species Protection Bulletins (hereafter referred to as Bulletins), which are extensions of the general labeling accessed through a website. EPA is using a web-based system, Bulletins Live! Two (BLT), to provide timely protections for listed species and to minimize pesticide product labeling changes.

EPA uses BLT when mitigation applies in a particular geographic region where listed species are present and, in some cases, during only certain times of the year. BLT simplifies compliance by offering a tool for users to identify where and when they are subject to the mitigation. When directed by product labeling, pesticide applicators are required to visit the BLT online database, and follow any mitigation specified in a Bulletin for the application area.

TCVP currently does not have any listed species bulletins. However, the Agency has identified as necessary the addition of the following Bulletins language be added to all TCVP product labels. This language instructs users to check the Bulletins Live! Two website in order to understand listed species use restrictions that may apply to them, if available. Including this language on product labels will help streamline implementation of any additional risk reduction measures that may be identified during any necessary ESA consultation.

The BLT language is as follows:

> "**ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS**: Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at **https://www.epa.gov/pesticides/bulletins**. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov."

Although the BLT system has been in place for many years, there may be applicators who are unfamiliar with this system. Using the online tool to determine if mitigation is required for a particular treatment area may be a new step that many users will need to take prior to an application. However, the Agency anticipates that over time and with wider implementation, BLT will become a familiar tool that is integrated into a user's planning process for pesticide applications. In February 2022, EPA released an improved version of BLT[53], which allows users

[53] https://www.epa.gov/endangered-species/endangered-species-protection-bulletins

to more easily find the information they need for a particular pesticide product. The Agency has also developed a tutorial[54] that explains how to use the online system. In addition, the general label language referring users to BLT provides a phone number and email address for those needing technical assistance.

EPA is currently working on several ESA strategies such as the Vulnerable Species Pilot[55] and the Herbicide Strategy[56] to expedite and streamline the ESA consultation process and provide protections for listed species. Pesticide Use Limitation Areas (PULAs) and the associated geographically specific mitigation (i.e., bulletins) are not yet available under these efforts. While the BLT language above is being added on the pesticide label without being linked to PULAs or bulletins for TCVP at this time, pesticide users should be aware that as various ESA pilot efforts are finalized, EPA expects to add new PULAs and new bulletins to BLT. Before new PULAs and bulletins are added in BLT, EPA will notify stakeholders and provide an opportunity for public comment. See Appendix C: Listed Species Assessments for more information.

3. Advisory Pollinator Stewardship Label Language

EPA has found that exposure to TCVP may present risks of concern to adult bees and other terrestrial invertebrates. Given the use pattern for TCVP, bees and other beneficial insects are more likely to be exposed to TCVP from residues on the ground or from runoff. Since TCVP is not used on any crops, the likelihood of exposure for pollinating insects is reduced. However, ground nesting bees are of concern for exposure to TCVP.

EPA has identified advisory language to be added to labels for insect pollinators for TCVP products applied to poultry, livestock, or their premises. This advisory language distills the most important information that TCVP applicators need to know to voluntarily reduce risk to insect pollinators.

The pollinator hazard statement is as follows:

> "*This product is highly toxic to bees and other pollinating non-target insects exposed to direct treatment and/or residues*."

EPA has identified as necessary adding the pollinator hazard statement above for products containing TCVP with use patterns that may result in exposure to insect pollinators, particularly ground nesting bees.

Best management practices describe ways to manage pesticide applications in order to protect non-target organisms and mitigate environmental impacts. The Agency has identified as necessary adding the following labeling to highlight pollinator best management practices:

"Advisory Best Management Practices for Pollinator Protection

The following best management practices (BMPs) can help reduce risk to pollinators:

[54] https://www.epa.gov/endangered-species/bulletins-live-two-blt-tutorial
[55] https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0327
[56] https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0365

- Use Managed Pollinator Protection Plans (MP3s) when they are available. These plans may be available from state lead agencies and promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other pest management professionals to reduce exposure of bees and other pollinators to pesticides.
- Use integrated pest management (IPM) to prevent or mitigate potential negative effects to pollinators and consider multiple pest management options before resorting to a pesticide application."

For additional resources on pollinator BMPs and Pollinator Protection Plans, visit https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators.

C. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. Throughout the registration review process, EPA has sought to include all communities and persons, including minority, low-income, and indigenous populations who may be disproportionately overburdened by the exposure to TCVP.

One community which may also experience disproportionate exposure to pesticides is comprised of people who handle TCVP in livestock operations. EPA has conducted assessments of risks to those who handle TCVP or may be exposed to TCVP when treating livestock and livestock premises and has found risks of concern for TCVP. Application methods resulting in risks of concern include use of electrostatic dusters and application of TCVP with handheld equipment such as mechanically-pressurized handguns or manually-pressurized handwands. EPA has identified as necessary prohibiting application with electrostatic dusters. EPA is also including additional PPE for handheld application methods above certain rates. These measures will fully mitigate the risks of concern to occupational handlers.

EPA has also evaluated risk to residential handlers and adults/children that may be exposed to residues after pesticide application and has not found risks of concern. The Agency sought information during the public comment periods throughout registration review on any other groups or segments of the population who, as a result of their proximity and exposure to pesticides, unique exposure pathway (e.g., as a result of cultural practices), location relative to physical infrastructure, exposure to multiple stressors and cumulative impacts, lower capacity to participate in decision making, or other factors, may have unusually high exposure to TCVP compared to the general population or who may otherwise be disproportionately affected by the use of TCVP as a pesticide. EPA requested but did not receive any comments concerning environmental justice.

D. Tolerance Actions

The Agency plans to exercise its FFDCA authority to modify the tolerances for TCVP as summarized in Table 7, below. Tolerances for residues of TCVP in livestock commodities are established under 40 CFR §180.252. The current tolerance expression is for the combined

residues of tetrachlorvinphos [(Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate] and its metabolites, 1-(2,4,5-trichlorophenyl)-ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)-ethanediol.

EPA has determined that des-O-methyl tetrachlorvinphos must be included in the tolerance expression. To allow separate risk assessments for 1) cholinesterase inhibition (parent TCVP only) and 2) carcinogenicity (parent plus metabolites), the tolerances for each livestock commodity should also specify the maximum residues of TCVP *per se* from the total residues. The tolerance definition should be modified as follows, to be consistent with the Tolerance Expression Guidance (D. Wilbur, July 12, 2022, "Final Guidance on Tolerance Expressions"):

> Tolerances are established for residues of the insecticide tetrachlorvinphos, including its metabolites and degradates, in or on the commodities in Table 7. Compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of tetrachlorvinphos [(Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate) and its metabolites chloro-1-(2,4,5-trichlorophenyl)-vinylmonomethyl phosphate, 1-(2,4,5-trichlorophenyl)-ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)-ethanediol, calculated as the stoichiometric equivalent of tetrachlorvinphos, in or on the commodity.

Table 7. TCVP 40 CFR §180.252: Summary of Tolerance Actions

Commodity	Established Tolerance[1] (ppm)	Maximum Residues[2] (ppm)	Reassessed Tolerance[3,4] (ppm)	Comments; *Correct Commodity Definition*
Cattle, fat (of which no more than 0.1 ppm is tetrachlorvinphos *per se*)	0.2	0.84 (0.56) subcutaneous fat; 0.75 (0.34) peritoneal fat	0.9	*Cattle, fat (of which no more than 0.6 ppm is tetrachlorvinphos per se)*
Cattle, kidney (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	1.0	--	Remove	See cattle, meat byproducts
Cattle, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.5	--	Remove	
Cattle, meat (of which no more than 2.0 ppm is tetrachlorvinphos *per se*)	2.0	0.27 (0.21) muscle	0.3	*Cattle, meat (of which no more than 0.2 ppm is tetrachlorvinphos per se)*
Cattle, meat by products, except kidney and liver	1.0	--	Remove	See cattle, meat byproducts
Cattle, meat by products	None	0.16 (<0.01) liver; 0.28 (0.015) kidney; 0.84 (0.56) subcutaneous fat; 0.75 (0.34) peritoneal fat; 0.27 (0.21) muscle	0.9	*Cattle, meat byproducts (of which no more than 0.6 ppm is tetrachlorvinphos per se)* [5]
Egg (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.2	0.29 (0.026)	0.3	*Egg (of which no more than 0.03 ppm is tetrachlorvinphos per se)*

Table 7. TCVP 40 CFR §180.252: Summary of Tolerance Actions				
Commodity	**Established Tolerance[1] (ppm)**	**Maximum Residues[2] (ppm)**	**Reassessed Tolerance[3,4] (ppm)**	**Comments; *Correct Commodity Definition***
Hog, fat (of which no more than 0.1 ppm is tetrachlorvinphos *per se*)	0.2	0.84 (0.56) subcutaneous fat; 0.75 (0.34) peritoneal fat	0.9	*Hog, fat (of which no more than 0.6 ppm is tetrachlorvinphos per se)*
Hog, kidney (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	1.0	--	Remove	See hog, meat byproducts
Hog, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.5	--	Remove	
Hog, meat (of which no more than 2.0 ppm is tetrachlorvinphos *per se*)	2.0	0.27 (0.21) muscle	0.3	*Hog, meat (of which no more than 0.2 ppm is tetrachlorvinphos per se)*
Hog, meat byproducts, except kidney and liver	1.0	--	Remove	See hog, meat byproducts
Hog, meat by products	None	0.16 (<0.01) liver; 0.28 (0.015) kidney; 0.84 (0.56) subcutaneous fat; 0.75 (0.34) peritoneal fat; 0.27 (0.21) muscle	0.9	*Hog, meat byproducts (of which no more than 0.6 ppm is tetrachlorvinphos per se)* [5]
Milk, fat (reflecting negligible residues in whole milk and of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.05	0.072 (0.036) for milk; 0.078 (<0.01) for cream	0.08	*Milk (of which no more than 0.04 ppm is tetrachlorvinphos per se)*
Poultry, fat (of which no more than 7.0 ppm is tetrachlorvinphos *per se*)	7.0	1.298 (0.099) abdominal fat	1.5	*Poultry, fat (of which no more than 0.1 ppm is tetrachlorvinphos per se)*
Poultry, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	2.0	--	Remove	See poultry, meat byproducts
Poultry, meat (of which no more than 3.0 ppm is tetrachlorvinphos *per se*)	3.0	0.40 (0.082) muscle	0.4	*Poultry, meat (of which no more than 0.1 ppm is tetrachlorvinphos per se)*
Poultry, meat byproducts, except liver	2.0	--	Remove	See poultry, meat byproducts
Poultry, meat byproducts	None	0.52 (0.016) liver; 0.58 (0.022) kidney; 0.40 (0.082) muscle; 19.41 (6.03) skin with fat; 1.30 (0.099) abdominal fat	20	*Poultry, meat byproducts (of which no more than 6.0 ppm is tetrachlorvinphos per se)* [5]

[1] Time-limited tolerances; current tolerance expression is for the combined residues of tetrachlorvinphos [(Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate] and its metabolites, 1-(2,4,5-trichlorophenyl)-ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)-ethanediol; expression should also include des-O-methyl tetrachlorvinphos.

[2] Total residues of tetrachlorvinphos and its metabolites, TCVP-deme, TCPEone, TCPEol (free and conjugated forms), and TCPEdiol (free and conjugated), expressed in terms of parent equivalents; the value in parentheses represents the maximum residues of the parent tetrachlorvinphos.

[3] Reassessed tolerance is based on the maximum residue from the respective magnitude of the residue study; the maximum residues of the parent tetrachlorvinphos are reported in the corrected commodity definition.

[4] The residue data for cattle can be used to set tolerances for hog commodities since residues in hog tissues are not likely to be greater than those in cattle tissues.
[5] According to the 18 July 2007 Minutes of the HED ChemSAC meeting, the guidance document will be revised to include language detailing the use of the highest residue data for any tissue (liver, kidney, fat, skin or muscle) to determine the tolerance for meat byproducts. A single tolerance on "meat byproducts" will be recommended based on that highest residue, and individual tolerances will no longer be set on liver, kidney, or meat byproducts (except liver and kidney).

E. Interim Registration Review Decision

The Agency is issuing this ID in accordance with 40 CFR §§ 155.56 and 155.58. Based on the Agency's review of TCVP at this time in the registration review process, EPA is implementing certain changes to the affected registrations and their labeling. EPA determined that the mitigations identified in Sections IV.A–B and Appendices A and B will address specific risks of concerns identified at this point in the ongoing registration review process. The Agency has made the following interim decision: (1) Additional data are required for TCVP; and (2) EPA has determined that TCVP does not meet the registration standard without changes to the affected registrations and their labeling. EPA has determined that the mitigation specified in Sections IV.A-B and Appendices A and B are necessary to address risk concerns.

The Agency conducted multiple detailed HH DRAs and an Eco DRA. In these risk assessments, EPA identified multiple potential human health risks of concern for TCVP when used as directed on current labels: inhalation risks for occupational handlers from mixing, loading, and applying TCVP to poultry and livestock and their premises for several scenarios. EPA has also identified risks to certain non-target organisms including freshwater invertebrates, mammals, birds, and the species for which they are surrogates. Risks of concern to terrestrial and aquatic taxa are mainly from runoff and down-the-drain exposure. Risk to birds, mammals, freshwater fish, and estuarine/marine fish and invertebrates is estimated to be low. However, risk has been identified to terrestrial and freshwater invertebrates from current uses of TCVP.

EPA also determined that continuing to register TCVP would provide high benefits for some uses in poultry, cattle, swine, and equine facilities due to limited alternatives and/or pest resistance in those production systems. TCVP provides benefits in pet protection due to its effectiveness in controlling fleas and ticks that can vector both animal and human diseases.

During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[57] Here, EPA has determined that TCVP does not meet the FIFRA registration standard without the changes to the affected registrations and their labeling described in Section IV.A and Appendices A and B. EPA has determined that there are occupational handler risks from registered uses of TCVP that are inconsistent with the FIFRA registration standard. Although there are several benefits to TCVP use, the benefits do not

[57] 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(c)(5); *see also* 7 U.S.C. §§ 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" – FIFRA's risk-benefit standard – and "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]"). In a PID, EPA sets out a proposed interim decision that includes EPA's "proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings." 40 C.F.R. §§ 155.56, 155.58(b)(1).

outweigh the human health and ecological risks identified and thus need to be mitigated to meet the FIFRA registration standard.

EPA's conclusions from the 2023 HH DRA is that there is no human dietary risk from registered uses of TCVP that is inconsistent with the FFDCA safety standard. Taking into consideration the available information on toxicity and exposure, EPA assessed TCVP's potential aggregate risks, including dietary (food and water) and non-occupational residential exposures, and did not find risks exceeding the Agency's level of concern.

However, the current tolerance expression does not include the residue des-O-methyl tetrachlorvinphos. Therefore, EPA intends to revise the existing tolerances to include this metabolite in the tolerance expression and to revise the tolerances for consistency with the Tolerance Expression Guidance (D. Wilbur, July 12, 2022, "Final Guidance on Tolerance Expressions").

EPA has identified as necessary the following mitigation measures to reduce exposure and risk:

- Prohibit electrostatic duster applications
- Prohibit filling poultry dust boxes with shaker cans or plunger dusters
- Addition of personal protective equipment
- Indoor use only for application to poultry, poultry premises, and litter
- Use limitations for dustbags and/or face/backrubbers for grazing animals
- Effluent discharge and water protection statements
- Statements prohibiting down-the-drain disposal
- Mandatory non-target organism statements
- Advisory statement on covering outdoor garbage and manure piles
- Resistance management
- Label updates for EPA Registration Number 7455-38
- Label updates for direct animal spray applications
- Updates to the terms and conditions of registration for pet products
- Ecological incident reporting label language
- Bulletins Live! Two labeling
- Advisory pollinator stewardship label language

In this ID, the Agency is not making effects determinations for individual listed species or designated critical habitat, though the required mitigation is expected to reduce the extent of environmental exposure and to listed species whose range or designated critical habitat co-occur with the use of TCVP. The Agency will complete effects determinations and any necessary Endangered Species Act (ESA) Section 7 consultation with the Services before issuing a final registration review decision for TCVP. For more information, see Appendix C.

At the end of the registration review process, EPA will decide whether each TCVP pesticide registration "continues to satisfy the FIFRA standard for registration."[58] However, the mitigation specified in this ID may not be sufficient for EPA to determine that TCVP registrations continue to satisfy the FIFRA standard for registration. EPA may determine that additional mitigations or other measures are necessary in subsequent interim determinations or its final registration review decision. For TCVP, EPA has identified in this ID additional information that is needed to complete registration review and will issue a data call-in for that information, as discussed in Section IV.E.

The Agency has not made ESA effects determinations for any individual listed species or designated critical habitat for TCVP registrations. However, the mitigation in this ID will reduce environmental exposure to TCVP and may reduce effects on listed species whose range or critical habitat co-occur with the use of TCVP. Additionally, EPA has added FIFRA IEM measures in Section IV.B of this ID, which are intended to reduce effects to non-target organisms, including listed species. EPA also believes that the FIFRA IEM measures discussed in Section IV.B would fulfill EPA's obligations under Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022). Section 711 requires EPA to "include, where applicable, measures to reduce the effect of the applicable pesticide on" listed species and designated critical habitats in any ID noticed in the Federal Register between December 29, 2022 and October 1, 2026 for which EPA has not "made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)]." Section 711 also requires EPA to "take into account the input" of the Secretary of Agriculture and other members of the Interagency Working Group (IWG), established under FIFRA Section 3(c)(11), in developing such measures. EPA has considered input from USDA and other members of the IWG in developing the FIFRA IEM measures. EPA has previously requested public input on the FIFRA IEM measures described in this ID. The Agency will complete effects determinations and any necessary Endangered Species Act (ESA) Section 7 consultation with the Services before issuing a final registration review decision for TCVP. For more information, see Appendix C.

F. Data Requirements

The ecological effects and environmental fate database for TCVP is not considered complete, and the Agency may need additional data to confirm environmental fate and ecological effects to birds, estuarine/marine organisms, and terrestrial invertebrates.

Given that TCVP use patterns fall under the terrestrial outdoor use category, the following environmental fate and ecological effect studies could be required:

- Photodegradation in water (OCSPP 835.2240)
- Aerobic aquatic metabolism (OCSPP 835.4300)
- Anaerobic aquatic metabolism (OCSPP 835.4400)

[58] 40 C.F.R. §§ 155.40(a), 155.57; 7 U.S.C. § 136a(g); *see also* 7 U.S.C. §§ 136a(c)(5) (FIFRA registration standard), 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA's risk-benefit standard] and "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]"). This document is not a "registration review decision" within the meaning of FIFRA Section 3(g) and 40 C.F.R. § 155.57.

- Terrestrial field dissipation (OCSPP 805.6100)
- Oyster acute toxicity (OCSPP 850.1025)

Guideline 850.3020, which addresses acute contact toxicity for adult honey bees, was satisfied by MRID 00036935 (Atkins *et al*. 1975). Given that TCVP is an insecticide and there are uncertainties regarding the potential risks to terrestrial invertebrates, the following studies could be required:

- Tier 1
    - Honey bee adult acute oral toxicity, Non-Guideline (OECD TG 213)
    - Honey bee adult chronic oral toxicity, Non-Guideline (OECD TG 245)
    - Honey bee larvae chronic oral toxicity, Non-Guideline (OECD GD 239)

Although the ecological effects database is incomplete, available data were sufficient to conduct the 2015 Eco DRA and are sufficient to support this ID because the additional mitigation will reduce or eliminate potential risks of concern. The Agency will issue a DCI to establish a timeline for submitting these data.

EPA intends to request submission of enhanced pet incident and sales data as a separate action. To determine whether the FIFRA registration standard is met for the pet use, EPA expects that this will include a request for enhanced incident reporting and sales data for these uses akin to what is submitted for spot-on products.[59] These data would allow the Agency to conduct a comparative assessment of pet incidents across registered pet products based on sales data to better determine whether any changes to the pet product registrations and labels are necessary. EPA is interested in feedback from stakeholders on the most efficient way these data can be provided to the Agency and types of analyses that could be submitted to expedite the Agency's assessment.

V. NEXT STEPS AND TIMELINE

A Federal Register Notice will announce the availability of the TCVP ID. A final registration review decision for TCVP will only be made after EPA (1) completes effects determinations for listed species and their designated critical habitats and (2) meets EPA's ESA section 7 obligations (e.g., initiate any necessary consultation with the Services, consistent with ESA § 7(a)(2)).

Implementation of Mitigation Measures

The mitigations discussed in Part IV are implemented through label amendments and/or registration changes. Registrants: Submit a cover letter, a completed Application for Registration (EPA form 8570-1) and electronic copies of the amended product labels within 60 days after the announcement of this ID in the Federal Register. Submit two copies for each label, a clean copy and an annotated copy with changes. Include the following statement on the Application for Registration (EPA form 8570-1):

[59] *See* https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects.

"I certify that this amendment is consistent with the TCVP Interim Registration Review Decision and satisfies the requirements of EPA regulations at 40 CFR Section 152.44, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the statute or regulations, this product may be in violation of FIFRA and may be subject to regulatory and/or enforcement action and penalties under FIFRA."

Submit the required documents to the Registration Review section of the EPA's Pesticide Submission Portal (PSP), which can be accessed through the EPA's Central Data Exchange (CDX) at https://cdx.epa.gov/. Registrants may instead send paper copies of their amended product labels, with an application for a fast-track, Agency-initiated non-PRIA label amendment to Patricia Biggio at the following address, so long as the labels and application are submitted within the timeframe specified above:

VIA US Mail
USEPA Office of Pesticide Programs
Pesticide Re-evaluation Division
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

After all the label amendments or registration changes have been submitted, EPA will review them to ensure that they incorporate the necessary mitigation. If they meet the necessary changes, EPA intends to approve the requested changes and/or amendments. If the registrant does not submit the label amendments or registration changes, EPA reserves the right to take appropriate action under FIFRA. 40 CFR § 155.58. This ID does not effect a change in the existing registrations, and no registrations will be canceled involuntarily unless EPA follows the procedures and substantive requirements of 7 U.S.C. section 136d or is under court order to cancel. *See* 7 U.S.C. section 136a(g)(1)(A)(v).

Appendix A: Summary of Mitigation Actions for Tetrachlorvinphos

Registration Review Case #: 0321
PC Codes: 083701 and 083702
Chemical Type: Insecticide
Chemical Family: Organophosphate
Mode of Action: Acetylcholinesterase inhibition

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Actions
• Occupational handler using electrostatic dusters	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying, Vapor from volatile residues of pesticides, etc…)	• Inhalation	• Short- and intermediate-term	• AChE Inhibition, neurotoxicity	Prohibit application with electrostatic dusters
• Occupational handlers filling poultry dust boxes with shaker cans and plunger dusters and handling dust boxes for poultry treatment	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying, Vapor from volatile residues of pesticides, etc…)	• Inhalation	• Short- and intermediate-term	• AchE Inhibition, neurotoxicity	Prohibit filling poultry dust boxes with shaker cans and plunger dusters.
• Occupational handlers mixing, loading, and applying wettable powder formulations with mechanically pressurized handguns	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying, Vapor from volatile residues of pesticides, etc…)	• Inhalation	• Short- and intermediate-term	• AChE Inhibition, neurotoxicity	Require an APF10 respirator for mechanically pressurized handgun applications for rates equal to or greater than 7 lbs a.i./A or 0.042 lb a.i./gallon or higher.

Registration Review Case #: 0321
PC Codes: 083701 and 083702
Chemical Type: Insecticide
Chemical Family: Organophosphate
Mode of Action: Acetylcholinesterase inhibition

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Actions
• Occupational handlers mixing, loading, and applying liquid formulations with mechanically pressurized handguns	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying, Vapor from volatile residues of pesticides, etc…)	• Inhalation	• Short- and intermediate-term	• AChE Inhibition, neurotoxicity	Require an APF10 respirator for mechanically pressurized handgun applications at rates equal to or greater than 6.5 lbs ai/Acre or 0.026 ai/gallon or higher.
• Occupational handlers mixing, loading, and applying wettable powder formulations with backpack sprayers	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying, Vapor from volatile residues of pesticides, etc…)	• Inhalation	• Short- and intermediate-term	• AChE Inhibition, neurotoxicity	Require an APF10 respirator for mechanically pressurized handgun applications for rates equal to or greater than 14.4 lbs a.i./Acre.
• Occupational handlers mixing, loading, and applying liquid formulations with backpack sprayers	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying, Vapor from volatile residues of pesticides, etc…)	• Inhalation	• Short- and intermediate-term	• AChE Inhibition, neurotoxicity	Require an APF10 respirator for backpack sprayer applications for rates equal to or greater than 33.5 lbs a.i./Acre.
• Occupational handlers mixing, loading, and applying wettable powder formulations with manually-	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying, Vapor from volatile	• Inhalation	• Short- and intermediate-term	• AChE Inhibition, neurotoxicity	Require an APF10 respirator for manually pressurized handwand applications for rates equal to or greater than 14.4 lbs a.i./Acre.

Registration Review Case #: 0321 PC Codes: 083701 and 083702 Chemical Type: Insecticide Chemical Family: Organophosphate Mode of Action: Acetylcholinesterase inhibition					
Affected Population(s)	**Source of Exposure**	**Route of Exposure**	**Duration of Exposure**	**Potential Risk(s) of Concern**	**Required Actions**
pressurized handwand	residues of pesticides, etc…)				
• Occupational handlers mixing, loading, and applying liquid formulations with manually-pressurized handwand	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying, Vapor from volatile residues of pesticides, etc…)	• Inhalation	• Short- and intermediate-term	• AChE Inhibition, neurotoxicity	Require an APF10 respirator for manually pressurized handwand applications for rates equal to or greater than 33.5 lbs a.i./Acre
• Occupational handlers loading and applying wettable powder and dust formulations with shaker cans to swine, cattle, and horses	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying)	• Inhalation	• Short- and intermediate-term	• AChE Inhibition, neurotoxicity	Require an APF10 respirator for application of dust via shaker can to swine, cattle, and horses
• Occupational handlers applying roost paint (made from slurries of wettable powder and dust formulations) by airless sprayer	• Air (e.g., respirable particles contaminated with pesticides, Respirable aerosols during spraying)	• Inhalation •	• Short- and intermediate-term	• AChE Inhibition, neurotoxicity	Require an APF10 respirator for application of roost paint (made from slurries of wettable powder and dust formulations) by airless sprayer
• Freshwater invertebrates	• Water (non-dietary) • Residues (at/on site of treatment)	• Dermal absorption	• Acute • Steady state	• AChE Inhibition, neurotoxicity	For grazing animal operations: "Dustbags or face/backrubbers must be covered or moved indoors if NOAA/

Registration Review Case #: 0321 PC Codes: 083701 and 083702 Chemical Type: Insecticide Chemical Family: Organophosphate Mode of Action: Acetylcholinesterase inhibition					
Affected Population(s)	**Source of Exposure**	**Route of Exposure**	**Duration of Exposure**	**Potential Risk(s) of Concern**	**Required Actions**
					National Weather Service predicts a total rainfall of 1 inch or greater within 48 hours, only when, at any point during the 48-hour period, the precipitation potential is 50% or greater. Detailed National Weather Service forecasts for local weather conditions should be obtained on-line at: www.weather.gov or by contacting your local National Weather Service Forecasting Office." For all livestock and poultry operations: • "Covering outdoor garbage piles as soon as possible or moving garbage indoors after application will reduce runoff."
• Infants and Children • Women 13-49 years of age • All adults	• Dietary (food and drinking water drinking water)	• Ingestion	• Chronic	• AChE Inhibition, neurotoxicity	To determine the appropriate tolerance levels in livestock commodities for direct animal spray applications (EPA Reg. No. 11556-156 and 11556-162, and 47000-126), require: For direct animal spray on cattle: • Specify a maximum of three applications per year, with a minimum 14-day retreatment interval • Provide conversion factors to allow calculation of direct animal spray treatment rate in terms of pounds a.i./animal.

Registration Review Case #: 0321 PC Codes: 083701 and 083702 Chemical Type: Insecticide Chemical Family: Organophosphate Mode of Action: Acetylcholinesterase inhibition					
Affected Population(s)	**Source of Exposure**	**Route of Exposure**	**Duration of Exposure**	**Potential Risk(s) of Concern**	**Required Actions**
					• A maximum single application rate of 19 g/ai/animal/treatment. For direct animal spray on poultry: • Specify a maximum of seven applications per year, with a minimum two-week retreatment interval, and • A maximum single application rate of 0.18 g a.i./bird (0.006 oz a.i). • The label must specify the weight (in pounds) or volume (in fluid ounces or gallons) of the product to be applied. Require that the labels specify the weight or volume of product to be applied. • Amend EPA Reg. No. 11556-162 to provide conversion factors to allow calculation of direct animal spray treatment in terms of g/ai/animal
• Honey bees (pollinators/ terrestrial invertebrates)	• Residues from poultry and livestock application and residues from application to poultry and livestock premises	• Contact	• Acute	• AChE Inhibition, neurotoxicity	• Pollinator hazard statement and best management practices for pollinator protection.
• Cats and dogs treated with TCVP	• Residues (at/on site of treatment)	• Dermal • Incidental	• Acute • Steady State	• AChE Inhibition, neurotoxicity	• Registrants must submit annual enhanced incident reports and annual sales information in doses sold for this product.

Registration Review Case #: 0321
PC Codes: 083701 and 083702
Chemical Type: Insecticide
Chemical Family: Organophosphate
Mode of Action: Acetylcholinesterase inhibition

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Actions
				• Physical hazards from wearing a collar	
• Listed species	• Air (e.g., respirable particles contaminated with pesticides) • Water (non-dietary) • Residues (at/on site of treatment)	• Ingestion • Dermal absorption	• Acute • Steady state	• AChE Inhibition, neurotoxicity	• Add Bulletins Live! Two language and incident reporting language.

Appendix B: Labeling Changes for Tetrachlorvinphos Products

Description	Label Language for Tetrachlorvinphos End Use Products	Placement on Label
Mode/Mechanism of Action Group Number	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP"** in the second column • Include the **MODE/MECHANISM/SITE OF ACTION CODE** in the third column (for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action; for Herbicides this is **MODE OF ACTION)** • Include the type of pesticide (i.e., **INSECTICIDE)** in the fourth column. **TETRACHLORVINPHOS** | **GROUP** | **1B** | **INSECTICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Application Method Prohibitions ***For all products that do not prohibit these application methods***	Note to registrant - If your label has any of the application methods specified below, remove these application methods from TCVP product labels and include the following statement(s) as applicable to your label. *"Do not apply via foggers, misters, electrostatic dusters, or any other aerosolizing method."*	Restrictions Section Under Directions for Use
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable

Additional PPE required for filling and handling dust boxes in poultry houses	"Mixers and loaders filling poultry dust boxes must wear: • Coveralls worn over long-sleeved shirt and long pants • Chemical-resistant gloves • Chemical-resistant shoes plus socks	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Additional PPE required for mixing, loading, and applying by handheld application methods	**APF10 respirators are required for mixers, loaders, and applicator for:** • Wettable powder via mechanically pressurized handgun at rates equal to or greater than 7 lb a.i./acre or 0.042 lb a.i./gallon • Wettable powder via manually pressurized handwand at rates equal to or greater than 14.4 lb a.i./acre or higher • Wettable powder via backpack sprayer at rates equal to or greater than 14.4 lb a.i./acre or higher, • Liquid formulations via mechanically pressurized handgun at rates equal to or greater than 6.5 lbs ai/acre or 0.026 ai/gallon • Liquid formulations via manually pressurized handwand at rates of equal to or greater than 33.5 lb a.i./acre • Liquid formulations via backpack sprayer at rates equal to or greater than 33.5 lb a.i./acre or higher • Application with a shaker can to poultry or other livestock and to swine bedding • Applications of roost paint (made from slurries of liquid and/or dust formulations) applied with an airless sprayer "Wear a minimum of a NIOSH-approved elastomeric half mask respirator; OR a NIOSH-approved gas mask; OR a NIOSH-approved powered air purifying respirator with cartridges and combination HE filters.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Updated Respirator Language	[**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:] "Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products. [**Note to registrant:** For respiratory protection from organic vapor and particulates (or aerosols), use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." [**Note to registrant:** For products requiring protection for organic vapor only, use the following language:]	In the Personal Protective Equipment (PPE) within the Precautionary Statements

	"Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full-face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air purifying respirator with OV cartridges." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	
Respirator Fit Testing Requirements for Non-WPS Uses	**"Respirator fit testing, medical qualification, and training** Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is: • Fit-tested and fit-checked, • Trained, and • Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined annually by a qualified medical practitioner or if their health status or respirator style or use conditions change. Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements."	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Use limitations for livestock operations	For grazing operations: "*Dustbags or face/backrubbers must be covered or moved indoors if NOAA/National Weather Service predicts a total rainfall of 1 inch or greater within 48 hours, only when, at any point during the 48-hour period, the precipitation potential is 50% or greater. Detailed National Weather Service forecasts for local weather conditions should be obtained on-line at: www.weather.gov or by contacting your local National Weather Service Forecasting Office.*"	Directions for Use
Prohibit filling poultry dust boxes with shaker cans, plungers, or dusters	Update labels to include the following for advisory language on garbage piles: "*Do not fill poultry dust boxes with shaker cans or plunger dusters. Dust boxes must be filled by scooping or pouring dust directly into the box.*"	Directions for Use
Limit all poultry and poultry premises applications to indoor use only	For poultry use directions, please include the following: "*Poultry Use Directions (Applications to poultry, poultry litter, and poultry premises are for indoor use only)"*	Directions for Use

Mandatory Non-target Organism statement	Remove the following statement: "*This product is toxic to fish. 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*." And replace with or add: *"This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of treated materials, including manure and litter, equipment washwaters or rinsate. Runoff may adversely affect aquatic invertebrates, and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."*	Directions for Use
Discharge statement	Update labels to include the following: *"Do not spray the product into fish pools, ponds, stream, or lakes. Do not apply directly to sewers or storm drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur."* *"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA"*	Directions for Use
Water protection statement	Update poultry and livestock labels to include the following: *"Do not spray the product into fish pools, ponds, streams, or lakes. Do not apply directly to sewers or storm drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur."*	Environmental Hazards
Pollinator Hazard Statement For all products applied outdoors livestock, or their facilities	Update poultry and livestock labels to include the following: "*This product is highly toxic to bees and other non-target insects exposed to direct treatment.*"	Environmental Hazards
Best Management Practices for	**"Advisory Best Management Practices for Pollinator Protection** Following best management practices (BMPs) can help reduce risk to pollinators. To protect wild and managed pollinators, the following BMPs should be implemented:	Environmental Hazards

Pollinator Protection For all products applied outdoors to poultry, livestock, or their facilities	• Use Managed Pollinator Protection Plans (MP3s) when they are available. These plans may be available from state lead agencies and promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other pest management professionals to reduce exposure of bees and other pollinators to pesticides. • Use integrated pest management (IPM) to prevent or mitigate potential negative effects to pollinators and consider multiple pest management options before resorting to a pesticide application." • For additional resources on pollinator BMPs and Pollinator Protection Plans, visit https://www.epa.gov/pollinator-protection/tools-and-strategies-pollinator-protection."	
Resistance-management labeling statements for insecticides and acaricides	Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year). See section 3 (Scope) of the PRN to determine whether the resistance management measures outlined in the PRN apply to your product.	Directions for Use
Require treated garbage piles to be covered	Update labels to include the following for advisory language on garbage piles: "*Covering outdoor garbage piles as soon as possible or moving garbage indoors after application will reduce runoff.*"	Directions for Use
Required disposal statement for products not labeled for use directly into drains and sewers.	Include the following statement for all product disposal: *"Do not allow to enter indoor or outdoor drains. Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options."* Also include a graphic on the product package showing an image of a diagonal strikethrough over a drain. The pictogram must be legible (*i.e.*, no smaller than 1.5 square centimeters or 0.25 square inches unless this size is greater than 10% of the size of the label). **Use the following pictogram on product labels:** 	Storage and Disposal
Ecological Incidents Statement	"**REPORTING ECOLOGICAL INCIDENTS**: For guidance on reporting ecological incidents, including death, injury, or harm to plants and animals, including bees and other non-target insects, see EPA's Pesticide Incident Reporting website: https://www.epa.gov/pesticide-incidents or call (registrant phone number)".	Directions for Use, under the heading "REPORTING ECOLOGICAL INCIDENTS"

For all products with outdoor uses		
Endangered Species Protection Requirements For all products, excluding those • labeled/ registered solely for residential use; or • where exposure is negligible or there are no toxic effects expected across uses included on a product label (e.g., cattle ear tag, fly baits)	"**ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS**: Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov."	Directions for Use, at the beginning under the heading "ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS"
Label Updates for Direct Animal Spray Applications		
Maximum number of annual applications and conversion factors	For direct animal spray on cattle: • Specify a maximum of three applications per year, with a minimum 14-day retreatment interval • Provide conversion factors to allow calculation of direct animal spray treatment rate in terms of pounds a.i./animal. • A maximum single application rate of 19 g/ai/animal/treatment. For direct animal spray on poultry: • Specify a maximum of seven applications per year, with a minimum two-week retreatment interval, and • A maximum single application rate of 0.18 g a.i./bird (0.006 oz a.i). • The label must specify the weight (in pounds) or volume (in fluid ounces or gallons) of the product to be applied.	Directions for Use

For EPA Registration Number 7455-38		
Label Update	For livestock use products: "*Handlers must wear: long-sleeved shirt and long pants; shoes and socks; and chemical-resistant gloves*."	In the Personal Protective Equipment (PPE) within the Precautionary Statements

Appendix C: Listed-Species Assessment

This Appendix provides general background about the Agency's assessment of the effects of pesticides on listed species and designated critical habitats under the Endangered Species Act (ESA).

Developing Approaches for ESA Assessments and Consultation for FIFRA Actions

In 2015, EPA, along with the Services—the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS)—and the United States Department of Agriculture (USDA) (referred to as "the agencies") released their joint Interim Approaches[60] for assessing risks to listed species from pesticides. The agencies jointly developed these Interim Approaches in response to the 2013 National Academy of Sciences' recommendations that discussed specific scientific and technical issues related to the development of assessments of pesticides' effects to listed species. Since that time, the agencies have been continuing to work to improve the approaches for assessing effects to listed species. After receiving input from the Services and USDA on proposed revisions to the interim method and after consideration of public comments received, EPA released an updated Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides ("Revised Method") in March 2020.[61]

The agencies also continue to work collaboratively through a FIFRA Interagency Working Group (IWG). The IWG was created under the 2018 Farm Bill to recommend improvements to the ESA section 7 consultation process for FIFRA actions and to increase opportunities for stakeholder input. This group is led by EPA and includes representatives from NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). The IWG outlines its recommendations and progress on implementing those recommendations in reports to Congress.[62]

Consultation on Chemicals in Registration Review

EPA initially conducted biological evaluations (BEs) using the interim method on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned as the start of an iterative process. Later that year, NMFS issued a final biological opinion for these three pesticides. In 2019, EPA requested to reinitiate formal consultation with NMFS on malathion, chlorpyrifos and diazinon to consider new information that was not available when NMFS issued its 2017 biological opinion. EPA received a final malathion biological opinion[63] from FWS in February 2022 and a final biological opinion from NMFS on malathion, chlorpyrifos and diazinon in June 2022. In August 2023, the Agency

[60] https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report
[61] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional
[62] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act
[63] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions

implemented the FWS malathion biological opinion by issuing Endangered Species Protection Bulletins[64] and approving malathion label amendments[65] to incorporate measures to protect listed species. EPA plans to implement the NMFS biological opinion on malathion, chlorpyrifos and diazinon according to the 18-month timeframes specified in the biological opinion.

In 2020, EPA released draft BEs for the first two chemicals conducted using the 2020 Revised Method—carbaryl and methomyl. Subsequently, EPA has used the Revised Method to complete final BEs for carbaryl, methomyl, atrazine, simazine, glyphosate, clothianidin, imidacloprid, and thiamethoxam. EPA is currently in consultation with the Services on these active ingredients.

EPA's New Actives Policy and the 2022 Workplan

In January 2022, EPA announced a policy[66] to evaluate potential effects of new conventional pesticide active ingredients to listed species and their designated critical habitat and initiate consultation with the Services, as appropriate, before registering these new pesticides. Before the Agency registers new uses of pesticides for use on pesticide-tolerant crops, EPA will also continue to make effects determinations. If these determinations are likely to adversely affect determinations, the Agency will not register the use unless it can predict that registering the new use would not have a likelihood of jeopardizing listed species or adversely modifying their designated critical habitats. EPA will also initiate consultation with the Services as appropriate.

In April 2022, EPA released a comprehensive, long-term approach to meeting its ESA obligations, which is outlined in *Balancing Wildlife Protections and Responsible Pesticide Use*.[67] This workplan reflects the Agency's most comprehensive thinking to date on how to create a sustainable ESA-FIFRA program that focuses on meeting EPA's ESA obligations and improving protection for listed species while minimizing regulatory impacts to pesticide users and collaborating with other agencies and stakeholders on implementing the plan.

On November 16, 2022, EPA released the *ESA Workplan Update: Non-target Species Mitigation for Registration Review and Other FIFRA Actions*.[68] As part of this update, EPA announced its plan to consider and include, as appropriate, a menu of FIFRA Interim Ecological Risk Mitigation intended to reduce off-target movement of pesticides through spray drift and runoff in its registration review and other FIFRA actions. These measures are intended to reduce risks to non-target organisms efficiently and consistently across pesticides with similar levels of risks and benefits. EPA expects that these mitigation measures may also reduce pesticide exposures to listed species.

The *ESA Workplan Update* also discussed additional efforts to expedite and streamline ESA consultation, including the Vulnerable Species Pilot, regional strategies (i.e., a Hawaii Strategy), approaches for specific niche pesticide uses (e.g., mosquito adulticide applications), and programmatic approaches to consultation (e.g., the Herbicide Strategy).

---

[64] https://www.epa.gov/endangered-species/endangered-species-protection-bulletins
[65] https://www.regulations.gov/document/EPA-HQ-OPP-2009-0317-0154
[66] https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides.
[67] https://www.epa.gov/endangered-species.
[68] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf.

In June 2023, EPA announced proposed mitigation for the Vulnerable Species Pilot, an implementation plan, and information on potential expansion of the pilot.[69] EPA also published interactive maps (StoryMaps) for the 27 pilot species to convey geospatial information about the location of the affected species and the location of draft pesticide application minimization and avoidance zones to protect these species.[70] Visit the public docket for more information about the Vulnerable Species Pilot (docket EPA-HQ-OPP-2023-0327 at www.regulations.gov).

In July 2023, EPA published the framework of the draft Herbicide Strategy[71] for public comment along with various supporting documents. For more information about the Herbicide Strategy, visit the public docket (docket EPA-HQ-OPP-2023-0365 at www.regulations.gov).

EPA continues to work on these pilot efforts and once finalized, expects to implement these through registration review and new active ingredient registration.

[69] https://www.regulations.gov/document/EPA-HQ-OPP-2023-0327-0002
[70] View the StoryMaps for the 27 pilot species here:
https://storymaps.arcgis.com/collections/896d140363174c9d8ee78e4c471bd7fd
[71] https://www.regulations.gov/document/EPA-HQ-OPP-2023-0365-0009

Appendix D: Endocrine Disruptor Screening Program

The Federal Food Drug and Cosmetic Act (FFDCA) §408(p) requires EPA to develop a screening program to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." (21 U.S.C. 346a(p)). In carrying out the Endocrine Disruptor Screening Program (EDSP), FFDCA section 408(p)(3) requires that EPA "provide for the testing of all pesticide chemicals," which includes "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including all active and pesticide inert ingredients of such pesticide." (21 U.S.C. 231(q)(1) and 346a(p)(3)). However, FFDCA section 408(p)(4) authorizes EPA to, by order, exempt a substance from the EDSP if the EPA "determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen." (21 U.S.C. 346a(p)(4)).

The EDSP initiatives developed by EPA in 1998 includes human and wildlife testing for estrogen, androgen, and thyroid pathway activity and employs a two-tiered approach. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid pathways. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship for any adverse estrogen, androgen, or thyroid effect. If EPA finds, based on that data, that the pesticide has an adverse endocrine effect on humans, FFDCA § 408(p)(6) also requires EPA, "… as appropriate, [to] take action under such statutory authority as is available to the Administrator … as is necessary to ensure the protection of public health." (21 U.S.C. 346a(p)(6))[72].

Between October 2009 and February 2010, EPA issued Tier 1 test orders/data call-ins (DCIs) for its first list of chemicals ("List 1 chemicals") for EDSP screening and subsequently required submission of EDSP Tier 1 data for a refined list of these chemicals. EPA received data for 52 List 1 chemicals (50 pesticide active ingredients and 2 inert ingredients). EPA scientists performed weight-of-evidence (WoE) analyses of the submitted EDSP Tier 1 data and other scientifically relevant information (OSRI) for potential interaction with the estrogen, androgen, and/or thyroid signaling pathways for humans and wildlife.[73]

In addition, for FIFRA registration, registration review, and tolerance-related purposes, EPA collects and reviews numerous studies to assess potential adverse outcomes, including potential outcomes to endocrine systems, from exposure to pesticide active ingredients. Although EPA has been collecting and reviewing such data, EPA has not been explicit about how its review of required and submitted data for these purposes also informs EPA's obligations and commitments under FFDCA section 408(p). Consequently, on October 27, 2023, EPA issued a Federal Register Notice (FRN) providing clarity on the applicability of these data to FFDCA section 408(p) requirements and near-term strategies for EPA to further its compliance with FFDCA

[72] For additional details of the EDSP, please visit https://www.epa.gov/endocrine-disruption.
[73] Summarized in *Status of Endocrine Disruptor Screening Program (EDSP) List 1 Screening Conclusions*; EPA-HQ-OPP-2023-0474-0001; https://www.regulations.gov/document/EPA-HQ-OPP-2023-0474-0001

section 408(p). This FRN, entitled *Endocrine Disruptor Screening Program (EDSP): Near-Term Strategies for Implementation' Notice of Availability and Request for Comment* (88 FR 73841) is referred to here as EPA's EDSP Strategies Notice. EPA also published three documents supporting the strategies described in the Notice:

- *Use of Existing Mammalian Data to Address Data Needs and Decisions for Endocrine Disruptor Screening Program (EDSP) for Humans under FFDCA Section 408(p)*;
- *List of Conventional Registration Review Chemicals for Which an FFDCA Section 408(p)(6) Determination is Needed;* and,
- *Status of Endocrine Disruptor Screening Program (EDSP) List 1 Screening Conclusions* (referred to here as List 1 Screening Conclusions).

The EDSP Strategies Notice and the support documents are available on www.regulations.gov in docket number EPA-HQ-OPP-2023-0474. As explained in these documents, EPA is prioritizing its screening for potential impacts to the estrogen, androgen, and thyroid systems in humans, focusing first on conventional active ingredients. Although EPA voluntarily expanded the scope of the EDSP to screening for potential impacts to the estrogen, androgen, and thyroid systems in wildlife, EPA announced that it is not addressing this discretionary component of the EDSP at this time, considering its current focus on developing a comprehensive, long-term approach to meeting its Endangered Species Act obligations (See EPA's April 2022 ESA Workplan[74] and November 2022 ESA Workplan Update[75]). However, EPA notes that for 35 of the List 1 chemicals (33 active ingredients and 2 inert ingredients), Tier 1 WoE memoranda[76] indicate that available data were sufficient for FFDCA section 408(p) assessment and review for potential adverse effects to the estrogen, androgen, or thyroid pathways for wildlife. For the remaining 17 List 1 chemicals, Tier 1 WoE memoranda made recommendations for additional testing. EPA expects to further address these issues taking into account additional work being done in concert with researchers within the EPA's Office of Research and Development (ORD).

As discussed in EPA's EDSP Strategies Notice and supporting documents, EPA will be using all available data to determine whether additional data are needed to meet EPA's obligations and discretionary commitments under FFDCA section 408(p). For some conventional pesticide active ingredients, the toxicological databases may already provide sufficient evaluation of endocrine potential for estrogen, androgen, and/or thyroid pathways and EPA will generally not need to obtain any additional data to reevaluate those pathways, if in registration review, or to provide an initial evaluation for new active ingredient applications. For instance, EPA has endocrine-related data for numerous conventional pesticide active ingredients through either a two-generation reproduction toxicity study performed in accordance with the current guideline (referred to here as the updated two-generation reproduction toxicity study; OCSPP 870.3800 - Reproduction and Fertility Effects) or an extended one-generation reproductive toxicity (EOGRT) study (OECD Test Guideline 443 - Extended One-Generation Reproductive Toxicity Study). In these cases, EPA expects to make FFDCA 408(p)(6) decisions for humans without

[74] https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf
[75] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf
[76] https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-tier-1-screening-determinations-and

seeking further estrogen or androgen data. However, as also explained in the EPA's EDSP Strategies Notice, where these data do not exist, EPA will reevaluate the available data for the conventional active ingredient during registration review to determine what additional data, if any, might be needed to confirm EPA's assessment of the potential for impacts to estrogen, androgen, and/or thyroid pathways in humans. For more details on EPA's approach for assessing these endpoints, see EPA's EDSP Strategies Notice and related support documents.

Also described in the EPA's EDSP Strategies Notice is a framework that represents an initial approach by EPA to organize and prioritize the large number of conventional pesticides in registration review. For conventional pesticides with a two-generation reproduction toxicity study performed under a previous guideline (i.e., an updated two-generation reproduction toxicity study or an EOGRT is not available), EPA has used data from the Estrogen Receptor Pathway and/or Androgen Receptor Pathway Models to identify a group of chemicals with the highest priority for potential data collection (described in EPA's EDSP Strategies Notice as Group 1 active ingredients). For these cases, although EPA has not reevaluated the existing endocrine-related data, EPA has sought additional data and information in response to the issuance of EPA's EDSP Strategies Notice to better understand the positive findings in the ToxCast™ data for the Pathway Models and committed to issuing DCIs to require additional EDSP Tier 1 data to confirm the sufficiency of data to support EPA's assessment of potential adverse effects to the estrogen, androgen, and/or thyroid pathways in humans and to inform FFDCA 408(p) data decisions. For the remaining conventional pesticides (described in EPA's EDSP Strategies Notice as Group 2 and 3 conventional active ingredients), EPA committed to reevaluating the available data to determine what additional studies, if any, might be needed to confirm EPA's assessment of the potential for impacts to endocrine pathways in humans.

TCVP is on List 1. In 2015, EPA published the Tier 1 WoE analyses for TCVP, and that evaluation determined that no further data to assess the potential for impacts on the estrogen, androgen, or thyroid pathways are needed for humans or wildlife[77]. Based on that evaluation, EPA has concluded at this time that the points of departure for human health risk assessment to evaluate the EPA-registered uses and established tolerances of TCVP are protective of potential adverse estrogen, androgen, and thyroid effects in humans. Although there was evidence that TCVP interacts with the thyroid pathway in mammals, the effects were observed at doses higher than the current PODs for human health risk assessment. Therefore, EPA has completed its FFDCA section 408(p)(6)-related commitments and obligations "to ensure the protection of public health" at this time.

[77] https://www.regulations.gov/document/EPA-HQ-OPP-2008-0316-0033