

**UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

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THE HARTZ MOUNTAIN CORPORATION,)	
)	
Petitioner,)	
)	No. _____
v.)	
)	
U.S. ENVIRONMENTAL PROTECTION)	
AGENCY,)	
)	
)	
Respondent.)	
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PETITION FOR REVIEW

Pursuant to section 16(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136n(b), and Federal Rule of Appellate Procedure 15(a), The Hartz Mountain Corporation hereby petitions this Court for review of the United States Environmental Protection Agency’s “Agency Response to the Natural Resources Defense Council’s (NRDC) April 2009 Tetrachlorvinphos Petition,” Document ID EPA-HQ-OPP-2009-0308-0028.¹ A copy of the challenged action is attached to this Petition as Exhibit A.

¹ The challenged action contains a signature date of October 6, 2022 but was entered on Regulations.gov on October 12, 2022.

The Hartz Mountain Corporation's principal place of business is within this Circuit. Accordingly, this Court has jurisdiction to review the challenged action pursuant to 7 U.S.C. § 136n(b).

Respectfully submitted,

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Dated: October 21, 2022

CERTIFICATE OF SERVICE

Pursuant to Fed. R. App. P. 15(c), on this date, I hereby certify that I will cause to be delivered, by U.S. mail, postage prepaid, a copy of the foregoing Petition for Review to the following:

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/s/ Amanda Shafer Berman
Amanda Shafer Berman

Dated: October 21, 2022

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**RULE 26.1 DISCLOSURE STATEMENT OF
THE HARTZ MOUNTAIN CORPORATION**

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioner The Hartz Mountain Corporation submits this corporate disclosure statement.

The Hartz Mountain Corporation is a New Jersey corporation. The Hartz Mountain Corporation is jointly owned by Unicharm Corporation, Sumitomo Corporation, and Sumitomo Corporation of Americas. Unicharm Corporation and Sumitomo Corporation are publicly traded on the Tokyo Stock Exchange. Sumitomo Corporation of Americas is a wholly owned subsidiary of Sumitomo Corporation. Thus, shares of Sumitomo Corporation of Americas are not publicly traded. No other corporation holds a 10% or greater ownership interest in Hartz.

Respectfully submitted,

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*Counsel for Petitioner The Hartz Mountain
Corporation*

Dated: October 21, 2022

Docket Number: EPA-HQ-OPP-2009-0308
www.regulations.gov




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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Agency Response to the Natural Resources Defense Council's (NRDC) April 2009 Tetrachlorvinphos Petition

October 2022

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Ed Messina, Esq.
Office Director
Office of Pesticide Programs

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List of Acronyms and Abbreviations

AChE	Acetylcholinesterase
A.I.	Active Ingredient
ALJ	Administrative Law Judge
APA	Administrative Procedure Act
BEAD	Biological and Economic Analysis Division
DAF	Dermal Absorption Factor
DCI	Data Call-In
EPA	Environmental Protection Agency
ET	Exposure Time
F _{AR}	Fraction Application Rate
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HEC	Human Equivalent Concentration
HED	Health Effects Division
LOC	Level of Concern
MOA	Mode of Action
MOE	Margin of Exposure
NOIC	Notice of Intent to Cancel
NRDC	Natural Resources Defense Council
OP	Organophosphate
ORE	Occupational and Residential Exposure
POD	Point of Departure
RBC	Red Blood Cell
RfC	Reference Concentration
RED	Reregistration Eligibility Decision
SAP	FIFRA Scientific Advisory Panel
SOP	Standard Operating Procedure
TC	Transfer Coefficients
TCVP	Tetrachlorvinphos
TR	Transferable Residue Measure
TRED	Tolerance Reassessment Eligibility Decision
UE	Unit Exposure
UF _{DB}	Database Uncertainty Factor
USDA	United States Department of Agriculture

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I. Executive Summary

This document constitutes the Environmental Protection Agency's (EPA or the Agency) response to the Natural Resources Defense Council's (NRDC) petition dated April 23, 2009 (Petition) requesting that EPA cancel all pet uses of the pesticide tetrachlorvinphos (TCVP). The Agency previously denied the 2009 NRDC Petition to cancel all pet uses for TCVP in 2020. NRDC challenged that denial in the Ninth Circuit Court of Appeals, which issued an Order on April 20, 2022 vacating EPA's denial of NRDC's petition and remanding to EPA to issue a revised response within 120 days of the court's June 13 mandate (*i.e.*, by October 11, 2022).

The factual background relevant to NRDC's petition and recent litigation is discussed in Section II of this document. Section III explains EPA's initial rationale and conclusions from the 2020 risk assessment leading to EPA's 2020 petition denial. Section III also explains EPA's rationale and conclusions from a new October 2022 risk assessment, which includes a more robust analysis of previously submitted data underlying EPA's current petition response. Section IV discusses the benefits TCVP pet products provide their users and the potential impacts associated with the changes necessary to address any risks of concern, while section V provides specific information on how EPA has identified risks of concern. For the reasons discussed below, EPA is granting NRDC's petition to cancel the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) registrations for all six remaining pet collars containing TCVP and denying the remainder of NRDC's petition to cancel all pet uses of TCVP¹. Should the Agency receive data that bears upon the conclusions as described in this response, the Agency will review that data, make its review publicly available, update the TCVP risk assessment as appropriate, and make this information available for public comment. Hartz is currently working on two studies and plans to submit the data for EPA review.

As discussed in Section III, in 2020, in response to NRDC's petition, EPA completed a revised residential exposure and risk assessment of registered TCVP pet product uses at the time (dust/powders, liquid sprays and collars) and an addendum to that assessment to account for proposed mitigation. In addition to the proposed mitigation, the 2020 collar assessment had been refined based on data from a dust torsion study that was conducted to inform the liquid-to-dust ratio of TCVP used in the exposure calculations and to account for trimming of the collar when applied to the animal. In 2020, based on performed mitigation (as discussed below, including voluntary cancellation of the only two dust/powder products, voluntary cancellation of one cat collar, one use deletion of a dust product, and label amendments and product redesign for the remaining collars), EPA found no risks of concern for liquid spray products and the remaining collars, as amended, and all dust products had been voluntarily cancelled.

In 2020, the Hartz Mountain Corporation (Hartz) and Chem-Tech Ltd. (Chem-Tech), submitted requests under FIFRA section 6(f)² to either terminate uses on cats and dogs from

¹ This applies to all pet collar products containing TCVP, including those products sold by supplemental distributors.

² In this document EPA often uses the more commonly known FIFRA sections rather than the U.S. Code citations.

their dust products or request voluntary cancellation of their dust products, and EPA has processed those requests. Hartz also submitted a request under FIFRA section 6(f) to voluntarily cancel EPA Registration No. 2596-63 (a cat collar) and Hartz requested label and registration (design) amendments for the remaining pet collars. These amendments included restricting use to cats or dogs at least 12 weeks of age and weighing at least 5 pounds, and redesign of certain collars to reduce their size/weight to reduce the total amount of TCVP being applied. The final cancellation of the cancelled Hartz products became effective on December 30, 2020 (85 FR 86557). The Hartz label amendments for the following collar registrations were approved between October 20 and October 21, 2020:

- HARTZ 2 IN 1 COLLAR FOR CATS, EPA Reg. No. 2596-49
- HARTZ 2 IN 1 COLLAR FOR DOGS, EPA Reg. No. 2596-50
- HARTZ 2 IN 1 LONG LASTING COLLAR FOR DOGS, EPA Reg. No. 2596-62
- HARTZ 2 IN 1 SEVEN MONTH COLLAR FOR CATS, EPA Reg. No. 2596-83
- HARTZ 2 IN 1 SEVEN MONTH COLLAR FOR DOGS, EPA Reg. No. 2596-84
- HARTZ RABON COLLAR WITH METHOPRENE, EPA Reg. No. 2596-139

EPA did not find risks of concerns with these changes in 2020. As a result of that assessment, only the liquid sprays and collars (as amended) remained as currently registered uses.

As part of developing this revised petition response, EPA reevaluated whether the methodology used in the 2019 torsion study provided adequate information to determine a liquid to dust ratio for use in the collar exposure calculations. EPA concluded that the 2019 torsion study only provided a measure of total release of material from the collar and does not appear to distinguish between liquid and dust fractions. Since EPA determined the liquid-to-dust ratio in TCVP in pet collars could not be determined based on the available data, EPA returned to the approach used in the 2016 human health risk assessment, *Tetrachlorvinphos (TCVP) Revised Human Health Risk Assessment for Registration Review*³, which provided three risk estimates, based on three different liquid-to-dust ratios, to bracket the potential liquid-to-dust ratio. In addition, as part of developing the revised petition response, EPA identified additional collar trimming information in studies submitted for registration of pet collars and used these data to provide updated factors to account for trimming of pet collars after application as a refinement for the pet collar post-application assessment in cases where the product label directs users to trim the collar.

This updated risk assessment (the October 2022 draft⁴ risk assessment (DRA)) is fully discussed in Section III of this document. All three liquid-to-dust ratios result in risk estimates

³ Available at <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0316-0055>.

⁴ Because this response was prepared at the same time EPA was preparing a risk assessment for the entire TCVP case for registration review, EPA is relying on the 2022 registration review risk assessment as support for this response. That risk assessment is broader in scope than required for this response and is titled as a Draft Risk Assessment in line with how EPA has implemented its registration review program. The risk assessment is a “draft” only in the sense that it will be made available for comment for purposes of the TCVP registration review case under

for pet collars that exceed EPA's level of concern. However, EPA still did not find risks of concern resulting from liquid spray pet uses of TCVP.

EPA's October 2022 DRA for TCVP addresses the arguments raised in NRDC's petition regarding whether TCVP pet uses pose unacceptable risks. The October 2022 assessment and the registration review currently underway will address the issues noted by NRDC as they relate to the 2006 TCVP Reregistration Eligibility Decision (RED). To the extent that NRDC suggests that EPA perform a new organophosphate (OP) cumulative risk assessment, EPA is currently reviewing the organophosphates as a whole (including TCVP) in registration review pursuant to FIFRA section 3(g), and 40 CFR Part 155, which will include a new OP cumulative risk assessment. As noted previously in this document, should the Agency receive data that bears upon the conclusions for TCVP pet collars, the Agency will review that data, make its review publicly available, update the TCVP risk assessment as appropriate, and make this information available for public comment. Any relevant data and conclusions associated with TCVP pet collars included in the single chemical assessment would be included in the OP cumulative as applicable. Hartz is currently working on two studies and plans to submit the data for EPA review.

II. Background

TCVP is a member of the organophosphate (OP) class of pesticides. Like other OPs, TCVP's mode of action (MOA) involves the inhibition of the enzyme acetylcholinesterase (AChE). TCVP was first registered as a pesticide in 1966 and is an insecticide used to control fleas, ticks, various flies, lice, and insect larvae on livestock and domestic animals and their premises. TCVP is also applied as a perimeter treatment. All crop uses of TCVP were voluntarily cancelled by 1987.

The Reregistration Eligibility Decision (RED) for TCVP was initially completed in September 1995. An interim Tolerance Reassessment and Risk Management Decision (TRED)⁵ for TCVP was completed in July 2002. A residential exposure assessment was originally completed in 1999⁶ in support of the TRED, which concluded that there were no residential risks of concern resulting from handler and post-application exposure. The residential assessment was refined in 2002. Both the TRED and 1999 assessment can be found at www.regulations.gov in public docket numbers EPA-HQ-OPP-2002-0295 and EPA-HQ-OPP-2008-0316. The Agency completed the updates to the OP cumulative risk assessment (considering all OPs, including TCVP, sometimes referred to as the "OP Cumulative") in July 2006⁷, and, as a result, the TCVP TRED and RED were considered final at that time and can be found in public docket number EPA-HQ-OPP-2006-0618. There were no risks of concern identified in the residential

FIFRA § 3(g). The DRA represents EPA's current view on the human health risks associated with TCVP's pet uses. EPA's risk assessments, be they titled draft or final, are subject to change based on new information.

⁵ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2002-0295-0012>.

⁶ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0010>.

⁷ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2006-0618-0002>.

assessment portion of the OP Cumulative, which considered exposure from the pet uses of TCVP along with all other OP uses.

A. Registration Review of TCVP

The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used without causing unreasonable adverse effects on human health and the environment taking into account the risks and benefits associated with the use of the product.⁸

The TCVP registration review docket opened in June 2008 with the TCVP Summary Document and supporting documents⁹ stating what EPA knew about TCVP at that time and what additional risk analyses and data were needed to make a registration review decision. A Generic Data Call-In (GDCI) was issued December 29, 2009, requiring the submission of studies to inform the Agency's evaluation of risk from all TCVP exposure pathways, including those related to pet uses. The TCVP Task Force, comprised of the TCVP registrants, committed to conducting the studies, and anticipated submission beginning March 2012.

Concurrent with the TCVP Task Force's data development for registration review, the Agency focused on its review of the risk from pet uses to address NRDC's petition. The Agency began with a summary of pet collar risk estimates from the RED in order to frame the path forward for updating the pet use risk assessment in the February 2010 memorandum, *Tetrachlorovinphos, PC Code 083701, DP Barcode 346880: Summary of Pet Collar Risk Estimates*. This memorandum outlined the risk assessment methods that changed since the previous assessment for the TCVP RED and identified significant uncertainties that needed to be addressed in a new risk assessment. EPA completed an updated TCVP assessment on the pet uses on November 5, 2014, *Residential Exposure Assessment in Response to the Natural Resources Defense Council Petition to Cancel All Pet Uses for Tetrachlorovinphos*, in advance of the Agency's comprehensive December 21, 2015 TCVP Draft Human Health Risk Assessment for registration review, in continued efforts to respond to NRDC's petition.

On November 6, 2014, EPA denied NRDC's petition on the basis of the November 5, 2014 risk assessment.¹⁰ In January 2015, NRDC filed suit in the U.S. Court of Appeals for the Ninth Circuit on the merits of EPA's denial. Then, in its August 5, 2015, Opening Brief, NRDC raised for the first time the issue of whether the TCVP in pet collars should be considered a liquid or solid formulation, pointing out that one particular TCVP pet collar's label stated that

⁸ See FIFRA section 2(bb).

⁹ Available at <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0316>.

¹⁰ Available at <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0308-0010>.

“[a]s the collar begins to work, a fine white powder will appear on the surface.” The brief also argued that the Agency “failed to consider the Davis study for the estimation of post-application risks for exposures to the TCVP pet collar.”

The issue that NRDC raised as to whether TCVP pet collars should be considered a liquid or solid formulation stems from the fact that there are no exposure data specific to pet collars, meaning there are no data available that provide information on potential exposures for people while putting pet collars on animals nor are there any data available on potential exposures for people while contacting their pets after a collar has been applied. Therefore, in order to assess pet collars, EPA has to use the pet product exposure data that is available which is representative of liquid formulations (*e.g.*, shampoo products, spot-on products) and dust formulations. These data indicate that there is higher potential exposure from dust products than liquid products. In its 2012 Residential SOPs¹¹, EPA chose to use the liquid formulation data as representative of pet collars in lieu of product-specific exposure data. NRDC argued in its brief that EPA was underestimating exposure by grounding its risk assessment on a liquid-formulation exposure model and not a dust-formulation exposure model for pet collars. In response to the liquid/solid formulation issue, the 2015 DRA included separate assessments for pet collars where the liquid and dust/solid pet product exposure data were used separately (*i.e.*, assuming pet collars are entirely liquid formulations and assuming pet collars are entirely dust/solid formulations) to provide a range of potential exposures/risks.

The study identified by NRDC (the Davis study¹²) is a literature study that includes glove residue data collected by adult volunteers petting TCVP treated dogs, plasma cholinesterase (ChE) measures from treated dogs, tee shirt samples collected from children exposed to TCVP treated dogs, and urinary biomonitoring for adults and children exposure to TCVP treated dogs. In EPA’s 2015 memorandum, the Agency acknowledged consideration of the potential effect of using the Davis study as the basis for residential post-application assessment of exposures from TCVP pet collars, the study was reviewed, an OPP ethics review was conducted, and preliminary risk estimates were presented with use of these data. However, formal use of the Davis study was put on hold pending review by EPA’s Human Studies Review Board (HSRB) in January 2016.

In January 2016, EPA took the Davis study to the HSRB to determine if the Agency could rely on the study. 40 CFR 26.1703 prohibits EPA from relying on data from any research involving intentional exposure of any pregnant human subject (and therefore her fetus), nursing woman, or child, unless the EPA has: (a) obtained the views of the HSRB; (b) provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data; (c) determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction to protect public health than could be justified without the data; and

¹¹ https://www.epa.gov/sites/production/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf.

¹² *Assessing Intermittent Pesticide Exposure from Flea Control Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos*, Journal of Exposure Science and Environmental Epidemiology, Davis, M. et al., v.18, 564-570 (2008).

(d) published a full explanation of the decision to rely on the data, including a thorough discussion of the ethical deficiencies of the underlying research and the full rationale for finding that the standard in item (c) was met. The HSRB concluded that: “The research is scientifically sound and, if used appropriately, the pet fur transferable residue data from the rubbing protocol used in the study can provide useful information for evaluating potential exposures of adults and children from contact with dogs treated with tetrachlorvinphos containing pet collars.”¹³

EPA subsequently completed the TCVP Revised Human Health Risk Assessment for Registration Review, dated December 21, 2016, in which post-application risks were assessed using the Davis Study data. The December 21, 2016 risk assessment also assessed pet collars using assumptions of varying liquid-to-dust ratios of active ingredient (a.i.) in the exposure calculations to determine the impact on the outcome of the assessment.

At the time, EPA was uncertain as to whether the pet collar risk assessment should be based on a liquid-formulation exposure model or a dust-formulation exposure model, or some combination. This risk assessment was posted in the docket¹⁴ on December 29, 2016.

EPA issued a Data Call-In (DCI)¹⁵ to Hartz on June 3, 2019 requiring a mechanical torsion study in order to resolve the remaining uncertainty regarding the collar formulation. Hartz submitted the study on August 28, 2019. Following EPA’s initial review in 2019, the data were considered acceptable. EPA incorporated the 2019 mechanical torsion data (using a value of 0.38% dust in the exposure calculations for pet collars), and an assumption for collar trimming when applied to an animal (20% based on available data), in its July 2020 revised residential exposure and risk assessment “*Tetrachlorvinphos: Revised Residential Exposure and Risk Assessment for the Registered Pet Product Uses*.”¹⁶ The registrants mitigated risks identified in the revised residential pet product assessment, so EPA also completed an addendum, “*Tetrachlorvinphos: Addendum to the Revised Residential Exposure and Risk Assessment for the Registered Pet Product Uses*”¹⁷, which reflects the amendments to those registrations. In January 2022, EPA completed a revised comprehensive DRA for registration review, “*Tetrachlorvinphos (TCVP). Second Revision: Human Health Risk Assessment for Registration Review*,” which covered all registered uses of TCVP, and included the updated residential assessment for pet uses as presented in the 2020 assessments.

Since January 2022, EPA has re-evaluated the torsion study data and has identified concerns related to the methodology used in the study and whether it adequately provides information about the liquid-to-dust ratio of TCVP flea and tick collars. EPA has outlined these concerns in “*Addendum to the Data Evaluation Record for the Study “Determination of TCVP*

¹³ See https://www.epa.gov/sites/production/files/2016-04/documents/hsrb_final_report_january_2016_meeting_-_3-30-2016.pdf

¹⁴ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0055>.

¹⁵ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0078>.

¹⁶ Available at <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0316>.

¹⁷ Available at <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0316-0086>.

and DCA Residues Released from Hartz Flea and Tick Collars by Torsion Stressing”¹⁸ and has re-classified the study as unacceptable for the purpose of providing information on the liquid-to-dust ratio of TCVP flea and tick collars. As a result, EPA is no longer confident with using a value of 0.38% dust derived from the 2019 mechanical torsion study for pet collar exposure calculations. Hartz provided preliminary new torsion data in September 2022 and anticipates formally submitting the study for Agency review in October 2022, so EPA was unable to incorporate it into the DRA in the time ordered by the Ninth Circuit Court of Appeals on April 20, 2022. In light of the Court’s April 20, 2022 Opinion and Order remanding this Petition Response to EPA, the Agency has also updated its recommendations related to the adjustment factor for trimming of pet collars based on a review of additional collar trimming information in studies submitted for pet collar registrations. EPA has revised the January 2022 DRA (“*Tetrachlorvinphos (TCVP). Third Revision: Human Health Draft Risk Assessment for Registration Review*,” referred to as the October 2022 risk assessment¹⁹) such that the residential assessment for pet collars returns to the approach taken in the 2016 risk assessment, using three ratios of liquid-to-dust (e.g., 99%/1%, 1%/99%, 50%/50%) to assess pet collar exposure, and also incorporates the updated assumptions for collar trimming. In addition, the October 2022 assessment incorporates new dermal absorption *in vitro* data (MRID 51890001), submitted in April 2022, to refine the dermal absorption factor used in the risk assessment.

The October 2022 DRA identifies risks of concern for all remaining pet collar products and confirms EPA’s decision to grant NRDC’s petition for pet collars. The October 2022 DRA also confirms that risk estimates for three pet spray products containing TCVP result in no risks of concern.

TCVP remains under registration review per FIFRA section 3(g), and per the Agency’s standard practice, it will open a public comment period on the TCVP risk assessment as well as the Proposed Interim Decision (PID) once completed. Hartz is currently working on two studies and plans to submit the data for EPA review. Through registration review, EPA will consider any new data submitted, update the TCVP risk assessment as appropriate, and specify any changes in our conclusions on TCVP pet collars in the TCVP PID, which is currently expected to be completed in early 2023. EPA will open a public comment period for an updated risk assessment concurrently with the TCVP PID.

B. Summary of NRDC’s Petition to Cancel All Pet Uses

On April 24, 2009, EPA received a petition under the Administrative Procedure Act (APA), 5 U.S.C. § 551, *et seq.*, from NRDC, dated April 23, 2009, to cancel all pet uses of TCVP, as well as an April 2009 “Issue Paper” issued by NRDC entitled “Poisons on Pets II: Toxic Chemicals in Flea and Tick Collars.” The Petition raised the following issues:

¹⁸ Available at <https://www.regulations.gov/docket/EPA-HQ-OPP-2009-0308>.

¹⁹ Available at <https://www.regulations.gov/docket/EPA-HQ-OPP-2009-0308>.

- NRDC argued that EPA failed to consider pet collar exposures in the 2002 revised human health risk assessment underlying the 2006 RED. NRDC argued that despite finding that pet collar uses provided the highest exposure levels for adults, EPA still chose not to conduct a risk assessment for pet collars, and that EPA ignored the possibility that the pet collar uses could expose infants and children to unsafe levels of TCVP.
- NRDC argued that EPA used faulty exposure assumptions in the 2006 organophosphate cumulative risk assessment. NRDC argued that the EPA's organophosphate cumulative risk assessment for pet products significantly underestimated toddlers' exposure to pesticide residue on a pet from TCVP pet products, particularly flea collars.
- NRDC argued that use of TCVP pet collars results in unacceptably high exposures, pointing to NRDC's April 2009 "Issue Paper" entitled "Poisons on Pets II: Toxic Chemicals in Flea and Tick Collars," and to a 2008 study entitled "*Assessing Intermittent Pesticide Exposure from Flea Control Collars Containing the Organophosphate Insecticide Tetrachlorvinphos*," *Journal of Exposure Science and Environmental Epidemiology*, Davis, M. et al., v.18, 564-570 (2008) (the "Davis Study").

The Petition concluded that EPA's 2006 RED for TCVP is "arbitrary and capricious, and contrary to law," and that "EPA must ... cancel all pet uses of [TCVP]." Petition at 6.

On June 5, 2009, EPA announced receipt of NRDC's petition and "Issue Paper" in the Federal Register (74 FR 27035) and posted the Petition in public docket number EPA-HQ-OPP-2009-0308 in regulations.gov for a 60-day public comment period, during which time interested stakeholders could review and comment on the Petition.

During the comment period, EPA received approximately 8,600 form letters as part of a mass campaign supporting NRDC's petition. The Agency also received a comment from The Humane Society of the United States (HSUS) that supported NRDC's petition, and a comment from Hartz, which opposed NRDC's petition. In addition, Hartz provided additional information, including a dislodgeable residue study, to help refine the Agency's pet use risk assessment. EPA considered the substantive comments received during that public comment period in 2009 and released a Response to Comments document²⁰ concurrently with the Agency's initial response to the NRDC Petition in 2014, as discussed in further detail in section II.D. of this document below. Consistent with EPA's Response to Comments document, the Agency has continued to review new information and this response to NRDC's petition includes updated risk and benefit assessments.

C. EPA's Review of NRDC's Issue Paper

As mentioned above, along with the Petition, NRDC submitted an April 2009 NRDC "Issue Paper" entitled "Poisons on Pets II: Toxic Chemicals in Flea and Tick Collars" (hereinafter "Poison on Pets II") for EPA's consideration of potential exposures from TCVP pet

²⁰ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0308-0012>.

collars. This “Issue Paper” consisted of a study overview and summarized findings along with a methodological appendix but did not include the full study report including all the raw data. In a letter dated May 28, 2009, the Agency requested additional scientific information from NRDC so that EPA could fully analyze and independently verify the results of the study report, including all raw data and the protocol for the pet residue study. EPA also requested information on the ethical conduct of the study regarding the use of human subjects, as required by 40 CFR § 26.1303 under Subpart M – “Requirements for Submission of Information on the Ethical Conduct of Completed Human Research.”

On June 25, 2009, NRDC submitted a response letter.²¹ Although NRDC’s June 25, 2009 letter included a copy of the original protocol intended to support NRDC’s argument that the studies underlying the “Poison on Pets II” report were not “human studies” under 40 CFR Part 26, the letter did not include either the scientific information to enable EPA to verify the results of the study report or the information on the ethical conduct of the studies required by 40 CFR § 26.1303. NRDC’s letter stated:

“... NRDC will await EPA’s final determination that the study does not constitute research with human subjects and that the Agency will include it as part of its assessment of our Petitions. Once EPA makes that final determination, then we will provide the underlying data supporting our report.” NRDC Letter, June 25, 2009, at 3.

In a letter dated August 7, 2009, EPA informed NRDC that the Agency (EPA’s Office of Pesticide Programs, in consultation with EPA’s Human Subjects Research Review Officer in the Office of the Science Advisor) still regarded the two studies described in the “Poison on Pets II” report as research with human subjects covered by EPA’s rules in 40 CFR Part 26, “Protection of Human Subjects.”²²

To date, NRDC has not submitted the necessary raw data to allow EPA to verify the “Poisons on Pets II” study report findings. Without the raw scientific data, this information was not considered in EPA’s evaluation of NRDC’s petition.

D. EPA’s Initial Response to NRDC’s Petition and Subsequent Litigation

On April 23, 2009, NRDC filed a petition under the APA asking EPA to cancel all pesticide registrations for the use of TCVP to control fleas and ticks on pets (“pet uses”).

As of February 2014, EPA had not responded to NRDC’s 2009 petition and NRDC filed a mandamus petition in the U.S. Court of Appeals for the D.C. Circuit to compel a response. In November 2014, EPA completed a new risk assessment in response to NRDC’s 2009 petition and, on the basis of that risk assessment, denied NRDC’s petition. NRDC’s 2014 mandamus petition was therefore dismissed as moot in December 2014.

²¹ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0308-0006>.

²² Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0308-0007>.

In January 2015, NRDC filed suit in the U.S. Court of Appeals for the Ninth Circuit on the merits of EPA's denial of its APA petition. In its August 5, 2015 Opening Brief, NRDC raised for the first time the issue of whether the TCVP in pet collars should be considered a liquid or solid formulation. While EPA had previously categorized the a.i. in all pet collar products as liquid formulations as supported by the best available science at the time of development of the relevant SOP,²³ NRDC's August 5, 2015 Opening Brief pointed out that the label for Hartz UltraGuard Flea and Tick Collar for Dogs (EPA Reg. No. 2596-84) at the time stated that "as the collar begins to work, a fine white powder will appear on the surface." This statement on the label came after the instructions for the user to unroll and stretch the collar to activate the insecticide generator.

In 2015, while the Ninth Circuit litigation was ongoing, and as scientific methodologies and understanding had evolved, EPA reconsidered its position for purposes of developing the TCVP Revised Human Health Risk Assessment for Registration Review (which would ultimately be issued December 21, 2016, and posted to the docket on December 29, 2016)²⁴ by (re)assessing pet collars containing TCVP using assumptions of varying liquid-to-dust ratios (99%/1%, 1%/99%, 50%/50%) in the collar, knowing that the collars were not likely 100% dust or 100% liquid given the label language. These varied assumptions were incorporated into the exposure calculation to account for the uncertainty in the liquid-to-dust ratio. Without having chemical-specific composition information related to TCVP pet collars, this approach was taken to account for a range of possibilities which could occur. EPA also determined that the Food Quality Protection Act (FQPA) safety factor should be retained for TCVP to address uncertainties in the dose-response relationship for neurodevelopmental effects for the OPs in infants, children, and women of childbearing age for all residential exposure scenarios.²⁵ In

²³ Available at https://www.epa.gov/sites/production/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf.

²⁴ Available in regulations.gov at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0055>.

²⁵Section 408(b)(2)(C), 21 U.S.C. 346a(b)(2)(C), was added to the FFDCA through the Food Quality Protection Act of 1996 (FQPA), and provided heightened protections for infants and children. Among other things, that provision directs EPA to apply, "[i]n the case of threshold effects, ... an additional *tenfold margin of safety* for the pesticide chemical residue and other sources of exposure ... to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." (Emphasis added). This additional tenfold margin of safety is referred to as the "FQPA 10X safety factor." This provision applies when EPA is establishing, modifying, leaving in effect, or revoking tolerances – which are rules that set maximum amount of pesticide residues that can be present in or on food – and is applied when assessing pesticides that bear labeling for use on food (i.e., *food use* pesticides) as a result of the definition of "unreasonable adverse effects on the environment" at section 2(uu) of FIFRA, 7 U.S.C. 136(bb). That definition states in relevant part: "The term 'unreasonable adverse effects on the environment' means (1) 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, or (2) a *human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21.*" (Emphasis added).

As noted in footnote 4, *supra*, the DRA that supports this Response to NRDC's Petition to cancel "pet uses" was drafted for the broader purposes of "registration review" of TCVP, which includes *all uses* of TCVP including food uses. When assessing pesticides resulting in residues in or on food under FIFRA 2(bb) consistent with the safety standard in the FFDCA, the FFDCA requires EPA to apply the "FQPA 10X safety factor" for the

September 2015, EPA therefore sought a voluntary remand of its 2014 denial of NRDC's 2009 APA petition. In arguing for remand without vacatur, EPA informed the court and parties that it intended to issue a new risk assessment before the end of 2016 and respond to the Petition within 90 days after the final risk assessment was issued. In June 2016, the court granted EPA's motion for remand and denied NRDC's motion for vacatur.

In addition, as mentioned above, in January 2016 EPA took the Davis Study to the HSRB, which concluded that the study was scientifically valid and met the appropriate human ethics requirements. EPA therefore relied on the Davis Study in developing the December 21, 2016 TCVP Revised Human Health Risk Assessment for Registration Review, as the Davis Study provided transferable residue data for pet fur and resulted in greater potential risks than those estimated using the pet collar residue transfer study EPA had relied upon in previous assessments.

As also mentioned above, EPA completed a new TCVP Human Health Risk Assessment on December 21, 2016 (posted to the docket on December 29, 2016).²⁶ While that risk assessment identified some potential risks of concern, the risk assessment left some key questions unresolved, such as whether the TCVP in the pet collars should be considered "liquid" or "solid" (which, in turn, could affect the assessment of risk). With the remaining uncertainty around the physical form of TCVP present in the collars, the Agency was unable to fully respond to NRDC's petition. Therefore, on March 21, 2017 (90 days after finalizing the new TCVP risk assessment), EPA informed NRDC that EPA intended to merge the Petition response with its TCVP registration review decision under FIFRA section 3(g) that was then scheduled to be issued in the fall of 2017.

EPA's assessment of the pet collars hinged on the uncertainty regarding the physical form of TCVP released from collars, and the Agency determined that the best solution would be to require a study from the registrant of the pet collars, Hartz, assessing the percentage of the collars' total mass available for release as dust. Therefore, EPA issued a DCI to Hartz on June 3, 2019, pursuant to FIFRA section 3(c)(2)(B), requiring a mechanical torsion study.²⁷ That DCI requested that a protocol be submitted to EPA for review prior to the conduct of the study.

protection of infants and children, unless there is reliable data to show that a different margin of safety would be safe. 21 U.S.C. 346a(b)(2)(C). Due to the uncertainty surrounding the potential for neurodevelopmental outcomes associated with exposures to TCVP, including from exposures associated with the pet uses, EPA retained the FQPA 10X safety factor for assessing the risk of those uses as part of its DRA. The FQPA 10X safety factor, in this case, is equivalent to the traditional uncertainty factor applied in situations of a database uncertainty. *See USEPA, Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment*. Feb. 28, 2002 (FQPA safety factor incorporates other traditional uncertainty factors to account for data deficiencies that raise concern for infants and children, including database uncertainty factor). That same database uncertainty exists regardless of whether EPA assesses all uses of TCVP together or if EPA assesses the pet uses alone, and thus the additional 10X uncertainty factor for assessing pet uses is appropriate.

²⁶ Available in regulations.gov at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0055>.

²⁷ Available in regulations.gov at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0078>.

Five days before EPA issued the DCI, on May 29, 2019, NRDC filed a mandamus petition with the Ninth Circuit Court of Appeals asking the court to order EPA to respond to NRDC's 2009 petition. The torsion study, along with additional transfer residue data, were submitted to the Agency on August 28, 2019; however, a protocol for the torsion study had not been submitted prior for EPA review as requested. On April 22, 2020, the court issued an Order directing EPA to either initiate cancellation of the TCVP pet use registrations or deny NRDC's 2009 petition within 90 days of the court's order (*i.e.*, by July 21, 2020). The Agency completed the review of the submitted data in December 2019 and the Agency incorporated these data into the July 2020 revised residential exposure and risk assessment.

In its initial review of the torsion study, EPA had focused on the change in collar weight from the study and assumed it could provide an approximation of dust released from the collar. The study found that 0.38% of the collars' mass was lost as a result of mechanical torsion, and EPA used that figure as a percentage dust value in the pet collar exposure calculations, which assumed that the remaining portion of exposure was attributable to liquid TCVP. This assumption was incorporated into EPA's 2020 revised risk assessment and 2020 petition response.²⁸

On July 21, 2020, in compliance with the court's order, the Agency responded to NRDC's 2009 petition by denying the Petition, concluding risk estimates for TCVP liquid spray products do not exceed the Agency's level of concern; therefore, those products remain registered. Based on EPA's initial assessment of the 2019 mechanical torsion study and incorporation of the 0.38% value, risk estimates for some pet collars did not exceed the Agency's level of concern while others did. Risk estimates for all pet dust products exceeded EPA's level of concern. The primary pet product registrant, Hartz, voluntarily cancelled all dust powders and one pet collar and redesigned and/or relabeled the remaining collar registrations to reduce risk estimates below levels of concern. Additionally, Chem-tech Ltd. voluntarily submitted a request to terminate pet uses from CLEAN CROP LIVESTOCK 1% RABON DUST (EPA Registration No. 47000-123).

On September 18, 2020, NRDC filed a petition for review in the Ninth Circuit Court of Appeals, seeking judicial review on the merits of EPA's July 21, 2020 denial of NRDC's petition to cancel pet uses of TCVP. In the briefing and oral argument regarding this litigation, the Agency provided detailed explanation regarding the data and calculations used in the revised residential exposure and risk assessment for all TCVP pet product uses, entitled "*Tetrachlorvinphos: Revised Residential Exposure and Risk Assessment for the Registered Pet Product Uses.*"

On April 20, 2022, the court issued an opinion holding that the EPA's denial of NRDC's petition was not supported by substantial evidence and did not provide a "reasoned explanation" for its denial of NRDC's petition in the written record. The court held that the Agency relied on

²⁸ Available at <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0308-0018>

“mistaken calculations” central to the denial of NRDC’s petition. The court vacated the 2020 Petition denial citing a lack of substantial evidence on the amount of TCVP dust released by the pet collars, and the assumption that pet owners will trim the collars by at least 20%. The decision was remanded to the Agency for a revised response.

As noted above, as part of developing this revised petition response, EPA re-evaluated the data provided in the 2019 torsion study and, as a result, identified concerns about whether the methodology used (*i.e.*, collar weight and wipe measurements) could really distinguish between dust and liquid fractions. The material measured via wiping could potentially represent total release (both liquid and dust) and not necessarily just dust. The study therefore does not help determine the percentage of the collars’ overall mass available for release as dust. The original and revised data evaluation records (DERs) for these data are available in public docket EPA-HQ-OPP-2008-0316 at www.regulations.gov.²⁹

III. EPA’s Revised Residential Exposure and Risk Assessment

There is one risk assessment pertinent to this petition response:

- An October 2022 comprehensive draft risk assessment (DRA) for registration review: “*Tetrachlorvinphos (TCVP). Third Revision: Human Health Draft Risk Assessment for Registration Review*,” which includes an updated residential exposure and risk assessment for pet product uses.

EPA risk assessments rely on the most recent guidance and risk assessment methodologies available at the time they are completed. The human health risk assessments that NRDC’s petition alleges failed to properly identify risks were originally completed in 1999 and 2006 and utilized exposure assumptions and methodologies based on Standard Operating Procedures (SOPs) for pet product risk assessments in place at that time. Since 2012, TCVP residential pet product assessments assessed residential handler and post-application risk from exposure to TCVP pet products using the Agency’s 2012 SOPs for Residential Pesticide Exposure Assessment³⁰. Development of the 2012 SOPs included external peer review, including the Agency presenting a draft of the SOPs to the FIFRA Scientific Advisory Panel (SAP) for comment in 2009.

In developing the 2020 risk assessments and petition response, EPA considered, among other things, the information contained in the Petition, new data relevant to the assessment of exposure from pet collars (*i.e.*, additional Hartz studies: MRID 50881801/ D453149 and MRID 50931601/ D454190), an efficacy study to inform assumptions on collar trimming (MRID 51079501) and updated residential exposure assessment methodologies and reevaluation of

²⁹ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0083> and <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0084>.

³⁰ https://www.epa.gov/sites/production/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf.

existing data (*i.e.*, the Davis Study). As mentioned above, EPA incorporated the 2019 mechanical torsion data, and an assumption for collar trimming when applied to a cat or dog (based on available data), in its July 2020 revised residential exposure and risk assessment “*Tetrachlorvinphos: Revised Residential Exposure and Risk Assessment for the Registered Pet Product Uses*”³¹. The registrants mitigated risks identified in the revised residential pet product assessment, so EPA also completed an addendum, “*Tetrachlorvinphos: Addendum to the Revised Residential Exposure and Risk Assessment for the Registered Pet Product Uses*”³², which reflects the amendments to those registrations. In briefings for NRDC’s September 18, 2020 petition for review, NRDC claimed that EPA’s assumption that owners would trim 20% of collars conflicts with its 2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment. The court found that EPA did not provide an adequate justification for its reliance on the efficacy study used to support the 20% collar trimming assumption. NRDC also claimed that EPA miscalculated the liquid-to-dust ratio from the raw data from the torsion study.

Additional data has been incorporated since the 2020 petition response into the October 2022 updated risk assessment and this current petition response, including additional efficacy and transferable residue studies from Hartz and registrants of other pet collar products to further inform the assumptions on collar trimming (MRIDs 51025813, 48987301, 51169106, 51160711, 51079501, 51025814, 50881801, 48646602, and 43722809) and new *in vitro* dermal absorption data (MRID 51890001). In addition, EPA reevaluated the 2019 mechanical torsion study and updated its review of a previously submitted transferable residue study and has updated the pet collar assessment to reflect these changes.

The October 2022 DRA addresses all currently registered uses of TCVP, including pet products (*i.e.*, collars and liquid sprays). Like reregistration, registration review considers all the uses of an a.i. along with new data and other information to ensure that the pesticide continues to meet the standard for registration under FIFRA. To the extent that NRDC’s 2009 petition may be suggesting that EPA perform a new cumulative risk assessment, EPA is currently reviewing the organophosphates (OP) as a whole (including TCVP) in registration review pursuant to section 3(g) of FIFRA, which includes a new OP cumulative risk assessment. EPA has determined it is unnecessary to update the cumulative risk assessment to respond to NRDC’s requests to cancel all TCVP pet uses and will continue to pursue an updated OP cumulative risk assessment along the appropriate registration review timeline. EPA intends to update the cumulative assessment following the completion of registration review for all organophosphates.

The Agency completed a revised residential exposure and risk assessment for all currently registered TCVP pet product uses as part of its October 2022 draft risk assessment for registration review, “*Tetrachlorvinphos (TCVP). Third Revision: Human Health Draft Risk Assessment for Registration Review.*” Based on the data and updates noted above, that risk assessment incorporated an updated dermal absorption factor, a slight change to the transfer factor (F_{AR}), use of a range of liquid-to-dust ratios to assess pet collars, and updated

³¹ Available at <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0316>.

³² Available at <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0316-0086>.

recommendations for an adjustment factor to account for trimming of pet collars, all of which are discussed in more detail in the following sections. In the October 2022 DRA, the risk estimates for currently registered pet collars containing TCVP exceed EPA's level of concern, while the risk estimates for the currently registered liquid sprays containing TCVP do not exceed EPA's level of concern.

Hartz is currently conducting two studies to address the pet collar risk issues and formulation question. The first is a new torsion study conducted using a different methodology than the originally submitted torsion study, which will allow the Agency to better estimate risks from pet collars by allowing more accurate determination of the relative amounts of TCVP coming from the collar in solid (dust) versus liquid form. The second study is a unique pet fur clipping study which is designed to determine the relative amounts of solid (dust) vs. liquid TCVP on pet fur at different locations on a pet wearing a TCVP collar. If the pet fur study shows different relative amounts of solid vs. liquid on different areas of the pet (for example, neck vs. base of the tail), a better estimation of exposure to people contacting treated pets after application may be possible. The results of these studies will be used to reassess risks to people applying pet collars, and to people exposed through contact with the pet after the collar has been applied.

The following is a summary of the analysis and conclusions found in the revised residential exposure assessment for pet uses, included in the comprehensive "*Tetrachlorvinphos (TCVP). Third Revision: Human Health Draft Risk Assessment for Registration Review.*"

A. Toxicology and Uncertainty Factors

Like other OPs, the MOA for TCVP involves inhibition of the enzyme AChE via phosphorylation of the serine residue at the active site of the enzyme. This inhibition leads to accumulation of acetylcholine and ultimately to neurotoxicity in the central and/or peripheral nervous system.

TCVP has low acute toxicity by the oral, dermal, and inhalation routes of exposure. It is a slight dermal irritant, a moderate eye irritant, and a dermal sensitizer. TCVP is classified as a possible human carcinogen (Group C) based on statistically significant increases in combined hepatocellular adenoma/carcinomas in mice, and suggestive evidence of thyroid c-cell adenomas and adrenal pheochromocytomas in rats. The mutagenicity database for TCVP suggests that this chemical was not mutagenic in either the gene mutation assay or the primary rat hepatocyte unscheduled DNA synthesis assay. This chemical was positive for inducing chromosomal aberrations in Chinese hamster ovary (CHO) cells in the absence of metabolic activation but was negative in the presence of metabolic activation. Immunotoxicity was not observed at dose levels that exceed the limit dose.

As with other OPs, TCVP exhibits a phenomenon known as steady state AChE inhibition. After repeated dosing at the same dose level, the degree of inhibition comes into

equilibrium with the production of new, uninhibited enzyme. At this point, the amount of AChE inhibition at a given dose remains consistent across duration. In general, OPs reach steady state within 2-3 weeks; a pattern that is observed for most OPs, but not every OP, like TCVP, which shows no difference in response across duration. For TCVP, the steady state is reached after a single day of exposure. As such, the endpoint selection for TCVP considers data available for all durations of dosing when choosing the most protective point of departure. AChE data from the comparative cholinesterase assays (CCA) suggest that the fetus is not more sensitive than the pregnant dam and that pregnant females are not more sensitive than non-pregnant females with respect to cholinesterase inhibition. When comparing red blood cell (RBC) BMD₁₀ (benchmark dose) estimates from across the acute (single dose) CCA and repeat dose CCA studies, it is apparent that there are no age-related (or duration-related) differences. The acute, steady state, and incidental oral Points of Departure (PODs) selected for oral exposure risk assessment are based on RBC AChE inhibition in the postnatal day 11 (PND 11) and postnatal day 21 (PND 21) pups in the acute CCA since they provide the most robust dose-responses and are protective of all life stages as well as brain AChE inhibition. Although the steady state dietary POD was selected from an acute CCA, the acute study is considered appropriate for longer term durations since AChE data across the TCVP database demonstrate that there is no progression of AChE inhibition over exposure duration, and steady state inhibition occurs essentially after a single dose. A route-specific inhalation study was used to assess inhalation risks based on RBC cholinesterase inhibition and is the most appropriate and protective POD based on the route and duration of exposure.

No quantification of dermal non-cancer risk is required for TCVP since there were: (1) no treatment-related effects (no clinical signs) at doses up to and including the limit dose of 1000 mg/kg/day in the dermal toxicity study; (2) both RBC and brain cholinesterase activity were assessed in the dermal study and neither compartment was affected at the limit dose; and (3) no quantitative susceptibility was observed for juvenile or gestational life stages in the developmental, reproductive, or CCA toxicity studies. Despite the determination of the lack of non-cancer dermal hazard for TCVP, dermal exposures from TCVP must be quantified for the purpose of cancer risk assessment. Because the cancer assessment is based on an oral study, a dermal absorption factor (DAF) of 3% was used in the route-to-route extrapolation. The DAF is based on the results of human *in vitro* data.

For assessing all TCVP uses, which include food uses for which tolerances are necessary, EPA has determined that the FQPA safety factor (SF) of 10X should be retained to address uncertainties in the dose-response relationship for neurodevelopmental effects for the OPs in infants, children, and women of childbearing age for all residential exposure scenarios. The FQPA safety factor does not apply when assessing pet uses on their own, but EPA is applying an equivalent 10X uncertainty factor for pet uses alone for the same reasons as the Agency is applying the FQPA safety factor for the consideration of all uses – including food uses – for TCVP registration review under FIFRA § 3(g). As the current assessment of pet uses for the purposes of this Petition Response was done in conjunction with all other uses of TCVP in the DRA for the purposes of registration review of TCVP, the DRA (and thus the current assessment

of pet uses) uses the terminology of the “FQPA SF.” *See also* footnotes 4 and 25 of this document.

For the non-cancer residential incidental oral exposures, the level of concern (LOC) is 1000 (*i.e.*, risk estimates are not of concern when the margin of exposure (MOE) is \geq the LOC) which includes a 10X uncertainty factor for interspecies extrapolation, a 10X uncertainty factor for intraspecies variation, and a 10X FQPA Safety Factor. For the non-cancer residential inhalation exposures, the LOC is 300 which includes a 3X uncertainty factor for interspecies extrapolation, a 10X uncertainty factor for intraspecies variation, and a 10X FQPA safety factor. The interspecies extrapolation factor for the inhalation route has been reduced from 10X to 3X because the reference concentration (RfC) methodology for inhalation has been used to determine a human equivalent concentration (HEC) and takes into consideration the pharmacokinetic differences between animals and humans.

B. Residential Handler Exposures

In the October 2022 revised residential exposure assessment, EPA identified that there is the potential for residential exposures from the use of TCVP pet products. Residential handler exposures to TCVP pet products may occur via the dermal or inhalation routes while the product is placed on a cat or dog. A steady-state non-cancer residential handler exposure assessment (inhalation only; no non-cancer dermal endpoint) was performed for homeowners applying TCVP products to cats and dogs. In addition, a residential handler cancer assessment was conducted due to TCVP being classified as a Group C possible human carcinogen with a linear low-dose approach for quantification of risk using the oral slope factor (Q1*) of 1.83×10^{-3} (mg/kg/day)⁻¹.

1. Residential Handler Assumptions and Inputs

Application Rates for All Pet Uses: The following provides a summary of the application rates per type of TCVP pet use.

For TCVP liquid sprays (trigger and pump spray products), all registered products direct the user to apply a specific number of “strokes” per animal size (*i.e.*, how many times should the product be sprayed over the animal). In order to determine the amount of a.i. applied per treatment as specified by number of strokes, EPA requested additional information and received data from Hartz. Hartz provided information regarding the total volume of product released per stroke for pump and trigger spray products: 0.19 and 0.93 grams, respectively. Only trigger spray products are available for dogs; however, both pump and trigger spray products are available for cats. Additionally, in 2014, EPA approved an amendment for the Hartz’s product label of EPA Registration No. 2596-140 that now includes a recommended number of strokes per animal size. Previously, the label did not specify a number of strokes per cat/dog. The recommendation of strokes provided a range for the assessment, assuming that the user follows the label.

For pet collars, the application rates used in risk assessments typically represent the maximum amount of a.i. that could be applied by weight of the treated animal (small, medium, and large). This is only possible when the product is manufactured for use, or is labeled specifically, for different animal weight ranges. If EPA does not have this information, a number of assumptions are used (as described in HED's 2012 Residential SOPs (Treated Pets SOP)). The majority of pet collar formulations are registered as a single collar for use on all animal weight ranges; this is the case for TCVP (*i.e.*, the collars being assessed do not have separate registrations for different animal sizes). These collars have been assumed for use on different weight ranges as specified in the Residential SOPs which include:

- Cats – Small (up to 5 lbs), Medium (6 to 12 lbs), Large (13 lbs and up).
- Dogs - Small (up to 20 pounds), Medium (21 to 50 lbs) and Large (51 lbs and up).

While the pet collar product labels recommend trimming of the pet collar after it is applied to the animal, this would not apply to a handler since they would be exposed to the full length of the collar during application. Therefore, while the product label directions for trimming of the collar was accounted for in the residential post-application exposure calculations as described in Section C below, it was not accounted for in the residential handler exposure calculations.

Pet Collar Formulation: As already noted, there are no exposure data specific to pet collars. EPA has exposure data representative of either liquid formulations or dust formulations. These data indicate that there is higher potential exposure from dust products than liquids products. Per EPA's 2012 Residential SOPs³³, pet collar products are assessed as a liquid formulation (*i.e.*, using inputs and assumptions reflective of liquid formulations) because collar-specific exposure data are not available. However, in NRDC's opening brief on its Petition for Review of EPA's 2014 denial of NRDC's 2009 petition, the NRDC asserted that EPA incorrectly considered the TCVP pet collar formulation to be a liquid formulated product noting that a label for a TCVP pet collar product states that "as the collar begins to work, a fine white powder will appear on the surface." This statement on the label came after the instructions for the user to unroll and stretch the collar to activate the insecticide generator. HED reviewed this information and agreed that exposure to the a.i. as a dust/solid formulation could occur. Due to the uncertainty associated with pet collar formulation type, and without chemical- or product-specific data, HED's standard approach is to assess a range of ratios to cover the range of potential exposures (e.g., 99%/1%, 1%/99%, 50%/50% dust to liquid). This is consistent with the approach taken for TCVP in the 2016 DRA.³⁴

In order to determine the maximum amount of dust that could be released from collars, HED requested a "dust torsion" study for TCVP pet collars to refine those ratio assumptions. In

³³ Available at <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

³⁴ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0054>.

dust torsion studies, pieces of the pet collar are subjected to mechanical torsion and stress by twisting and pulling multiple times at 180° angles to maximize any potential release of solids from the collar. The torsion of the collar is meant to exaggerate the typical or expected movement of the collar during activation and during use in order to give an upper bound estimate of the amount of dust that could be produced.

EPA issued a DCI³⁵ to Hartz on June 3, 2019, requiring a mechanical torsion study in order to resolve the remaining uncertainty regarding the collar formulation. The DCI specified that “A protocol must be submitted to the Agency for review and approval prior to study inception.” However, Hartz did not submit a protocol for review before conducting the torsion study and instead only submitted the final study report on August 28, 2019 (MRID 50931601).

The study was conducted by measuring the “mass lost” from the collar by gravimetric measurement of the collar weight before and after torsion, as well as measuring TCVP via chemical analysis of wipe samples taken after each of three torsion cycles of ten twists. HED had initially focused on the change in collar weight from the study and assumed it could provide an approximation of dust released from the collar that could be used in the pet collar exposure calculations, which assume some portion of exposure is attributable to liquid TCVP and some portion of exposure is attributable to dust TCVP. This study was originally reviewed in 2019.³⁶ The study was initially found to be acceptable for use in risk assessment and a value of 0.38% dust was used in the TCVP pet collar exposure calculations based on the change in collar weight before and after the three torsion cycles.

Upon re-evaluation, HED identified concerns with the methodology used in the torsion study and whether it adequately provides information about the dust/liquid ratios that should be used to assess the collars. HED prepared a revised DER³⁷ which provides a detailed explanation of those concerns and reclassifies the study as unacceptable for the purpose of providing information on the liquid-to-dust ratio of TCVP flea and tick collars. As a result, the current assessment continues to use the approach taken in the 2016 risk assessment, using three ratios of liquid- to-dust (99%/1%, 1%/99%, 50%/50% dust to liquid) to assess the pet collar uses. As noted above, Hartz is currently working on two studies that EPA will review when they are made available. These data are being submitted to address the dust/liquid formulation uncertainty and will be used to reassess risks to people applying pet collars, and to people exposed through contact with the pet after the collar has been applied.

Unit Exposures for all Pet Uses: Unit exposures (UEs) are a ratio, for a given formulation and application equipment, of an individual’s exposure to the amount of a.i. handled, expressed as mass a.i. exposure per mass a.i. handled (e.g., mg exposure/lb a.i. handled).

³⁵ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0078>.

³⁶ Available at <https://www.regulations.gov/docket/EPA-HQ-OPP-2009-0308>.

³⁷ Available at <https://www.regulations.gov/docket/EPA-HQ-OPP-2009-0308>.

For TCVP liquid spray products, chemical-specific UE data are not available. In the absence of that, the Agency used UE values from the 2012 Residential SOPs as a surrogate to estimate handler exposures. Surrogate UE data for a groomer trigger pump spray application to dogs was used to estimate handler exposures from TCVP pump spray products.

For TCVP pet collars, chemical- and collar-specific UE data are not available. In order to assess exposure to a liquid formulation, exposure data for spot-on applications (as provided in the 2012 Residential SOPs) were used as surrogate data. Using the available spot-on data, the dermal UE is 120 mg/lb a.i. and there is no inhalation UE as inhalation exposure from the application of spot-on products is considered to be negligible. In order to assess exposure to a dust formulation, EPA used a TCVP-specific dust/powder applicator study (MRID 45519601). For the dust data, the dermal UE is 1,700 mg/lb a.i. and the inhalation UE is 3.1 mg/lb a.i. Incorporation of exposure to a dust in the pet collar handler calculations results in a higher potential exposure due to the higher UEs associated with dusts vs. liquids.

As noted earlier, for pet collars, HED has been conducting assessments assuming the a.i. is present as both solid and liquid forms concurrently, using both the liquid and dust UEs for handlers. Due to the uncertainty associated with pet collar formulation type, and without chemical-specific data, HED typically assumes a range of ratios to cover a range of potential exposures (e.g., 99%/1%, 50%/50%, and 1%/99% dust/liquid). This approach was taken for TCVP in the 2016 ORE assessment. The current assessment continues to use the approach taken in the 2016 risk assessment, using three ratios of liquid-to-dust (e.g., 99%/1%, 1%/99%, 50%/50%) to assess the pet collar uses.

Amount Handled: Per the Agency's 2012 Standard Operating Procedures (SOPs) for Residential Pesticide Exposure Assessment,³⁸ it is assumed that residential handlers of pet treatment products will treat two animals per application.

Exposure Duration: Residential handler exposure is expected to be short-term in duration. Intermediate- and long-term exposures are not likely because of the intermittent nature of applications by homeowners. However, because of the steady state AChE inhibition exhibited by the OPs, steady state exposures (typically 21 days and longer for OPs, but 1 day for TCVP) were assessed and presented for residential exposures to TCVP pet products.

Days per Year of Exposure: For the purpose of assessing residential handler cancer exposure/risk from TCVP product application, EPA has assumed four days per year for collars, and six days per year for dusts/powders and liquid sprays. The collar is based on a worst-case assumption of a single application every three months. Collar re-treatment intervals range from three to seven months. EPA assumed a bi-monthly re-treatment interval for dusts/powders and liquid sprays.

³⁸ Available at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

Years per Lifetime of Exposure and Lifetime Expectancy: It is assumed that residential handler exposure would occur for 50 years out of a 78-year lifespan. This factor is routinely used as a conservative estimate of the number of years an individual could continually use a single pesticide product. Life expectancy values are from the Exposure Factors Handbook 2011 Edition Table 18-1.³⁹ The table shows that the overall life expectancy is 78 years based on life expectancy data from 2007. In 2007, the average life expectancy for males was 75 years and 80 years for females. Based on the available data, the recommended value for use in cancer risk assessments is 78 years.

2. Residential Handler Risk Estimates and Conclusions

Liquid Sprays: No non-cancer inhalation risk estimates of concern were identified for residential handlers for the TCVP pet liquid spray formulations (all MOEs \geq level of concern (LOC) of 300). Inhalation MOEs range from 8,900 to 120,000 (LOC = 300). Residential handler cancer risk estimates for TCVP liquid sprays range from 10^{-8} to 10^{-9} which are not of concern.

Pet Collars: No non-cancer inhalation risks of concern were identified for residential handlers for any liquid-to-dust ratio assumption (all MOEs \geq level of concern (LOC) of 300). As noted above, incorporation of exposure to a dust in the pet collar handler calculations results in a higher exposure and ultimately a higher risk; therefore, the risk estimates when assuming a higher percentage of dust are higher (*i.e.*, have lower MOEs) than the risk estimates when assuming a lower percentage of dust. When assuming a ratio of 99%/1% dust/liquid, MOEs range from 1,900 to 4,700; when assuming a ratio of 50%/50% dust/liquid, MOEs range from 3,800 to 9,400; and when assuming a ratio of 1%/99% dust/liquid, MOEs range from 190,000 to 470,000.

Similar to the non-cancer risk estimates, for the pet collar cancer risk estimates, incorporation of exposure to a dust in the handler cancer calculations results in a higher exposure and ultimately a higher cancer risk; therefore, the cancer risk estimates when assuming a higher percentage of dust are higher than the cancer risk estimates when assuming a lower percentage of dust. Residential handler cancer risks (combined dermal and inhalation) estimated for TCVP pet collars assuming a ratio of 99%/1% dust/liquid range from 10^{-7} to 10^{-8} ; assuming a ratio of 50%/50% dust/liquid are all 10^{-8} ; and when assuming a ratio of 1%/99% dust/liquid range from 10^{-8} to 10^{-9} , which are not of concern.

A complete listing of all MOEs can be found in Tables G.1c and G.2 of the October 2022 revised human health risk assessment. A complete listing of all residential handler cancer exposure and risk estimates can be found in Tables H.1 and H.2 in the October 2022 revised human health risk assessment.

³⁹ Available at <https://www.epa.gov/sites/production/files/2015-09/documents/efh-chapter18.pdf>.

C. Residential Post-Application Exposure

In the October 2022 revised human health risk assessment, EPA identified that there is the potential for post-application exposure for individuals exposed as a result of contacting a cat or dog previously treated with TCVP pet products. A steady state non-cancer residential post-application exposure assessment (incidental oral only ((i.e., hand-to-mouth exposure); no dermal POD selected)) was performed for individuals coming into contact with treated cats and dogs. Since there is no non-cancer dermal hazard for TCVP, a quantitative non-cancer post-application dermal exposure assessment was not performed for adults or children. Residential post-application inhalation exposure is expected to be negligible from TCVP pet products and, thus, a quantitative assessment was not performed. Per the Residential SOPs, the combination of low vapor pressure (2.6×10^{-7} mmHg at 25°C) and the small amounts of pesticide applied to pets is expected to result in negligible levels of chemical in the air, and therefore negligible inhalation exposures. In addition, a residential post-application cancer assessment was conducted due to TCVP being classified as a Group C possible human carcinogen by the Agency with a linear low-dose approach for quantification of risk using the oral slope factor (Q1*) of 1.83×10^{-3} (mg/kg/day)⁻¹.

1. Residential Post-application Assumptions and Inputs

Application Rate for all Pet Uses: The application rates used in the assessment of pet products typically represent the maximum amount of a.i. that could be applied by weight of the treated animal (small, medium, and large). However, this is only possible when the product is manufactured for use, or is labeled specifically, for different animal weight ranges. If this information is not provided, a number of assumptions are used which are described in HED's 2012 Residential SOPs (Treated Pets SOP).

For pet collars, the maximum amount of a.i. that could be applied is more complicated to determine since all of the a.i. in a collar is not available immediately for post-application exposure. Collars are designed to provide a slow release of the a.i. In many cases, however, when doing a post-application assessment, the amount of a.i. released is unknown; therefore, the application rate is assumed to be the total a.i. in the collar. This does not overestimate exposure, however, because when calculating post-application exposure, EPA adjusts the application rate by a transfer factor to account for the fraction of the application rate that is available to transfer to a person (this factor is described in more detail below). This transfer factor is determined by dividing the amount of residue on a gloved hand after petting or stroking a treated animal and comparing it to the total amount of a.i. applied. Therefore, when calculating exposure, the assumption is that a person is potentially exposed to a fraction of the total a.i. This fraction is discussed in more detail below (*Transfer Data for Non-Cancer and Cancer Assessment*).

For TCVP pet collars, the labels direct users to cut off and dispose of any excess length once the product is fit and buckled into place. Since the application rate for pet collars is

calculated as the total amount of a.i. in the collar (which is the total weight of the collar multiplied by the % a.i.), a trimmed collar would represent a lower amount of a.i. applied to the animal, and therefore, a lower potential for exposure. In the 2012 Treated Pet SOP, it is recommended that the full length of the collar be assumed in pet collar post-application assessments, since, at the time, data were not available to inform the exact length that is cut off; therefore, the corresponding a.i. loss could not be quantified. However, the 2012 Residential SOPs allow for use of other relevant information pertinent to the pesticide under examination when assessing risks. In the 2016 assessment, HED assessed post-application exposure to the TCVP pet collars assuming the full collar length. In 2020, Hartz informed HED that a submitted efficacy study could provide information on collar trimming (MRID 51079501⁴⁰) and HED used this information to refine the post-application pet collar assessment⁴¹. In the efficacy study, a total of 63 dogs (range in weight of 11 to 22 kg) and 16 cats (range in weight of 2.35 to 3.87 kg) were included in the data summary. The weights of the collars were provided, including the pre-cut weight, the weight of the cut-off piece, and the weight of the fitted collar. The percent of collar removed was calculated by taking the weight of the cut-off piece and dividing by the weight of the pre-cut collar. The percent of the collar removed ranged from 20% to 43% for dogs, and from 18% to 38% for cats. In order to provide a conservative assumption of how much collar might be removed during use, HED chose a value of 20% to adjust the post-application application rate for pet collars.

Since the 2020 assessment, HED has identified additional collar trimming information in studies submitted for registration of pet collars. This new information comes from eight additional studies and provides 237 data points for dogs and 123 data points for cats, covering a wide range of animal breeds and weight ranges, as well as various types of collars representing multiple active ingredients, including TCVP. The studies include information on the collar weight before use, and the collar weight after it is trimmed to fit the animals in the studies, thereby providing information on the total amount of the collar that is typically trimmed during use. It is acknowledged that these are laboratory studies; however, this information is still considered relevant to residential post-application exposure assessment since the studies are meant to mimic typical use to provide relevant data for product registration. The product label directions are closely followed in these studies to ensure the data are representative of expected real-world usage. In addition, while laboratory studies can typically be conducted using similar sized animals (*e.g.*, beagles are typically chosen for laboratory studies), the studies included in this analysis provide a wider range of animal breeds (for both dogs and cats) and size ranges to ensure the data are as representative as possible.

These data have been reviewed, and updated factors to account for trimming of pet collars after application have been identified as a refinement for the pet collar post-application assessment in cases where the product label directs users to trim the collar. A review of these

⁴⁰ MRID 51079501. *Efficacy and Repellence of Ectoparasitocidal Treatments Against Ticks (Dermacentor Variabilis, Ixodes Scapularis, Rhipicephalus Sanguineus), Fleas (Ctenocephalides Felis) and Mosquitos (Aedes Aegypti) on Dogs.* May 7, 2019. Table 4 (p. 37 – 39).

⁴¹ Available at <https://www.regulations.gov/docket/EPA-HQ-OPP-2009-0308>

data is provided in “*Pet Collar Trimming Factor for Use in Exposure and Risk Assessments: A Refinement of the Treated Pet SOP*”⁴² and a summary of the recommendations is provided below. The range in weights of the dogs in the studies ranged from 13 to 75 pounds, and there was a clear difference in the amount of collar trimmed for small (up to 20 pounds), medium (21 to 50 pounds) and large (greater than 50 pounds) dogs. For small dogs more collar was trimmed than for medium dogs, and more collar was trimmed for medium dogs than for large dogs. For this reason, different trimming assumptions are recommended for different sized dogs based on an analysis of the data for each size range. A value that would be protective of the trimming data for that specific size range was chosen. For cats, the range in weight of the animals in the studies was smaller and only ranged from five to around 13 pounds. Across the different cat weights/sizes, there was not a clear difference in the amount of collar trimmed; therefore, a single trimming assumption is recommended for all size cats that is protective of all the cat trimming data for all the cat sizes. In addition, it is acknowledged that for some larger dogs and cats, it may be the case that the collar cannot, or does not need to be, trimmed (*i.e.*, the entire collar is applied to the dog or cat). This may be the case for larger breeds (e.g., dogs weighing more than 80 pounds and cats weighing more than 20 pounds). For those larger breeds, the recommendation is to conduct an assessment using an appropriate surface area for that animal weight range and assume no trimming of the collar.

- Dogs:
 - For small dogs (up to 20 pounds according to the 2012 Residential SOPs): assume 30% of the collar is trimmed
 - For medium dogs (21 to 50 pounds according to the 2012 Residential SOPs): assume 20% of the collar is trimmed
 - For large dogs (51 pounds and up according to the 2012 Residential SOPs): assume 15% of the collar is trimmed
 - For extra-large dogs (80 pounds and up), assume no trimming of the collar
- Cats:
 - For all sizes: assume 5% of the collar is trimmed
 - For extra-large cats (20 pounds and up), assume no trimming of the collar

Accounting for the percentage of the pet collar removed is believed to better represent typical usage of the product as it is fit to the treated animal. These assumptions are protective of the majority of the cat and dog collar data, and provide reasonable, conservative assumptions for how much of the collar may be trimmed during typical use.

Pet Contact/Transfer Coefficients: For the purpose of determining exposure to treated pets, the 2012 Residential SOPs make use of transfer coefficients (TCs). TC is an exposure rate for a selected activity which involves contact with a source, such as adults or children playing with treated pets or on treated turf. The TC concept is a long-standing established approach used to estimate residential, as well as occupational, exposures after treatment has occurred (*i.e.*, post-

⁴² Available at <https://www.regulations.gov/docket/EPA-HQ-OPP-2009-0308>.

application) and is the basis for the Agency's post-application exposure guidelines.⁴³ A TC, with units of cm^2/hour , is derived by taking the ratio of a study volunteer's dermal exposure per unit time (mg/hr), and the concurrent measure of residue available for transfer (mg/cm^2). Ideally, dermal exposure is based on activities representative of the use pattern, and residue transfer is determined concurrently by use of an established method specific to the use pattern. For pet product exposure assessments, TCs can be defined as animal surface area contact per unit time (cm^2/hour).

Currently, there is no exposure study available representing typical adult and child activities with pets and a concurrent transferable residue (TR) measure (*i.e.*, there are no TC studies available that represent pet owner activities with a treated pet). As noted in the 2012 Residential SOPs⁴⁴, there are groomer studies available conducted to monitor exposure during pet grooming activities. These studies are likely to result in a highly protective estimate of exposure per hour relative to exposure per hour associated with petting, hugging, or sleeping with a pesticide-treated pet since groomers directly handle pesticide products and have direct contact with treated pets. These pet grooming exposure studies have been submitted to the Agency, reviewed and determined to be acceptable for risk assessment.

In the groomer studies, human volunteers applied dust/powders or shampoo products to various dogs of differing sizes and fur lengths. As noted above, since the groomers extensively handled the dogs, it is expected that their resulting exposures are higher than would be reasonably anticipated from routine contact with treated pets by pet owners. The volunteers in the shampoo study, who were professional groomers, shampooed eight dogs for five minutes each, rinsed, and lifted them to counters for drying and combing. In the dust study, volunteers applied dust via shaker can to eight dogs each and then rubbed the dusts into the dogs' coats.

Both of these studies provide a measure of exposure (mg/hour), but do not provide a measure of concurrent TR (mg/cm^2) which is necessary to determine a TC. Therefore, in order to calculate a TC, the TR had to be estimated for the groomer studies. This can be done by multiplying the application rate in the studies by the fraction of a.i. available for transfer (*i.e.*, F_{AR}). The F_{AR} value comes from available transferable residue studies that measure how much residue is available for transfer and compare that to the application rate. An F_{AR} for pet products was calculated using eight available pet residue transfer studies for a variety of liquid pet products. The F_{AR} in these studies was determined by measuring the amount of residue on a gloved hand after petting or stroking the treated animal and comparing it to the total amount of a.i. applied. The average F_{AR} from all available studies was 0.0096 (*i.e.*, an average of 0.96% of the application rate applied is expected to transfer). Therefore, to estimate the transferable residue in the groomer studies, the application rate in those studies was multiplied by 0.0096. The resulting value was assumed to be the residue available for transfer and was used with the exposure value to calculate a TC for liquid and solid formulations.

⁴³ Available at <http://www.ecfr.gov/cgi-bin/text-idx?SID=6bfd4539761be8d5b20dfbf6bc19b9d0&node=40:25.0.1.1.9.9&rgn=div6>

⁴⁴ https://www.epa.gov/sites/production/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf

The 2012 SOPs recommend use of two different TCs dependent on the pet product formulation. One set of TCs are for liquid formulations [5,200 cm²/hour for adults and 1,400 cm²/hour for children (1 to <2 years old)] and the other set of TCs are for dust formulations [140,000 cm²/hour for adults and 38,000 cm²/hour for children (1 to <2 years old)].

For the liquid spray formulations, the liquid TCs were used to estimate post-application exposure.

For the pet collars, both the liquid and dust-specific pet product TCs were used to assess post-application exposure. As was mentioned above, due to the uncertainty as to the ratio of liquid-to-dust in the formulated pet collars, residential post-application exposures were evaluated assuming TCVP is simultaneously released at varying ratios of liquid-to-dust (*e.g.*, 99%/1%, 50%/50%, and 1%/99% dust/liquid), using both the liquid and dust TCs. Similar to handlers, incorporation of exposure to a dust in the pet collar post-application calculations results in much higher potential exposure due to the higher TCs associated with dusts vs liquids. In addition, for calculation of incidental oral (*i.e.*, hand to mouth exposures), the fraction of a.i. on the hands from the formulation-specific transfer coefficient studies are used (*e.g.*, 4% for liquid formulations and 37% for dust formulations) as recommended in the 2012 Residential SOPs.

Exposure Time: The exposure time (ET) assumption used to assess residential post-application exposure to TCVP pet products is based on the 2012 Residential SOPs. The value is derived from a study which sought to evaluate the times that individuals spend performing different activities around the home. Based upon the 2012 Residential SOPs, the point estimates recommended for adult and child ET with pets are 0.77 and 1 hours, respectively. In the study, animal care is defined as “care of household pets including activities with pets, playing with the dog, walking the dog and caring for pets of relatives, and friends.” The data identified the time spent with an animal while performing household activities as recorded in 24-hour diaries by study volunteers. While the activities defined do not necessarily represent the time volunteers were actively engaged in constant contact with the animal as is implicit in the post-application dermal and incidental oral algorithms, the data are the most accurate representation of time spent with pets available and, therefore, it is assumed that contact is continual throughout the timed activity. The Agency assumes the ET value reflects a reasonable high-end estimate of time spent in contact with a dog treated with TCVP pet products.

When use of the study data is coupled with high-end assumptions of pet contact, the result is an exposure assessment that inherently implies vigorous, continual contact for the entire duration of contact. While it is possible that an adult or child may be in close contact with a pet intermittently throughout the day, they would not be actively engaged in the highly vigorous contact implied by use of the TCs based on the applicator exposure data for the full exposure duration assumed. Further, it is possible that adults or children may be exposed from sleeping with a treated pet; however, they are not actively engaged in a high level of contact, or the

repeated mouthing behaviors exhibited by children during waking hours, which are inherently assumed in the assessment conducted.

Transfer Data for the Non-Cancer Assessment: Chemical-specific residue transfer studies were used for assessment of post-application exposures from registered TCVP pet products. As noted above, residue transfer studies provide an estimate of the fraction of the a.i. available for transfer (i.e., F_{AR}), also referred to as the transfer factor. The transfer factor is determined by measuring the amount of residue on a gloved hand after petting or stroking the treated animal and comparing it to the total amount of a.i. applied.

For liquid sprays, HED relied on a TCVP-specific residue transfer study (MRID 45485501). In 2014, in support of the Agency's response to the NRDC Petition, the study was reevaluated based on current standards of conduct for pet residue transfer studies⁴⁵. For the purposes of the non-cancer assessment for liquid sprays, a transfer factor of 0.81% (maximum observed) was used to estimate the transferable residue on the day of application (Day 0).

For pet collars, HED has relied on two TCVP-specific residue transfer studies. The first is a literature study⁴⁶ (Davis *et al.*), which was originally used in the December 2016 risk assessment, and the second is a TCVP pet collar residue transfer study submitted by Hartz in 2019 (MRID 50881801⁴⁷). In the 2016 TCVP risk assessment, a transfer factor of 0.3% (based on a study conducted for 12 days) was used from the Davis study for the non-cancer assessment, which reflected the potential transfer of residues to gloved hands after individuals continuously rubbed for five minutes over the neck of a dog including across the collar and along the tail region. After subsequent review of the methodology used to collect the residues, HED determined that this approach (rubbing continuously over the neck/collar) would likely result in an overestimate of transferable residue because of the repeated intentional high level of contact with the collars. As a result, the transfer factor was revised to reflect the potential transfer of residues after individuals continuously rubbed for five minutes over the neck of the dog with the collar removed for sampling (see further description below) and along the tail region which reduced the factor to 0.17%. This value closely aligns with the value identified from the 2019 TCVP pet collar residue transfer study which was conducted according to current practice for generating these types of data (i.e., with petting strokes conducted on the right side, on the left side, and along the back line of the dog).

Davis Study Residue Transfer Factor: In the 2016 risk assessment for TCVP, it was noted that the petting/rubbing method used in this study was not conducted based entirely upon current practice for studies of this type; however, the methodology was relevant for the time at which it was conducted, and it was deemed adequate for risk quantitation. Upon comparison of

⁴⁵ Britton, W. 2014. Tetrachlorvinphos: Reevaluation of "HED's Review of *Determination of the Dislodgeability of Tetrachlorvinphos (TCVP) from the Fur of Dogs Following the Application of an Insecticide Powder, Pump Spray or Aerosol*;" MRID 45485501. 5/16/14. D420285.

⁴⁶ Davis, M. et. al., *Assessing Intermittent Pesticide Exposure from Flea Control Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos*. Journal of Exposure Science and Environmental Epidemiology. (2008) 18, 564-57). D430707

⁴⁷ D453149. TCVP: Review and Summary of Residue Transfer Studies Submitted. MRID 50881801.

the Davis study data and the submitted TCVP transfer study (which was conducted according to current practice), HED reevaluated the methodology used in the Davis study; specifically, the information provided in the literature study regarding how the petting simulations were conducted. The study authors describe that dogs were petted by volunteers *continuously for a five-minute period* with cotton gloves. Transferable residue (petting/rubbing) samples were collected 1) from the fur of the neck (after application of the collar and rubbing over the collar), 2) from the fur of the neck (after application of the collar and then removal of the collar for sampling), and 3) along the back in the tail region after application of the collar, during two studies; the first study was conducted for 112 days and the second study was conducted for 12 days. Dogs wore the collars continuously throughout the study, but on sampling days, residue transfer was determined with continuous petting over the neck with the collars present for 5 minutes, and then continuous petting over the neck with the collars removed for 5 minutes. Collars were placed back on the dogs after each sampling event.

In the 2016 risk assessment, HED had relied on residues collected in the Davis Study from the fur of the neck (after application of the collar and rubbing over the collar) and from the tail region. The transferable residues collected from the fur of the neck (after application of the collar and then removal of the collar for sampling) were not included since it was thought that the collection of those residues was not consistent with the current practice for pet fur transfer residue studies. Current practice involves petting over the pet collar, assuming that the pet collar is secured in place as directed by product labeling. However, while the petting strokes should not take into account the location of the collar (*i.e.*, the petting should not intentionally avoid the collar), they should begin from the head/neck and end at the tail (*i.e.*, the petting stroke should not be limited to just over the neck and collar in the head/neck area). Therefore, it has been determined that the sampling in the Davis Study that involved continuous rubbing over the neck and collar for five minutes likely overestimated the potential transferable residue from typical contact with a pet or what would be expected to be measured following current practice. HED has determined that the residues collected from the fur of the neck (after application and then removal of the collar for sampling) likely do not underestimate exposure considering the continuous rubbing methodology that was followed. Therefore, for the current exposure assessment for pet collars, HED has updated the calculation of the fraction transferred value by dividing the sum of the residues measured from the fur of the neck (after application of the collar and then removal of the collar for sampling) and from the back in the tail region by the amount of a.i. in the pet collar (as reported in the Davis Study), 4,800 mg. The fraction transferred proposed for non-cancer post-application risk assessment, therefore, is 0.0017 (0.17%), and is based on the mean residues reported from the 12-day study [where $(8 \text{ mg} + 0.08 \text{ mg}) / 4,800 \text{ mg} = 0.0017$]. Upon reevaluation, HED has determined that the Davis Study fraction transferred and the fraction transferred determined from MRID 50881801 transfer study (described below) are similar.

MRID 50881801 Residue Transfer Factor: The Hartz Mountain Corporation submitted a TCVP-specific residue transfer study for pet collars in 2019 (MRID 50881801). The purpose of the study was to measure the transferability of the test substance, TCVP, from the hair of a dog

wearing a TCVP-impregnated collar. Each collar contained 14.55% TCVP (TCVP weight/collar weight). A total of 9 dogs were used in the study, randomly assigned to 3 groups. Dogs in Group 1 were petted for 5 simulations, dogs in Group 2 received 10 petting simulations, and dogs in Group 3 received 25 petting simulations. Each simulation consisted of three strokes conducted using a mannequin hand fitted with three cotton gloves. The first stroke was on the right side, the second on the left side, and the third was along the back line. Percent transferable residues of TCVP were calculated by either taking (1) the ratio of the residues of TCVP observed on the glove to the total amount of TCVP in the collar at application or (2) the ratio of the residues of TCVP observed on the glove to the applied TCVP dose. In the current TCVP pet collar post-application calculations, as noted above, the application rate is calculated as the total amount of a.i. in the collar. Therefore, the percent transferable residue relative to the total amount of TCVP in the collar (option #1 above) was used in the calculations. The average percent transferable residues of TCVP relative to the total amount of TCVP in the collar at application were 0.098% for Group 1 (5 petting simulations), 0.086% for Group 2 (10 petting simulations), and 0.20% for Group 3 (25 petting simulations). For the purpose of non-cancer post-application risk assessment, only the results from group 3 were used since that group used 25 petting simulations, which most closely compares with the current methodology recommendation, which is 20 petting simulations.

Since both studies are representative of potential exposure to currently registered TCVP pet collars and provide similar estimates of fraction transfer (0.17% and 0.20%), the higher value of 0.20% was used in the risk assessment.

Exposure Duration: Residential post-application exposure is expected to be short- and intermediate-term for liquid sprays. For pet collars, post-application exposures are expected to be long-term (greater than 6 months) due to the potential for extended usage in more temperate parts of the country, and the longer active lifetime of pet collar products. Again, because of the steady state AChE inhibition exhibited by the OPs, steady state exposures (typically 21 days and longer for OPs, but 1 day for TCVP) were assessed and presented for residential exposures to TCVP pet products.

Transfer Data for the Cancer Assessment: For purpose of quantification of estimated TCVP post-application cancer exposures/risks, HED used an average transfer factor from the TCVP liquid spray studies. HED used an average of the maximum observed percent residue transfer for each day tested for calculation of cancer exposures/risks resulting in a fraction transferred of 0.18% for liquid sprays.

For the assessment of pet collar cancer post-application risks, longer-term residue transfer values from the Davis study (112 days) were used to best represent the assumption of 180 days/year exposure for cancer assessment. As noted above for the non-cancer estimate, HED had previously included the residues from the fur of the neck with the collar present in the calculation of the fraction transferred. Updated calculations of the fraction transferred used for cancer post-application risk assessment was also conducted, resulting in a revised fraction

transferred of 0.00092 (0.09%), which is based on the mean residues (112 days) reported from the Davis study [where $(4.3 \text{ mg} + 0.13) / 4,800 \text{ mg} = 0.00092$].

Days per Year of Exposure: For the purpose of estimating adult dermal cancer risks, exposure was assumed for 180 of 365 total days per year, approximately representing contact with pets every other day. This factor is used as a health protective estimate of the number of days that an individual could be exposed to a treated animal per year of product use. The recommendation of 6 months exposure is conservative, particularly when (1) paired with the assumption that this exposure duration is repeated for 50 years during an adult's lifetime knowing that pet products change over the years and whether someone owns a pet may also change over the years and (2) paired with the conservative transfer coefficients based on groomer/applicator studies.

Years Per Lifetime of Exposure and Lifetime Expectancy: It is assumed that residential post-application exposure would occur for 50 years out of a 78-year lifespan. This factor is routinely used as a conservative estimate of the number of years an individual could continually use a single pesticide product. Life expectancy values are from the Exposure Factors Handbook 2011 Edition Table 18-1⁴⁸. The table shows that the overall life expectancy is 78 years based on life expectancy data from 2007. In 2007, the average life expectancy for males was 75 years and 80 years for females. Based on the available data, the recommended value for use in cancer risk assessments is 78 years.

2. Residential Post-application Risk Estimates and Conclusions

Liquid Spray Products: EPA has determined that all residential post-application exposures resulting from liquid spray products are not of concern because the MOEs range from 1,600 to 15,000, well above the LOC of 1000. Residential post-application cancer risks estimated for TCVP liquid sprays range from 10^{-7} to 10^{-8} and are not of concern.

Pet Collars: For all three assumed liquid-to-dust ratios, residential non-cancer post-application incidental oral risks for children 1 to <2 years old are of concern (MOEs < LOC of 1000). When assuming a ratio of 99%/1% dust/liquid, MOEs range from 7 to 20; when assuming a ratio of 50%/50% dust/liquid, MOEs range from 14 to 40; and when assuming a ratio of 1%/99% dust/liquid, MOEs range from 500 to 1,500. Residential post-application cancer risks (adult dermal only) were also identified for all three assumed liquid-to-dust ratios; estimated cancer risks assuming a ratio of 99%/1% dust/liquid range from 10^{-5} to 10^{-6} ; assuming a ratio of 50%/50% dust/liquid from 10^{-5} to 10^{-6} , which are risks of concern. When assuming a ratio of 1%/99% dust/liquid are all 10^{-7} , which are not of concern.

A complete listing of all MOEs can be found in Tables I.1b and I.2 in the October 2022 residential assessment. A complete listing of all residential post-application cancer exposure and

⁴⁸ Available at <https://www.epa.gov/sites/production/files/2015-09/documents/efh-chapter18.pdf>

risk estimates can be found in Tables J.1b and J.2 in the 2022 revised residential exposure assessment.

A summary of the October 2022 residential risk estimates resulting from the registered TCVP pet products is provided in the table below. For a more detailed explanation of residential exposure from the use of pet products containing TCVP and the Agency's conclusions, please refer to the October 2022 assessment, entitled "*Tetrachlorvinphos (TCVP) Third Revision: Human Health Draft Risk Assessment for Registration Reviews*".

Table 1: Summary of TCVP Pet Product Residential Risk Estimates (from October 2022 assessment)¹					
Reg. No. (Target Animal)	Size of Animal	Residential Handler Non-cancer MOEs (LOC = 300)	Residential Handler Cancer Risk Estimates	Residential Post- application MOEs ² (LOC = 1000)	Residential Post- application Cancer Risk Estimates
<i>Pet Collars - 99% Dust / 1% Liquid</i>					
2596-49 (Cat)	Medium	4,100	7E-08	7	2E-05
	Large			11	1E-05
	Extra Large			13	8E-06
2596-50, 62 (Dog)	Small	3,500	8E-08	10	1E-05
	Large	1,900	2E-07	17	7E-06
	Extra Large			20	5E-06
2596-83 (Cat)	Medium	4,700	6E-08	8	2E-05
	Large	3,500	8E-08	10	1E-05
	Extra Large			11	1E-05
2596-84 (Dog)	Small	3,500	8E-08	10	1E-05
	Large	1,900	2E-07	17	7E-06
	Extra Large			20	5E-06
2596-139 (Cat)	Medium	4,700	6E-08	8	2E-05
	Large	3,500	8E-08	10	1E-05
				11	1E-05
2596-139 (Dog)	Small	3,500	8E-08	10	1E-05
	Medium	2,500	1E-07	14	8E-06
	Large	1,900	2E-07	17	7E-06
	Extra Large			20	5E-06
<i>Pet Collars - 50% Dust / 50% Liquid</i>					
2596-49 (Cat)	Medium	8,000	4E-08	14	8E-06
	Large			22	5E-06
	Extra Large			26	4E-06
2596-50, 62 (Dog)	Small	6,900	5E-08	19	6E-06
	Large	3,800	8E-08	33	3E-06
				40	3E-06
2596-83 (Cat)	Medium	9,400	3E-08	16	1E-05
	Large	6,900	5E-08	19	6E-06
	Extra Large			23	5E-06
2596-84 (Dog)	Small	6,900	5E-08	19	6E-06
	Large	3,800	8E-08	33	3E-06
	Extra Large			40	3E-06
2596-139 (Cat)	Medium	9,400	3E-08	16	1E-05

Table 1: Summary of TCVP Pet Product Residential Risk Estimates (from October 2022 assessment)¹					
Reg. No. (Target Animal)	Size of Animal	Residential Handler Non-cancer MOEs (LOC = 300)	Residential Handler Cancer Risk Estimates	Residential Post- application MOEs ² (LOC = 1000)	Residential Post- application Cancer Risk Estimates
	Large	6,900	5E-08	19	6E-06
	Extra Large			23	5E-06
2596-139 (Dog)	Small	6,900	5E-08	19	6E-06
	Medium	4,900	6E-08	28	4E-06
	Large	3,800	8E-08	33	3E-06
	Extra Large			40	3E-06
<i>Pet Collars - 1% Dust / 99% Liquid</i>					
2596-49 (Cat)	Medium	400,000	6E-09	500	7E-07
	Large			800	5E-07
	Extra Large			950	4E-07
2596-50, 62 (Dog)	Small	340,000	6E-09	700	5E-07
	Large	190,000	1E-08	1,200	3E-07
	Extra Large			1,500	3E-07
2596-83 (Cat)	Medium	470,000	5E-09	580	7E-07
	Large	340,000	6E-09	690	5E-07
	Extra Large			810	4E-07
2596-84 (Dog)	Small	340,000	7E-09	700	5E-07
	Large	190,000	1E-08	1,200	3E-07
	Extra Large			1,500	3E-07
2596-139 (Cat)	Medium	470,000	5E-09	580	7E-07
	Large	340,000	6E-09	690	5E-07
	Extra Large			810	4E-07
2596-139 (Dog)	Small	340,000	6E-09	700	5E-07
	Medium	250,000	9E-09	1,000	4E-07
	Large	190,000	1E-08	1,200	3E-07
	Extra Large			1,500	3E-07
<i>Application of TCVP Liquid Sprays</i>					
2596-126, -140 (Cat) (Trigger)	Small	25,000	8.6E-09	1,600	3.0E-07
	Large	18,000	1.2E-08	3,100	1.6E-07
2596-140 (Cat) (Pump)	Small	120,000	1.8E-09	8,000	6.2E-08
	Large	87,000	2.5E-09	15,000	3.2E-08
2596-125, -140 (Dog) (Trigger)	Small	18,000	1.2E-08	2,300	2.1E-07
	Medium	16,000	1.4E-08	4,800	1.0E-07
	Large	8,900	2.4E-08	4,300	1.2E-07

As indicated throughout section III, the evaluation of the potential residential post-application health risks from exposures to cats and dogs treated with TCVP pet products is conservative, as it incorporates a number of conservative exposure assumptions in the calculation of risk estimates. For pet collars, exposure data reflective of adults and/or kids playing with a pet treated with a pet collar are not available. The only exposure data available for pets represents 1) contact with either a liquid (shampoo product) or a dust (shaker can product); not a pet collar, and 2) commercial pet grooming, not routine at-home playing with the treated pet. Commercial pet groomers directly handle the pesticide product and have direct contact with the

treated pet as they are making the applications; therefore, their exposure potential is much greater than someone at home handling a pet after treatment, particularly with a collar which is specifically designed to be a slow release of the a.i. The exposure calculations also assume an adult and/or child is sustaining that high level of contact with their pet (*e.g.*, shampooing their pet or rubbing a dust product into their pet's fur) for up to an hour per day.

IV. Benefits and Impact Assessment of Cancellation of Dust Products and Select Collars

In considering the Petition to cancel TCVP pet products (dusts, collars, and liquid sprays), EPA assessed the benefits of TCVP pet collars, considering the availability of other pet products⁴⁹. EPA also considered the importance of TCVP dust and powder products in the control of pests that infest pets.

Pet Insecticide Usage

Table 2 below provides information on the sales of consumer market pet insecticides in 2011 and 2016. Based on available private market research, sales of consumer market pet insecticides in 2016 were approximately \$1.5 billion, a 25 percent increase over sales in 2011 of \$1.2 billion, unadjusted for inflation.⁵⁰ In 2016, the top pet insecticide formulation, in terms of sales, was liquid products, which represented more than 80 percent of the market, followed by tablets for veterinary use with 12.7 percent of sales.⁵¹ As a proportion of sales, collars have remained similar over time. As discussed below, collars tend to be cheaper and provide longer-lasting control than liquid sprays and 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.

Product Form	2011		2016	
	\$ million	percent	\$ million	percent
Liquids ¹	949.7	78.0	1,188.9	80.7
Tablets ²	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

Source: Kline and Company. 2012. Consumer Markets for Pesticides and Fertilizers 2011. [Accessed June 2020.]; Non-Agricultural Market Research Proprietary Data. 2016. Studies conducted and sold by a consulting and research firm. Report on consumer pesticide usage. [Accessed June 2020.]

¹ Includes shampoos, dips, and topical spot-ons.

² Veterinary supplied oral treatments.

⁴⁹ Atwood, D., and S. Smearman. 2017. Alternatives Assessment for Tetrachlorvinphos (TCVP) (PC Code 083702) Impregnated Flea and Tick Collars on Dogs and Cats. Available at <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0316>.

⁵⁰ Non-Agricultural Market Research (Proprietary) Data. 2016. Studies conducted and sold by a consulting and research firm. Report on consumer pesticide usage. [Accessed June 2020.]

⁵¹ *Ibid*

Based on preliminary private market research of sales of brands carrying the TCVP flea collars, sales were estimated to be slightly more than 50 percent of the total pet collar sales in the U.S. in 2018 (NMRD, 2019; Personal communication with C. Doucoure, Email dated 6/11/2020, may contain CBI). During the same period, TCVP flea powder sales based on the Hartz Flea and Tick Powder were estimated to be between \$3 to \$5 million. Thus, based on 2016 sales figures, TCVP products likely account for a majority of the usage of powder and dust products.

Collars

TCVP pet collars are a relatively low cost means of controlling fleas and ticks on companion animals. Alternative control mechanisms include collars formulated with other insecticides; liquid insecticides such as shampoos, sprays, and topical spot-ons; dusts; and veterinary medicines. Most of these products can provide similar levels of control of both fleas and ticks as the TCVP collars, although shampoos may not provide long-term control of ticks.⁵² Alternative pet collars for dogs and cats mostly contain a combination of flumethrin and imidacloprid. Deltamethrin collars are also available for dogs. There are also several liquid products that would provide similar efficacy, although retreatment is necessary to achieve the duration of control provided by a collar. These products often combine a pyrethroid, or similar chemical, with imidacloprid, indoxacarb, or pyriproxyfen.⁵³

Collars tend to provide six to seven months of control. Treatment with liquid products or veterinary medicines may need to be done monthly. A check of prices at several major pest supply stores in 2017 suggests that, when converted to unit cost per month, TCVP collars tend to be lower cost relative to other products.⁵⁴ However, several topical spot-on products containing etofenprox are available that may be within two or three dollars of the TCVP collars and would probably be the most likely alternatives. Spot-on products are less convenient because they must be reapplied about every month. Collars containing other insecticides would be as convenient as TCVP collars but may be \$30 to \$60 more expensive per collar or five or six dollars more expensive on a monthly basis. Veterinary medicines, which require a prescription, tend to be substantially more expensive as well as less convenient to obtain and use.⁵⁵

There could also be some short-term costs to consumers who rely on known brands and will have to research other products. These costs may be modest. According to the American

⁵² Atwood, D., and S. Smearman. 2017. Alternatives Assessment for Tetrachlorvinphos (TCVP) (PC Code 083702) Impregnated Flea and Tick Collars on Dogs and Cats. Biological and Economic Analysis Division, Office of Pesticide Programs, U.S. EPA. 27 pp. Sept 15. Available at <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0316>.

⁵³ *Ibid*

⁵⁴ Atwood, D., and S. Smearman. 2017. Alternatives Assessment for Tetrachlorvinphos (TCVP) (PC Code 083702) Impregnated Flea and Tick Collars on Dogs and Cats. Biological and Economic Analysis Division, Office of Pesticide Programs, U.S. EPA. 27 pp. Sept 15. Available at <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0316>.

⁵⁵ *Ibid*

Veterinary Medical Association (AVMA, 2012), over 80 percent of dog owners and nearly 45 percent of cat owners take their pets to the veterinarian at least once per year and the veterinarian would be a ready source of information about pet insecticide products. More than 30 percent of pet owners purchase pet insecticide products from a veterinarian.⁵⁶

If EPA were to cancel all TCVP pet collars, there would likely be some increased costs for consumers, either monetarily due to the higher cost of alternative collars or through additional time and effort required for topical spot-on products or veterinary visits.

Impacts on Low Income Consumers

BEAD also assessed whether the lower cost in effort and money of TCVP pet collars and dust products could suggest that, if EPA were to cancel these products, their unavailability could disproportionately affect low-income pet owners. BEAD finds that this does not appear to be the case. Usage of pet collars may be somewhat more common among low-income households; about 30 percent of pet owners with a family income of less than \$25,000 per year used pet collars compared to about 25 percent of pet owners in other income categories⁵⁷. However, the usage of dust/powders is somewhat lower in low-income household compared to higher income groups.

Usage of topical spot-ons was similar across income categories with 48 percent of pet owners with income less than \$25,000 using spot-ons compared to rates of 47 to 57 percent for other income groups. Overall, usage of pet insecticides is similar for pet owners regardless of income.

If EPA were to remove TCVP pet collars, there may be some increase in costs for consumers, which could affect low-income pet owners. However, removal of TCVP pet collars would be unlikely to disproportionately impact low-income pet owners as usage of pet insecticide products is similar, regardless of income level. For example, seventy-two percent of low-income pet owners reported having used pet insecticides compared to 70 percent of all households⁵⁸. Within these economic groups, usage of pet collars is relatively similar, with about 30% of low-income households using pet collars compared to 25 percent of pet owners in other income categories. Other pet pest control options are available across a range of prices that perform comparably to TCVP.

Market Impacts

As noted in the Pet Insecticide Usage section above, TCVP pet collars account for a majority of current sales in those particular segments of the market. Demand for flea and tick

⁵⁶ Kline and Company. 2012. Consumer Markets for Pesticides and Fertilizers 2011. [Accessed June 2020.]

⁵⁷ *Ibid*

⁵⁸ *Ibid*

products may be greatest in the spring and summer months because pests are more active in warmer temperatures when people and their pets may spend more time outdoors.

V. EPA's Responses to NRDC's Petition Claims

A. Statutory Background

1. Pesticide Registration and Registration Review

FIFRA, 7 U.S.C. §§ 136-136y, in general, requires EPA approval of pesticides prior to their distribution or sale, and establishes a registration regime for regulating the use of pesticides. *Id.* FIFRA sections 3(a), 3(c). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause unreasonable adverse effects on the environment. *Id.* FIFRA section 3(c)(5); *see also id.* FIFRA section 2(bb). When determining whether a pesticide will cause unreasonable adverse effects on human health or the environment, EPA must balance the risks of the pesticide against the benefits of its use. *See* Sections III and IV. Specifically, FIFRA section 2(bb) requires EPA to “[take] into account the economic, social, and environmental costs and benefits of the use of any pesticide.” FIFRA section 2(bb). Once a pesticide is registered, EPA cannot unilaterally change the registration without either the registrant requesting an amendment to their registration or EPA taking action under FIFRA section 6 (e.g., initiating cancellation). *See* 40 CFR 152.44.

FIFRA also requires that EPA periodically review registered pesticides. FIFRA section 3(g). The purpose behind registration review is to account for “the rapid development of science and the subsequent application of that knowledge in how it impacts human health and the environment.” 70 Fed. Reg. at 40,252. Registration review therefore “establish[es] ongoing scientific look-back procedures” to account for this “continually evolving” landscape. *Id.* at 40,253.

The process EPA uses for evaluating the potential for health and ecological effects of a pesticide is called risk assessment, which is part of a risk management process. In registration review, that risk assessment typically includes an ecological risk assessment, a human health risk assessment, and, when appropriate, a cumulative risk assessment (evaluating the risk of a common toxic effect associated with concurrent exposure by all relevant pathways and routes of exposure to a group of chemicals that share a common mechanism of toxicity). EPA separately assesses the benefits the chemical provides the users (impacts of the loss of the chemical) and/or the impacts of potential mitigation.

The initial registration review cycle must be completed within 15 years after the first pesticide containing a new a.i. is registered, but not later than October 1, 2022. *Id.* Registration review does not result in the cancellation of a particular registration. *Id.* FIFRA section 3(g)(1)(A)(v). Instead, if EPA determines that a pesticide does not meet the standard for

registration, EPA must comply with the requirements of FIFRA section 6 to proceed to seek cancellation. *Id.* As noted earlier in this response, registration review is currently underway for all TCVP uses.

2. Pesticide Cancellation Process

In relevant part, FIFRA section 6(b) authorizes EPA to initiate cancellation proceedings “[i]f it appears to the [Agency] that a pesticide . . . generally causes unreasonable effects on the environment.” EPA can issue a notice of intent to either: (1) cancel the registration; or (2) hold a hearing to decide whether the registration should be cancelled. *Id.* Before issuing such a notice, EPA must consider a series of factors identified in the statute and complete a prescribed process for allowing the Secretary of the Department of Agriculture (USDA) and the FIFRA Scientific Advisory Panel (SAP) (a group of scientists charged with providing EPA with advice related to pesticide actions) to comment on the proposed notice at least 60 days prior to publication. *Id.*; *see also, id.* FIFRA section 25(d)⁵⁹. Additionally, when a public health use is involved (e.g., flea and tick protection), section 6(b) states that the Department of Health and Human Services (HHS) should also provide information on the benefits and use or an analysis thereof. Unless they waive review, USDA, HHS, and the SAP may comment during those 60 days. FIFRA sections 6(b) and 25(d). When a draft Notice of Intent to Cancel (NOIC) is based on scientific issues, the EPA may also convene a public meeting of the SAP following the procedures of the Federal Advisory Committee Act⁶⁰. EPA needs to address any comments it receives from the SAP or USDA before moving forward to publish the NOIC.

EPA must publish in the Federal Register the proposed NOIC; any comments from the USDA; and EPA’s response to such comments. *Id.* FIFRA section 6(b). After the NOIC is issued, the registrant may, within 30 days, request an evidentiary hearing before a hearing examiner (i.e., Administrative Law Judge (ALJ)). FIFRA section 6(d). Once a hearing is requested and an ALJ is appointed, control of the pace of the cancellation proceeding moves from the program office to the Office of the Administrative Law Judges. FIFRA implementing regulations set forth in 40 CFR Part 164 provide specifics on the cancellation process. The ALJ makes an initial decision based upon the record. Any order to cancel or revise the registration must be “based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.” *Id.* FIFRA section 6(d).

Given the many steps of the cancellation process, arriving at an initial order from the ALJ can take a significant amount of time. After the ALJ’s decision is issued, the cancellation proceeding may take additional time as it can be appealed by any party to the Environmental Appeals Board (EAB), which, on behalf of the Administrator, issues the final decision for the Agency. A final cancellation order following a public hearing is subject to judicial review within 60 days after entry of the order. Judicial review is only available to those adversely affected by

⁵⁹ The SAP must follow procedures set out in the Federal Advisory Committee Act. *See* 5 U.S.C. Appendix 2 (1972).

⁶⁰ *Id.*

the order and who participated as a party in the hearing (EPA cannot appeal an adverse decision). Products would remain on the market throughout the proceeding.

Alternatively, a registrant can request the voluntary cancellation of a registration pursuant to the procedures in FIFRA section 6(f). EPA must provide notice and a period for public comment before granting such a request. FIFRA section 6(f)(1). This process takes much less time and fewer resources than the adversarial cancellation process under FIFRA section 6(b).

To cancel pesticide registrations (or terminate uses) by any method under FIFRA section 6, EPA issues a cancellation order. In such cancellation order, EPA has the authority under FIFRA section 6(a) to allow for the sale, distribution, and use of existing stocks of the pesticide product despite it or its terminated use no longer being registered. EPA's issuance of a cancellation order is a separate final Agency action under FIFRA. If there is no public hearing (i.e., public comment period) on the cancellation order, judicial review in the U.S. district courts as set forth in FIFRA section 16(a).

B. Rationale for Granting Petition for Remaining TCVP Pet Collars

EPA has determined that all TCVP pet collar products have potential risks of concern as the non-cancer post-application MOEs are below the Agency's LOC (MOEs < 1000).

As previously described, EPA requested a "dust torsion" study for TCVP pet collars to refine liquid-to-dust ratio assumptions in 2019. The study was conducted by measuring the "mass lost" from the collar by gravimetric measurement of the collar weight before and after torsion, as well as measuring TCVP via chemical analysis of wipe samples taken after each torsion cycle. This study was originally reviewed in 2019 and found to be acceptable. Upon re-evaluation, HED identified concerns that the measurement of releases via wipe samples could potentially represent both liquid and dust rather than solely dust (particularly "dislodgeable" dust), as EPA had previously assumed. The study was re-classified as unacceptable due to these concerns. As a result, the current assessment uses the approach from the 2016 risk assessment, using three ratios of liquid-to-dust to cover a range of potential exposures from pet collar use (e.g., 99%/1%, 50%/50%, and 1%/99% dust/liquid).

Under the approach from the 2016 risk assessment, EPA has determined that all TCVP pet collar product registration have potential risks of concern as the non-cancer post-application MOEs are below the Agency's LOC (MOEs < 1000). EPA has also considered the number of alternatives for TCVP pet collars, the costs of those alternative, and the impacts of removing these products from the market, including a consideration of the impacts of lower income users. The EPA had determined that these benefits do not offset the identified unreasonable adverse effects for children exposed to pets with collars containing TCVP.

In particular, the benefits do not offset the potential unreasonable adverse effects for children exposed to pets with collars containing TCVP. Therefore, EPA is moving to draft a

proposed NOIC, as described above under “Pesticide Cancellation Process” as to the remaining collars. In August 2022, Hartz began conducting a new torsion study to define the liquid-to-dust ratio in TCVP pet collars, as well as a novel fur clipping study. Hartz is working on two studies and plans to submit the data for EPA review. EPA intends to incorporate into the drafting of the NOIC review of any data received in a timeframe that allows for such incorporation. Should the new data result in a change to the Agency’s conclusions, those conclusions will be captured in an updated risk assessment as well as the PID, both of which will be open for public comment. The Agency would not further pursue an NOIC if the updated data demonstrates that there is no longer a risk concern for any TCVP pet collars.

C. Rationale for Denying Remainder of Petition

As summarized above, NRDC’s petition raised several issues, and ultimately requested that EPA cancel all TCVP pet uses. EPA has considered that request to be the true thrust of the Petition and to the extent that the request was for EPA to initiate cancellation proceedings under section 6(b) of FIFRA, although EPA is moving to draft a proposed NOIC for the remaining pet collars, that request is denied for the non-collar products, as explained below. But as a preliminary matter, EPA briefly addresses the other issues raised in the petition:

- To the extent NRDC’s claimed flaws to the 2002 human health risk assessment was a request to revisit EPA’s reregistration decision, EPA declines to do so and notes that reregistration has been superseded by registration review. EPA will consider exposures to adults and children from any remaining TCVP pet uses as part of the full TCVP registration review human health risk assessment which is anticipated early 2023.
- As to NRDC’s claims that any EPA risk assessment underestimated exposures to children, including toddlers who are exposed through hand-to-mouth activity, as described above in Section III, EPA has completed a new non-occupational residential exposure assessment for all TCVP pet uses. The assessment addresses potential exposures from hand-to-mouth activity and incorporates new information regarding transferable residues, formulation types, and a refined dermal absorption factor. The assessment also provides a detailed description of the methodologies EPA used to calculate the appropriate assumption for collar trimming and liquid-to-dust ratio for use in the pet collar assessment⁶¹.
- To the extent NRDC was requesting that EPA rely on NRDC’s April 2009 Issue Paper, the Agency continues to not consider this due to the unavailability of the underlying data as described in Section II.C. To the extent NRDC was requesting that EPA rely on the Davis Study, the Agency notes that this study was considered in the new non-occupational residential exposure assessment for all TCVP pet uses as described in Section III.

⁶¹ Available at <https://www.regulations.gov/docket/EPA-HQ-OPP-2009-0308>.

1. Liquid Spray Pet Uses

Taking into consideration all of the information submitted to EPA by the Petitioner and the registrants, and described above in more detail, EPA determined that all of the liquid spray products are not of concern. For these products, the MOEs range from 1,600 to 120,000, which are well above EPA's level of concern of 1000. Because EPA did not find any risks of concern related to these uses, EPA did not assess the benefits of these products. Therefore, EPA finds that HARTZ 2 IN 1 FLEA AND TICK PUMP FOR DOGS II (EPA Registration No. 2596-125), HARTZ 2 IN 1 FLEA AND TICK PUMP FOR CATS II (EPA Registration No. 2596-126), and HARTZ RABON SPRAY WITH METHOPRENE PUMP FORMULATION (EPA Registration No. 2596-140) and the pet uses they include meet the FIFRA standard for registration, and EPA denies Petitioner's request to cancel these uses.

2. Dust and Powder Pet Uses

EPA had in the 2020 response determined that all of the dust/powder TCVP pet products have potential risks of concern because the residential post-application MOEs range from 98 to 640 (MOE < the LOC of 1000). The registrants agreed to voluntarily cancel their dust and powder pet products or terminate pet uses. On July 10, 2020, Hartz submitted requests to voluntarily cancel HARTZ 2 IN 1 FLEA AND TICK POWDER FOR CATS (EPA Registration No. 2596-78) and HARTZ 2 IN 1 FLEA AND TICK POWDER FOR DOGS (EPA Registration No. 2596-79). On June 19, 2020, Chem-Tech Ltd. voluntarily submitted a request to terminate cat and dog uses from CLEAN CROP LIVESTOCK 1% RABON DUST (EPA Registration No. 47000-123), and this cancellation went into effect on December 30, 2020.⁶² Hartz was allowed production of these products until July 31, 2020, and sale and distribution of existing stocks until March 31, 2021.

VI. Next Steps

EPA is moving to draft a proposed NOIC, as described above under "Pesticide Cancellation Process" as to the remaining collars. Hartz is working on two studies and plans to submit the data for EPA review. EPA intends to incorporate into the drafting of the NOIC review of any data received in a timeframe that allows for such incorporation. Should the new data result in a change to the Agency's conclusions, those conclusions will be captured in an updated risk assessment as well as the PID, which will be open for public comment. The Agency would not further pursue an NOIC if the data demonstrates that there is no longer a risk concern for any TCVP pet collars.

⁶² Available at <https://www.federalregister.gov/documents/2020/12/30/2020-28827/product-cancellation-order-for-certain-pesticide-registrations-of-tetrachlorvinphos>.

VII. Conclusion

The October 2022 revised residential exposure and risk assessment supports EPA's responses to NRDC's petition regarding whether TCVP pet uses pose unacceptable risks. EPA declines to revisit the 2006 RED or to perform a new cumulative risk assessment for organophosphates at this time, and notes that registration review of TCVP, along with the other organophosphates, is currently underway, pursuant to FIFRA § 3(g) and 40 CFR Part 155.

The October 2022 revised residential exposure and risk assessment discussed above uses appropriate, validated methodologies to calculate potential exposure to TCVP pet products. EPA will take appropriate regulatory action to address these registrations.

Therefore, NRDC's petition to cancel all pet uses for TCVP is hereby GRANTED for all six remaining pet collars containing TCVP and DENIED for the remainder of the pet uses of TCVP.

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