Case No. _____

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

PETITION FOR REVIEW
Of An Order Of The U.S. Environmental Protection Agency

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Dated: January 5, 2015

PETITION FOR REVIEW

Pursuant to Rule 15 of the Federal Rules of Appellate Procedure and section 16(b) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136n(b), Natural Resources Defense Council ("NRDC") hereby petitions this Court to review and set aside the final order of the U.S. Environmental Protection Agency ("EPA") denying NRDC's request to cancel all pet uses of the pesticide tetrachlorvinphos (Chemical Abstract Number 22248-79-9). The challenged final order was announced in a regulatory decision document that was entered on EPA docket EPA-HQ-OPP-2009-0308 with a date of signature of November 6, 2014. The order became final on November 20, 2014, at 1:00 p.m. eastern time, pursuant to 40 C.F.R. § 23.6. A copy of this final regulatory decision document is attached as Exhibit A to this petition.

Dated: January 5, 2015

Respectfully submitted,

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CORPORATE DISCLOSURE STATEMENT

Natural Resources Defense Council, Inc. ("NRDC") is a non-profit corporation with no parent corporation and no outstanding stock shares or other securities in the hands of the public. NRDC does not have any parent, subsidiary, or affiliate that has issued stock shares or other securities to the public. No publicly held corporation owns any stock in NRDC.

Dated: January 5, 2015

Respectfully submitted,

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EXHIBIT A

Natural Resources Defense Council, Inc. v. U.S. Environmental Protection Agency
Petition for Review

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

CERTIFIED MAIL

November 6, 2014

Miriam Rotkin-Ellman
Gina Solomon, MD, MPH
Mae Wu, Esq.
Natural Resources Defense Council
111 Sutter Street, 20th Floor
San Francisco, CA 94104

Re: Response to Natural Resources Defense Council's April 23, 2009 Petition Requesting Cancellation of All Pet Uses of Tetrachlorvinphos

Dear Ms. Rotkin-Ellman, Dr. Solomon, and Ms. Wu:

This letter 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). For the reasons identified below, the Agency denies NRDC's request to cancel all pet uses of TCVP.

The Petition asserts that EPA's revised human health risk assessment and organophosphate (OP) cumulative risk assessment underlying EPA's 2006 Reregistration Eligibility Decision (RED) for TCVP failed to adequately assess residential exposures to pet collars, and also presents NRDC's April, 2009 "Issue Paper" entitled "Poisons on Pets II: Toxic Chemicals in Flea and Tick Collars." The Petition concludes 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. As explained below, in response to NRDC's Petition, EPA has conducted an updated non-occupational residential exposure assessment for all TCVP pet product uses. Based on that assessment, EPA does not find risks of concern resulting from pet uses of TCVP and therefore declines today to initiate cancellation action against such uses as requested in the Petition. While EPA believes that the updated risk assessment addresses the arguments raised in 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 is currently underway, pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136a(g), and 40 CFR Part 155.

The first section of this letter discusses the factual background relevant to NRDC's Petition. The second section of this letter summarizes the claims made in NRDC's Petition. The third section of this letter responds to those claims by discussing the assumptions, routes of exposure considered, and conclusions reached in EPA's updated non-occupational residential exposure assessment for all TCVP pet product uses, conducted in response to NRDC's Petition. The fourth section of this letter is the conclusion.

I. Background

TCVP is a member of the organophosphate (OP) class of pesticides. Like other OPs, TCVP's mode of action involves the inhibition of the enzyme acetylcholinesterase (AChE).

The RED for TCVP was initially completed in September 1995. An interim Tolerance Reassessment Eligibility Decision (TRED) for TCVP was completed in July 2002. A residential exposure assessment was originally completed in 1998 in support of the TRED, and concluded that residential risks to handler and post-application exposure were below the Agency's levels of concern. The residential assessment was refined in 2002. Both the TRED and 1998 assessment can be found in public docket number EPA-HQ-OPP-2002-0295 at www.regulations.gov. The Agency completed the OP cumulative risk assessment in July 2006, 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. An update to the OP Cumulative risk assessment was completed in August 2006. There were no risks of concern identified in the residential assessment portion of the OP Cumulative, which considered exposure from the pet uses of TCVP. Additionally, the registration review docket for TCVP opened in 2008, and registration review is currently on-going. All registration review documents, as well as the RED, can be found in public docket number EPA-HQ-OPP-2008-0316.

On June 5, 2009, EPA announced receipt of NRDC's Petition to cancel all pet uses for TCVP 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. The public comment period ended on August 4, 2009, during which time EPA received approximately 8,600 form letters as part of a mass campaign supporting NRDC's petitions to ban TCVP pet uses and propoxur pet collars.[1] In addition, the Agency also received a comment from The Humane Society of the United States (HSUS) that supported the petition and a comment from one TCVP registrant, Hartz Mountain Corporation, which opposed the petition. Substantive comments are addressed in a separate "Response to Comments" document, attached hereto as Appendix A. Regarding HSUS's comment about potential adverse reactions to TCVP of companion animals, the Agency is committed to studying this issue more closely to understand what additional measures, if any, may be appropriate to reduce the incidence of these unfortunate and avoidable events. While this comment does not pertain to the human health issues raised by NRDC's Petition, the Agency will conduct an in-depth review and analysis of pet incident data resulting from pet products that contain TCVP during the registration review process for TCVP.

Since the closing of the public comment period in 2009, the Agency has considered the Petition to cancel all TCVP pet products and the risks posed by TCVP pet products, especially to children. EPA has taken numerous steps to evaluate the concerns outlined in the Petition, including the completion of a new TCVP residential risk assessment which incorporates the most recent science policies and risk assessment methodologies to assess all available TCVP pet product uses. The results of this new assessment are discussed in section III of this letter, below.

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[1] On January 22, 2014, EPA published in the Federal Register, pursuant to section FIFRA § 6(f), a notice of receipt of registrant requests to voluntarily cancel all propoxur pet collar registrations. *See* 79 Fed. Reg. 3586 (Jan. 22, 2014). On March 26, 2014, EPA published in the Federal Register a notice announcing EPA's Order for the cancellation of all propoxur pet collar registrations. *See* 79 Fed. Reg. 16793 (Mar. 26, 2014). The effective date of the cancellations that are the subject of that Order is April 1, 2015. Accordingly, by letter dated October 9, 2014, EPA denied as moot NRDC's petition seeking cancellation of such registrations.

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 collars. However, this "Issue Paper" consisted only of the study overview and summarized findings along with a methodological appendix, and 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. 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."

To date, NRDC has not submitted the necessary raw data to allow EPA to verify the "Poisons on Pets II" study findings. No other scientific information has been provided that would afford the Agency with a rationale to rely upon this study report for regulatory actions under FIFRA. Without the raw scientific data, this information could not be considered in EPA's evaluation of NRDC's Petition.

II. Petition Claims

NRDC's Petition argues that EPA did not assess the exposure from pet collar uses in the risk assessment underlying the RED, and that assumptions made pertaining to toddler exposures to TCVP were flawed in the OP cumulative risk assessment. NRDC argues that the decision to reregister TCVP pet uses was thus arbitrary and capricious and contrary to law, and that risks from pet uses of TCVP are unacceptable such that EPA should cancel such uses.

NRDC makes the following arguments in support of its position:

- **NRDC Argues that EPA Failed to Consider Pet Collar Exposures**: NRDC argues 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 Argues that EPA Used Faulty Exposure Assumptions**: NRDC argues that the EPA's organophosphate cumulative risk assessment for pet products significantly underestimated a toddler's exposure to residue on a pet from a flea collar. NRDC argues that the TCVP risk assessment assumed that toddlers were exposed for no more than one hour per day, but the EPA assumed a two hour per day exposure for toddlers in the dichlorvos (DDVP) case. NRDC further argues that EPA's underestimates include the use of hand-to-mouth activities at nine times per hour, while a published review of the scientific literature by EPA scientific experts indicated an average of 19.6 times per hour. NRDC further argues that the Agency failed to assess indirect hand-to-mouth activity, which is the exposure from toddlers who touch an object or food with pesticide-contaminated hands and then put that object or food into their mouths, while published studies show that there is noticeable indirect hand to mouth activity in infants and children.

- **NRDC Argues that Pet Collars Result in Unacceptably High Exposures**: NRDC argues that NRDC's report "Poison on Pets II" shows that residues of TCVP on the pets' fur are high enough to pose a significant risk to both children and adults who play with their pets.

III. EPA's Updated Risk Assessment for All TCVP Pet Uses

As noted above, in response to NRDC's Petition, EPA has conducted an updated non-occupational residential exposure assessment for all TCVP pet product uses. Based on that assessment, EPA does not find risks of concern resulting from pet uses of TCVP and therefore declines today to initiate cancellation action against such uses as requested in the petition. While EPA believes that the updated risk assessment addresses the arguments raised in 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 is currently underway, pursuant to FIFRA § 3(g) and 40 CFR Part 155.

In developing a response to this Petition, EPA considered, among other things, the information contained in the petition (to the extent it could without obtaining additional information from NRDC), new data relevant to the assessment of exposure from pet collars (*i.e.*, propoxur collar MRID 48589901), and updated residential exposure assessment methodologies, and the Agency completed a new residential exposure assessment for all TCVP pet product uses, entitled *Tetrachlorvinphos: Residential Exposure Assessment in Response to the Natural Resources Defense Council Petition to Cancel All Pet Uses for Tetrachlorvinphos*, dated November 5, 2014 (Attached hereto as Appendix B). This assessment concludes that all risks associated with TCVP pet products are below the Agency's level of concern (LOC) for all exposure scenarios. The key points of the assessment are outlined below, as part of the evaluation of NRDC's claims in its Petition.

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 1998 and 2006, and utilized exposure assumptions and methodologies based on Standard Operating Procedures (SOPs) for pet

product risk assessments in place at that time. The 2014 TCVP residential pet product assessment assessed residential handler and post-application risk from exposure to TCVP pet products using the Agency's 2012 SOPs for Residential Pesticide Exposure Assessment (available at http://www.epa.gov/opp00001/science/EPA-OPP-HED_Residential%20SOPS_Feb2012.pdf). Development of the 2012 SOPs included external peer review, including the Agency presenting a draft of the SOPs to the FIFIRA Scientific Advisory Panel (SAP) for comment in 2009. The updated residential exposure assessment also incorporates the following changes:

- the assumption of steady state exposures for TCVP exposure assessment;
- updated points of departure (PoDs) following re-evaluation of the TCVP toxicity database using the benchmark dose (BMD) techniques consistent with the methods currently used for other OPs;
- reduction of the total uncertainty factor (UF) for inhalation exposures from 100X to 30X due to use of the Agency's reference concentration (RfC) and human equivalent concentration (HEC) methodology;
- voluntary cancellation of TCVP trigger pump spray pet products (EPA Reg. Nos. 2596-122, 2596-123, and 2596-136);
- the re-evaluation of a previously submitted and reviewed pet residue transfer study for TCVP dust/powder and pump spray formulations; and
- the use of pet residue transfer study data specific to collar formulations.

The following is a summary of the analysis and conclusions found in the new 2014 TCVP residential risk assessment, entitled *Tetrachlorvinphos: Residential Exposure Assessment in Response to the Natural Resources Defense Council Petition to Cancel All Pet Uses for Tetrachlorvinphos.*

Toxicology and Uncertainty Factors

Like other OPs, the mode of action (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. For TCVP, AChE inhibition is the most sensitive endpoint in the toxicology database in multiple species, durations, lifestages, and routes.

The toxicology database for TCVP is complete. 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 both the gene mutation assay and primary rat hepatocyte unscheduled DNA synthesis assay. However, this chemical was positive for inducing chromosomal aberrations in Chinese hamster ovary 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, but this can vary among OPs. TCVP shows a shallow dose-response curve for cholinesterase inhibition; in other words, large increases in administered dose result in only small changes in AChE inhibition.

Based on the robust dataset from the OP cumulative risk assessment across the OPs, exposure assessments of 21 days and longer will be conducted for all routes of exposure; *i.e.*, oral, dermal, and inhalation, for all single chemical OP assessments. Given this, the 21-day and longer exposure assessment is scientifically supportable and also provides consistency with the OP cumulative risk assessment and across the OP registration review risk assessments.

The Food Quality Protection Act (FQPA) children's safety factor (SF) was reduced to 1X since there is no evidence of sensitivity of the young animal compared to the adult and there are no data gaps. A total uncertainty factor (UF) of 100X is appropriate for dermal and incidental oral routes of exposure (10X for interspecies extrapolation, 10X for intraspecies variation, and 1X FQPA SF). For the inhalation route of exposure, a total SF of 30X (3X for interspecies extrapolation, 10X for intraspecies variation, and 1X FQPA SF) is appropriate. The interspecies extrapolation is reduced from 10X to 3X because the reference concentration (RfC) methodology for inhalation is used to determine a human equivalent concentration (HEC) and takes into consideration the pharmacokinetic differences between animals and humans.

Residential Handler Exposures

Residential exposures are anticipated from the use of TCVP pet products. Residential TCVP handler exposures are anticipated to be short- (1 to 30 days) to intermediate-term (1 to 6 months) in duration. However, because of the steady state AChE inhibition exhibited by the OPs, steady state exposures (21 days and longer) were assessed and presented for residential exposures to 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 residential handler exposure assessment (combined dermal and inhalation) was performed for homeowners applying TCVP products to cats and dogs. A residential handler 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} $(mg/kg/day)^{-1}$.

A series of assumptions and exposure factors served as the basis for completing the residential handler risk assessment, which are detailed below.

Per the SOPs, it is assumed that residential handlers of pet treatment products will treat two animals per application. For TCVP dust and powder products, all products identify a specific amount to use per animal weight that allows for determination of the maximum application rate. For TCVP pump sprays, all registered products direct the user to apply a specific number of "strokes" per animal size. In order to determine the amount of active ingredient (a.i.) applied per treatment as specified by number of strokes, EPA requested additional information from a product registrant, Hartz Mountain Corporation, which holds most of the TCVP pet product registrations. 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, Hartz Mountain Corporation submitted an application for amendment to the product

label of EPA Reg. No. 2596-140, which was approved by the Agency in March 2014, to recommend a number of strokes per animal size. The specific number of strokers per animal size is located in Table 4.0 in the 2014 residential assessment. Previously, a number of strokes per cat/dog was not recommended.

For TCVP collars, the applicator is directed to cut off and dispose of any excess length once the product is fit and buckled into place. As described in the SOPs, because the exact length cannot be determined, the corresponding a.i. loss cannot be quantified and, therefore, exposure is conservatively assessed assuming the full collar length.

A series of assumptions and exposure factors served as the basis for completing the residential handler risk assessment. Each assumption and factor is detailed in the SOPs.

Unit Exposures and Area Treated or Amount Handled: Chemical-specific unit exposure data were provided in support of the residential handler risk assessment for the dust/powder formulations only (MRID 45519601). The study, "Determination of Dermal and Inhalation Exposures to Tetrachlorovinphos (TCVP) During the Application of an Insecticide Powder to a Dog," was previously reviewed by the Agency in January 2002 and determined to be acceptable, and the data was reflected in the TRED for TCVP in 2002. These exposure data were used as a surrogate to estimate handler exposures from the TCVP dust/powder products. The study resulted in average unit exposures for the dermal and inhalation routes of exposure of 1,700 mg/lb a.i. and 3.1 mg/lb a.i., respectively.

In the absence of exposure data for residential handling of pet collars and pump/trigger sprays, the Agency used exposure values from the 2012 Residential SOPs: Treated Pets as a surrogate to estimate handler exposures. Surrogate exposure data for a groomer trigger pump spray application to dogs was used to estimate handler exposures from TCVP pump spray products. No exposure data are available for assessment of handler exposures from the application of collars. In the absence of formulation-specific data, exposure data for spot-on applications was used to estimate handler exposures from the TCVP collar products.

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. Steady state exposures (21 days and longer) were assessed and presented for residential handler exposures to TCVP pet products because of the steady state AChE inhibition exhibited by the OPs.

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 6 days per year for dusts/powders and pump 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 pump sprays.

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 (U.S. EPA, 2011). 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.

Residential Handler Risk Estimates and Conclusions

EPA concluded that residential handler (adults) combined steady state (dermal and inhalation) exposures are not of concern to the Agency (*i.e.*, all aggregate risk indexes (ARIs) are greater than 1) from application of any registered TCVP pet products. A complete listing of all ARIs can be found in Table 5.1.1 in the 2014 residential assessment. The ARI approach was required to combine the dermal and inhalation routes of exposure because of the different LOCs. LOCs recommended for the dermal and inhalation routes of exposure are margins of exposure (MOEs) of 100 and 30, respectively. ARIs of less than 1 indicate risks of concern. The ARI approach normalizes MOEs from different routes to an LOC of 1 to facilitate aggregation of risks, as described in the Agency's *General Principles for Performing Aggregate Exposure and Risk Assessments.*[2]

Estimated residential handler cancer risk estimates range from 10^{-9} to 10^{-7}, which are below the Agency's LOC. A complete listing of all residential handler cancer exposure and risk estimates can be found in Table 5.1.2 in the 2014 residential assessment.

Residential Post-application Exposure

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. The quantitative exposure risk assessment for residential post-application exposures is based on the following scenarios:

1) Post-application dermal (adults and children 1 to < 2 years old) exposure from contacting cats and dogs treated with TCVP; and
2) Post-application incidental oral exposure (children 1 to < 2 years olds only) from contacting cats and dogs treated with TCVP.

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.

A series of assumptions and exposure factors served as the basis for completing the residential post-application risk assessment. Each assumption and factor is detailed in the SOPs.

Exposure Data: Surrogate and chemical-specific residue transfer studies were used for assessment of post-application exposures from registered TCVP pet products. These exposure data include the following residue transfer studies: propoxur collar (MRID 48589901); and TCVP powder and pump spray (MRID 45485501).

[2] http://www.epa.gov/opp00001/trac/science/aggregate.pdf

EPA previously conducted a data evaluation record (DER) of the TCVP exposure study for aerosols, powders, and pump sprays[3] in 2001. In support of the Agency's response to the NRDC petition, the study has been re-evaluated based on current standards of conduct for pet residue transfer studies[4]. The re-evaluation of the TCVP residue transfer study resulted in a number of changes from the 2001 DER. Table 5.2.1 from the 2014 residential assessment below presents a comparison of the methods used to evaluate the study data.

Comparison of 2001 and Current TCVP Pet Residue Transfer Study Reviews	
2001 Review	**Current Review**
Handwipe residue data were corrected for average field fortification recoveries <90%.	Handwipe residue data were corrected for average field fortification recoveries <120%.
TCVP residues on hands in μg/cm² were calculated using the surface area of the stroking area (defined as length of dog x length of study participant's hand).	TCVP residues are calculated in μg/cm² using the surface area of the entire dog, based on the weight of the test animal.
The percent of applied TCVP dislodged by the hand following treatment was calculated based on the amount of TCVP residue on the stroking area, which was determined from extrapolating residues detected in fur samples from a shaved area to the area of the stroking area.	The percent of applied TCVP transferred to the hand was calculated based on the total amount of active ingredient applied to the dog (calculated as the amount removed from container in grams x actual percent active ingredient in test product).
Regression analyses were conducted using the residue data in μg/cm².	The revised regression analyses were conducted using the percent of applied dose transferred to the hand.

It should be noted that the TCVP powder and pump spray post-application exposure study was not conducted in a manner reflective of current standards that require a defined stroking procedure and greater number of petting simulations. That is, the pet is to be stroked in a single motion with the grain of the fur starting with both sides (along the ribcage) of the cat or dog and followed by the same motion along the back (dorsally) from the base of the neck to the tail. The two sides and back, in this order, account for one petting simulation. A total of 20 petting simulations (or 60 stroking motions) are currently required. In the TCVP post-application exposure study, the dogs were stroked on only one side of the treated dog's back from head to rump five times. However, the study was reflective of current policy regarding pet residue transfer studies at the time that it was conducted. In order to account for the differences between the TCVP post-application exposure study and the currently recommended standard, the Agency used the maximum observed percent residue transfer on the day of product application (Day 0) for both formulations for exposure and risk quantification. Typically, the Agency assesses post-application risk with use of the mean percent residue transfer measured on Day 0; the use of the maximum value results in a more health protective risk assessment. Even though the post-application exposure study methods have evolved, the TCVP study employed a rigorous collection method and is not anticipated to underestimate exposure.

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[3] S. Hanley. Re-evaluation of *Determination of the Dislodgeability of Tetrachlorvinphos (TCVP) from the Fur of Dogs Following the Application of an Insecticide Powder, Pump Spray or Aerosol.* 3/25/02. D277543.

[4] W. Britton. 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.

Exposure Duration: Residential post-application exposure is expected to be short- and intermediate-term for dust/powders and pump/trigger sprays. For pet collars, post-application exposures is 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 (21 days and longer) were assessed and presented for residential post-application exposures to TCVP pet products.

Hand-to-Mouth Event Frequency: The 2012 Residential SOPs include a frequency estimate of 20 as the modeled number of hand-to-mouth events per hour for children 1-2 years old. There are currently no data available that specifically address the number of hand-to-mouth events that occur relative to the amount of time that a child spends with a pet. As a result, the estimate for frequency of hand-to-mouth events in indoor environments is based on the Xue et al. (2007)[5] meta-analysis of child hand mouthing frequency. The indoor data were selected, even though child exposure to treated pets can occur either indoors or outdoors, because the indoor data result in a greater frequency of contacts and, therefore, a more health protective risk assessment. Please see Table A.2 in Appendix A of the 2014 residential assessment for more information on hand-to-mouth exposure inputs.

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 18-1 (U.S. EPA, 2011). 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.

Pet Contact: 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 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, and is the basis for the Agency's post-application exposure guidelines[6]. A TC is derived by taking the ratio of study volunteer dermal exposure per unit time (mg/hr), and the concurrent measure of residue transfer. Ideally, dermal exposure is based on activities representative of the use pattern and residue transfer is determined by use of an established method specific to the use pattern. For pet exposures, TCs can be defined as animal surface area contact per unit time (cm^2/hr).

Currently, there is no exposure study available using typical adult and child activities with pets and a concurrent transferable residue (TR) measure. In the absence of direct exposure data for residential activities with pets, the Agency concluded that studies conducted to monitor pet grooming activities are likely to result in a highly protective estimate of pet contact relative to

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[5] Xue, J., Zartarian, V., Moya, J., Freeman, N., Beamer, P., Black, K., Tulve, N., Shalat, S. (2007), A Meta-Analysis of Children's Hand-to-Mouth Frequency Data for Estimating Nondietary Ingestion Exposure. Risk Analysis, 27(2):411-420.

[6] http://www.ecfr.gov/cgi-bin/text-idx?SID=6bfd4539761be8d5b20dfbf6bc19b9d0&node=40:25.0.1.1.9.9&rgn=div6

contact associated with petting, hugging, or sleeping with a pesticide-treated pet. These data were gathered while human volunteers applied dust/powders and shampoo products to various dogs of differing sizes and fur lengths. Since these individuals extensively handled the dogs, it is expected that their resulting exposures are higher than would be reasonably anticipated from routine contact with treated pets. The volunteers in the shampoo study, who were professional groomers, shampooed 8 dogs for 5 minutes each, rinsed, and lifted them to counters for drying and combing resulting in very high exposures. In the dust study, volunteers applied dust via shaker can to 8 dogs each and then rubbed the dusts into the dogs' coats. The applicator studies were not conducted in a manner which measured TR, or active ingredient per surface area. Therefore, the residue available on the animal for transfer was predicted by multiplying the arithmetic mean fraction of application rate from the analysis of all liquid formulated product data sets presented in the 2012 Residential SOPs, 0.96%. This approach has the effect of increasing TC estimates, thus resulting in TC values which are more protective of human health. Furthermore, the selection of the mean value, in lieu of the screening level fraction application rate (F_{AR}) value, 2%, further increases the TC estimates with use of the dust and shampoo studies.

Exposure Time: The exposure time (ET) assumption used to assess residential post-application exposure to TCVP pet products 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 are 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.

Residential Post-application Risk Estimates and Conclusions

Residential post-application steady state adult dermal (only) exposure and children 1 to 2 years old combined (dermal and incidental oral exposures) are not of concern to the Agency (*i.e,* all MOEs are greater than 100) for all TCVP pet products assessed. The combined MOE approach was used because the dermal and incidental oral routes of exposure have the same LOC. MOEs under 100 indicate risks of concern. The residential post-application MOEs range from 270 to 43,000. A complete listing of all MOEs can be found in table 5.2.2 in the residential assessment. Estimated residential handler cancer risk estimates range from 10^{-9} to 10^{-7}, and residential post-

application cancer risk estimates range from 10^{-8} to 10^{-6}, which are below the Agency's LOC. A complete listing of all residential post-application cancer exposure and risk estimates can be found in Table 5.2.3 in the 2014 residential assessment.

It should also be noted that the evaluation of the potential residential post-application health risks from exposures to cats and dogs treated with TCVP pet products is conservative. The risk estimates calculated are based upon protective assumptions of TCVP hazard, product application rates, durations of exposure, and contact with the treated animal, and they make use of the best available post-application exposure data.

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 2014 TCVP residential risk assessment, entitled *Tetrachlorvinphos: Residential Exposure Assessment in Response to the Natural Resources Defense Council Petition to Cancel All Pet Uses for Tetrachlorvinphos.*

IV. Conclusion

The 2014 residential assessment discussed above uses appropriate, validated methodologies to calculate potential exposure to TCVP pet products and shows that all identified risks associated with TCVP pet uses (including pet collars) result in risks that are below the Agency's level of concern. Again, while EPA believes that the updated risk assessment addresses the arguments raised in 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 is currently underway, pursuant to FIFRA § 3(g) and 40 CFR Part 155. Therefore, NRDC's petition to cancel all pet uses for TCVP due to alleged risks of concern is hereby denied.

Please contact Kelly Ballard at (703) 305-8126 or ballard.kelly@epa.gov, if you have any questions or concerns regarding this response.

Sincerely,

By Martin Mull, ACTING

Jack E. Housenger, Director
Office of Pesticide Programs

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing petition for review with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on January 5, 2015.

I further certify that I have mailed the foregoing document by certified mail, return receipt requested, to the following persons:

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Dated: January 5, 2015

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