Tetrachlorvinphos (TCVP) Updated Risk Assessment and Petition Response Path Forward

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Briefing Objective

- Determine how to respond to the NRDC's petition to cancel all pet care products containing TCVP
  - Discuss risks of exposure to TCVP pet products
  - Discuss potential rationale to grant or deny petition

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Potential Response Paths

- Based on scientific support, potential responses may lead to
  - Partial granting/denying the petition
  - Granting the petition
  - Denying the petition

Outline

- Use and Usage
- Benefits and Alternatives
- Environmental Justice Considerations
- Risk Assessments
- Petition Pathway Options
- Appendix
  - Comments on DRAs
  - Litigation History

Use

- TCVP is an organophosphate (OP) insecticide; the mode of action is neurotoxicity via acetyl cholinesterase (AChE) inhibition.
- There are two technical registrants: Hartz and Bayer, and about 40 end-use registrations.
- Registered uses are on livestock and domestic animals or as a perimeter treatment. There are no crop uses.
- The primary registrant for pet products (cats and dogs) is Hartz. There are 16 end-use pet product registrations.
  - Other sellers and distributors in addition to Hartz.
  - Pet products include flea and tick collars, powders, and pump sprays.

Hartz has 11 product registrations, but there are 16 total pet products; 4 might be "me-too"/repack and Hartz changes the size of some of it's collars

Usage

- Pet insecticide products were a $1.4 billion industry in 2016, with projected sales to approach $1.7 billion in the next year
- According to survey by American Veterinary Medical Association, in 2011, approximately 90% of dog owners and 70% of cat owners purchase pet insecticides
  - Primarily tick and flea products
  - Mainly liquids; collars and powders account for <10% of sales ($)
- However, people may use more than one type of product
  - 25% of owners purchase collars
  - Almost 10% purchase powders

Information from a 2017 Assessment. AVMA. 2012. US Pet Ownership and Demographics Sourcebook. American Veterinary Medical Association. pp. 136.

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Benefits and Alternatives

- Potential Alternatives to TCVP Collars
  - Collars containing amitraz and deltamethrin (dogs only), flumethrin/imidacloprid and scented oils (dogs and cats)
  - Topical (liquids) contain pyrethroids, fipronil, imidacloprid, indoxacarb, pyriproxyfen – usually in combination
- TCVP-containing collars typically cheaper than alternatives
  - Accounting for duration of control, may be $5-6/month more than TCVP collars
  - Some essentially the same cost, some > $20/month more

AVMA. 2012. US Pet Ownership and Demographics Sourcebook. American Veterinary Medical Association. pp. 136.

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Environmental Justice

- Unclear whether impact from cancellation of TCVP products would be greater on low income/marginal households
  - Use of pet collars/powders somewhat less likely among pet owners in single family dwellings (AMVA, 2012)
  - Use of pet collars/powders somewhat more likely if family income < $25,000/year – but also if income > $100,000/year (AMVA, 2012)
- Complex issue with contradictory factors

Ex. 5 Deliberative Process (DP)

AVMA. 2012. US Pet Ownership and Demographics Sourcebook. American Veterinary Medical Association. pp. 136.

Human Hazard Characterization

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- Risk assessment endpoints based on red blood cell AChE inhibition
  - Benchmark dose modeling (BMD) used to derive PODs
  - 10X FQPA SF retained for populations of concern
- Classified as a Possible Human Carcinogen (Group C): Q1* = 1.83×10^{-3} $(mg/kg/day)^{-1}$
- Given the timeframe, the September New Approach Method (NAM) SAP for OPs will not contribute to the TCVP risk assessment

Dietary Exposure and Risk Assessment

- Dietary Non-cancer
  - Population subgroup of concern Children 3-5 at 180% aPAD and 120% ssPAD
  - Refinements made using PDP data where available
    - Anticipated residues used for chicken skin
  - Drinking water refinements were included
- Dietary Cancer
  - Cancer Risk Estimates at 10^{-7}

Summary of Residential Risk Estimates – Pet Products (non-cancer LOC = 1000)

		Dusts/Powders	Trigger-Pump/Sprays	Pet collars (X = non-cancer risks identified)			
Handler	Non-cancer	No risks identified					
	Cancer	10^{-9} to 10^{-7}	10^{-9} to 10^{-8}	10^{-8}			
Post-application	Non-cancer	Risks for all registered products 47000-123 2596-78 2596-79	No risks identified 2596-126 2596-140 2596-125	***Products***		***Use of Davis data***	***Use of Hartz data***
				2596-49	Cat	X	X
				2596-50, 62	Small Dog	X	
					Large Dog	X	
				2596-63	Small Cat	X	X
					Large Cat	X	
				2596-83	Small Cat	X	X
					Large Cat	X	X
				2596-84	Small Dog	X	X
					Large Dog	X	
				2596-139	Cat	X	
					Dog	X	X
	Cancer	10^{-7} to 10^{-6}	10^{-7}	Range for all products:		10^{-6} to 10^{-5}	10^{-7} to 10^{-6}

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Residential Handler Risk Assessment

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- Residential handler exposures expected from use of pet collars, dusts, and pump/trigger sprays

- Non-Cancer Risk Estimates
  - Adult inhalation only (no dermal POD); LOC = 300
  - No risks of concern identified for all pet products (all MOEs ≥ 300)

- Cancer Risk Estimates range from 10^{-9} to 10^{-7}

Residential Post-application Risk Assessment

EPA

- Residential post-application exposures expected from contact with pets previously treated with collars, dust/powders, or pump/trigger sprays
- Exposure data issues related specifically to pet collars
- In NRDC opening brief from 2015, cited label language: *"as the collar begins to work, a fine white powder will appear on the surface."*
- Up to this point, HED had been assessing collars as liquid formulations, not dust formulations
- No exposure data available for collars to determine formulation type and/or relative fractions of liquid/dust available
- In Dec. 2016, HED began using ratio approach (e.g., % liquid:% dust) to address formulation uncertainty and requested data from pet collar registrants
- After 2016 TCVP risk assessment, started discussions with Hartz about this uncertainty and need for data

Residential Post-application Risk Assessment

- DCI issued in June 2019 to address formulation uncertainty
  - DCI was for a "dust torsion" study which is conducted to measure the amount of solids released from a pet collar when the collar is exposed to extreme mechanical torsion (twisting) and stress
  - Provides refinement for assumption of ratio of liquid:dust releasing from collar
- A TCVP pet collar dust torsion study was submitted by Hartz in August of 2019 in response to DCI
- In addition, Hartz submitted a residue transfer study to determine the amount of TCVP residues (solid or liquid) which transfer over time from the fur of an animal treated with the pet collar to the exposed person

Residential Post-application Risk Assessment

EPA

- Children 1 to <2 years incidental oral only (no dermal POD); LOC = 1000

- Dusts/Powders (3 products; for both cats and dogs)
  - Risks of concern identified
  - MOEs range from 98- 640
  - Cancer risk estimates range from 10^{-7} to 10^{-6}

- Pump/Trigger Sprays (3 products; for both cats and dogs)
  - No risks of concern identified
  - MOEs range from 1,600 – 15,000
  - Cancer risk estimates are all 10^{-7}

Residential Post-application Risk Assessment

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- Pet collars (7 products; for both cats and dogs)
  - Refined assessment using data submitted by Hartz (August 2019)
    - Dust torsion study: Refined assumption of liquid:dust ratio for pet collars (99.62% liquid/0.38% dust)
    - Transferable residue study: Fraction transferred = 0.0017; results based on 3 dogs
  - Risks of concern identified using:

    1) Previously submitted "Davis study" residue transfer data (fraction transferred = 0.004; results based on 23 dogs)
    - MOEs range from Ex. 5 Deliberative Process (DP)
    - Cancer risk estimates range from 10^{-6} to 10^{-5}

    2) Recently submitted Hartz study data:
    - MOEs range from Ex. 5 Deliberative Process (DP)
    - Cancer risk estimates in the Ex. 5 Deliberative Process (DP)

Aggregate Assessment

- Non-cancer
  - Cannot make non-cancer aggregate safety finding at this time
    - Acute aggregate = acute dietary (food + water) assessment = risks of concern
    - Steady-state aggregate = dietary (food + water) + residential = risks of concern

- Cancer
  - Aggregate cancer risk estimates for handlers are in the 10^{-7} to 10^{-6} range and for post-application are in the Ex. 5 Deliberative Process (DP)

Occupational Risk Assessment

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- Occupational handler exposures expected for livestock, kennel, outdoor perimeter, and pet treatments
- Handler - non-cancer
  - Inhalation only; LOC = 300
  - 172 occupational handler exposure scenarios assessed
  - The majority (142) are not of concern either at baseline or with currently required PPE (i.e., respirators)
  - 30 scenarios are of concern and include certain handheld equipment scenarios, fogging scenarios, and dust products. None are pet uses.
    - 19 are not of concern with consideration of increasing levels of respiratory protection
    - 11 remain of concern despite the addition of respiratory protection or engineering controls
- Handler - cancer
  - Occupational handler range: 10^{-10} to 10^{-4}

Draft Ecological Risk Assessment

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- TCVP registered for use as larvicide in manure. Residues can pass through livestock and remain active in manure.
- The ecological DRA identified risks to birds, mammals, and freshwater invertebrates.
- Based on available data, risk estimates would exceed acute risk LOC for adult bees from contact exposure.
- Tier 1 suite of laboratory-based studies of honey bees is incomplete
  - Missing acute/chronic oral toxicity for adult and larval bees.
- EPA received comments on the EFED DRA from the USDA, Bayer, and Centers for Biological Diversity (CBD).

The ecological DRA identified risks to birds (chronic RQs: 0.5 – 87), mammals (acute RQs <0.1 – 9.2; chronic RQs 0.05 – 8.35), and freshwater invertebrates (acute RQs 0.34 – 0.8; chronic RQs 5 – 9).
DRA did not quantify risks to terrestrial invertebrates; however, based on available data terrestrial invertebrate risk (adult acute contact RQ 0.078 - 0.77).

The Tier suite of laboratory-based acute and chronic toxicity studies with adult and larval bees is incomplete as only adult acute contact toxicity data are currently available for TCVP. Although the compound does not have any agricultural uses and is not applied directly to plants, the pass-through of residues in manure represents a potential route of exposure for ground-nesting non-Apis bees.

Submission of a complete set of Tier 1 honey bee toxicity data is needed for TCVP to fully assess Tier 1 risk to individual bees. Pending the results of Tier 1 studies, additional higher-tier data (e.g., nectar and pollen residue data and/or semi-field studies at environmentally relevant concentrations) may be useful for refining the understanding of potential exposure of bees from registered uses, and the extent of risk at the colony level.

Litigation and Potential Response Paths

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Litigation and Potential Response Path

- If chosen pathway leads to partially granting/denying the petition

Ex. 5 Deliberative Process (DP)

Litigation and Potential Response Path

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- If chosen pathway leads to granting the petition:

Ex. 5 Deliberative Process (DP)

Litigation and Potential Response Path

- If chosen pathway leads denying the petition

Ex. 5 Deliberative Process (DP)

Petition Pathway Forward

- OGC has requested management decision on petition response by May 13
  - As much time as possible is needed for petition response development.

Next Steps

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- Prepare and issue response to NRDC's 2009 petition by July 21
- Revised Human Health Draft Risk Assessment scheduled for Q3 (June)
- Proposed Interim Decision scheduled for Q4 (September)

Appendix

- DRA Comment Summary
- Litigation History

Comments on Draft Risk Assessments

- In 2009, the agency received approximately 8,600 form letters as part of a mass campaign supporting NRDC's petition to ban TCVP and propoxur pet products.
  - EPA also received a comment from The Humane Society of the United States that supported the petition and a comment from one TCVP registrant that opposed the petition.
- A total of 17 comments were received for the registration review docket
  - Comments from Bayer, Hartz, NRDC, USDA, and CBD
- The docket also includes responses to comments on other OP documents:
  - Responses to EDSP comments on preliminary OP HH DRAs
  - Responses to comments related to applying the FQPA 10X SF for OPs
  - Responses to ORE and dietary comments on preliminary OP HH DRAs

Litigation History

EPA

- April 23, 2009, NRDC filed a petition for EPA to cancel all pet uses for TCVP
- November 6, 2014: EPA denied the petition after conducting a revised risk assessment to evaluate residential exposure for all TCVP pet products
- January 5, 2015: NRDC filed a Petition for Review of EPA's denial in the 9th Circuit Court of Appeals. The DRAs are published in the docket on January 20, 2015
- December 21, 2016: The EPA issued a revised human health risk assessment for TCVP, indicating potential risks of concern for children, but highlighting major uncertainties in the assessment (e.g., liquid vs. solid formulation of active ingredient in pet collars)
- March 21, 2017: The EPA issued a letter in response to NRDC's 2009 cancellation petition stating that the agency intends to address any risk mitigation issues in the course of registration review

DRAs were published to the docket January 20, 2015

New DRA included Davis study

Litigation History

EPA

- From 2017 to 2018, EPA communicated with the registrant, Hartz Mountain Corporation, regarding the development of new pet collar data to address the composition and ratio (% liquid vs. dust) of material coming off pet collars
- May 29, 2019: NRDC filed a lawsuit seeking a court order for EPA to respond in full to the 2009 petition based on "unreasonable delay"
- September 9, 2019: The agency filed a Declaration and Answering Brief in response to the May 29, 2019 unreasonable delay suit, requesting that the Court allow until September 2021 to complete its response
- February 2020: Oral arguments were presented
- April 22, 2020: The Ninth Circuit Court ruled that EPA must respond to the petition within 90 days

June 3, 2019: The EPA issued a data call-in (DCI) requiring Hartz to submit a composition "torsion" study to address the composition of pet collars.
August 28, 2019: Hartz provided a response to the DCI committing to conducting the torsion study.