



Comments of the Natural Resources Defense Council on Registration Review: Propoxur

**Docket No. EPA-HQ-OPP-2009-0870
74 Federal Register 66645 (December 16, 2009)**

February 16, 2010

On November 26, 2007, the Natural Resources Defense Council (NRDC) submitted a petition to the U.S. Environmental Protection Agency (EPA) to cancel the pet collar uses of propoxur and supplemented that petition on April 29, 2009.¹ To date, EPA has not responded to NRDC's petition. This registration review process should not be a substitute to EPA making a final determination on our petition to cancel all pet collar uses of propoxur. Given the toxicity and exposure data that already exist and that we provided in our petition, EPA should act immediately to grant our petition and protect human health and the environment from this dangerous poison. The registration review process is estimated to take up to six years to finish, and EPA should not delay in canceling the pet collar uses. NRDC offers these comments to EPA on the review of propoxur's registration, but requests the Agency make a final decision on our pending petition soon.

NRDC appreciates this opportunity to comment on the registration review of propoxur. On December 16, 2009, EPA announced the establishment of the registration review docket for propoxur.² Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA must review the registration of a pesticide every fifteen years. When Congress passed the Food Quality Protection Act, which requires that registration review be undertaken by EPA, it explained the importance of the process:

It has become apparent that the rapid development of science and the subsequent application of that knowledge in how it impacts human health and the environment is not only important but continuing to evolve. The goal of establishing ongoing scientific look-back procedures will enable the important process of registration review to be considered every 15 years during a pesticide product's

¹ Docket number EPA-HQ-OPP-2009-0207

² 74 Fed. Reg. 66645, 66647 (Dec. 16, 2009).

market life. This creates a continuous reregistration process that both the Agency and the registrant can plan for, rather than creating the need for another complete, resource-intensive reregistration of all pesticide products at one time in the future.³

In support of this registration review for propoxur, EPA has docketed a preliminary work plan for anticipated data and assessment needs. NRDC believes that there are gaps in the preliminary work plan, and as such, the planned registration review will not sufficiently assess the dangers associated with the continued use of propoxur, especially in pet collars. As asserted in our petition, a full and proper assessment of the exposures from pet collars would show that the Agency is legally required under FIFRA to cancel all pet collar uses of propoxur.

Propoxur is an insecticide that belongs to a category of pesticides called n-methyl carbamates. In addition to neurological toxicity, propoxur is a known carcinogen. In August, 2006, California added propoxur to a list of chemicals known to the state to cause cancer.⁴ Because propoxur is a cholinesterase inhibitor, it was included as part of EPA's cumulative risk assessment for the N-methyl carbamates. It is not clear from the preliminary work plan whether cholinesterase inhibition and other non-cancer endpoints will be included as part of registration review. NRDC requests that EPA clarify that both non-cancer and cancer endpoints will be considered for propoxur's review.

NRDC is most concerned with the inadequacy of the residential post-application exposure assessments conducted for propoxur use in pet collars. There were significant gaps in EPA's exposure analysis both in the registration eligibility determination and the N-Methyl Carbamate cumulative risk assessment.

EPA should use data from residue testing

As reported in NRDC's "Poison on Pets II: Toxic Chemicals in Flea and Tick Collars" and noted in our petition, residues of propoxur on the pets' fur are significantly higher than EPA's residue estimates.⁵ NRDC tested the residues of propoxur left on pets after the pet had worn a collar for three days and fourteen days. Based on these tests, NRDC found that EPA's assumption about the fur residue concentration for propoxur from the pet collars significantly underestimated the actual concentrations. Whereas EPA assumed that 0.069 $\mu\text{g}/\text{cm}^2$ of propoxur was left on the fur, NRDC sampling found that the residue concentrations actually ranged from 0.37 $\mu\text{g}/\text{cm}^2$ to 11.36 $\mu\text{g}/\text{cm}^2$.

Based on exposure parameters taken from published and government agency studies and residues from the tested animals' fur, NRDC calculated that after three days of wearing a collar, the dose for toddlers with average contact with the pets was between 0.048

³ H.R. Report 104-669, p 1212-13.

⁴ California Health and Safety Code § 25249.5 et seq., commonly known as Proposition 65.

⁵ A copy of NRDC's report "Poison on Pets II: Toxic Chemicals in Flea and Tick Collars" has been attached to these comments.

mg/kg/day and 1.482 mg/kg/day, much higher than the reference dose (RfD) of 0.05 mg/kg/day. One sample tested was almost 300 times higher than the RfD for propoxur. Toddlers with behaviors leading to high exposure to a pet wearing the pet collar could be exposed to average doses 1131 times higher than the RfD at three days (with the peak dose of 21.795 mg/kg/day), and 203 times higher for pets wearing the collar for 14 days (with a peak dose of 1.482 mg/kg/day from the same dog).

NRDC also found that inadvertent direct contact with the flea collar was possible during routine pet handling activities. When this contact with the flea collar after a pet had worn it for 3 days was included, the estimated dose was more than double the dose if there is no direct contact. After 14 days, the residues which include direct contact with the collar were more than 10 times higher than without contact with the collar. As with the other scenarios, the actual residues reported in Poison on Pets II were significantly higher than EPA's assumptions.

At a minimum, NRDC's report shows that EPA must conduct residue testing for pet collars to obtain realistic estimates for residues, rather than rely on its faulty assumptions. The risk to children from exposure to propoxur from pet collar uses must be calculated accurately in this process. Based on the projected registration review timeline for propoxur, it will take the Agency six years to make a final registration review decision.⁶ As such, there is more than sufficient time for EPA to conduct residue testing of flea collars. However, the results from NRDC's "Poisons on Pets II" report alone are sufficient to support cancellation of propoxur use in flea collars well before the final registration review decision.

EPA should include inhalation exposures from all indoor uses

EPA's registration review of propoxur should include the inhalation exposures from all indoor uses. Several studies have shown that indoor air can be contaminated with propoxur.

First, NRDC's "Poison on Pets II" report, demonstrated that use of a propoxur containing flea collar could result in measurable concentrations of propoxur in the air. We found an average airborne level of propoxur of 0.5 ng/m³ over eight hours in a small room. Second, a separate study of pesticide concentrations in indoor air found propoxur in all of the samples tested, with ranges in concentration from 1.1 ng/m³ up to 317 ng/m³.⁷ Third, a December 2009 assessment by EPA's Health Effects Division of an emergency exemption request for propoxur showed that inhalation risks from crack and crevice treatments well exceeded the acceptable margin of exposure. This assessment alone underscores the need to conduct a full assessment of inhalation exposures for all indoor uses of propoxur.

⁶ U.S. EPA, Propoxur Summary Document Registration Review: Initial Docket, December 2009, available in Docket No. EPA-HQ-OPP-2009-0806, p. 8.

⁷ Whyatt, RM, et al. Within- and Between-Home Variability in Indoor-Air Insecticide Levels during Pregnancy among an Inner-City Cohort from New York City. *Environ Health Perspect.* 115(3) March 2007, p. 383.

EPA has not published an acceptable level for propoxur in air. The N-Methyl Carbamate Cumulative Risk Assessment did not consider the inhalation route of exposure from pet collars and failed to consider children's inhalation exposures. This gap in the preliminary work plan for propoxur should be filled, and data on levels of propoxur in residential air due to pet collars and other indoor uses should be collected. EPA needs to include the inhalation exposures to both adults and children in its exposure assessment for propoxur.

EPA should improve estimation of non-dietary ingestion and dermal exposures from pet collar residues

EPA's assessment of the non-dietary exposure must include the exposure from indirect hand-to-mouth activity where an individual touches an object or food with pesticide-contaminated hands, and then puts that object or food into his or her mouth. Published studies show that there is actually noticeable indirect hand-to-mouth activity in infants and children.⁸ One study found that, on average, a toddler will touch an object and then put that object into his or her mouth 15 times in one hour.⁹ At the high end of the study's distribution (90th percentile), that rate rises to 66 times per hour. This same study found a statistically significant positive correlation between the frequency of object or food in mouth activity and blood lead levels.

Previous EPA assessment of children's exposure to pet collar residues have relied on assumptions that are unrealistic, inconsistent with previous agency findings, and not supported in the literature. As part of the registration review EPA must use or develop more realistic assumptions for the following parameters: duration of time spent with a pet, frequency of pet contact, and hand-to-mouth frequency.

EPA's exposure assessment for residential post-application exposure to pesticides in flea collars in both the Organophosphate Cumulative Risk Assessment (2006) and the N-Methyl Carbamate Cumulative Risk Assessment (2007) rely on a study by Freeman et al. (2001) that included only three children with pets. Based on the results of this study, EPA assumed a triangular distribution with a minimum value of 0.03 hrs./day and a maximum value of 1.03 hours per day of time spent with a pet. These numbers are much smaller than the estimate used in the risk assessment performed for dichlorovos (DDVP) in flea collars and the EPA Standard Operating Procedures for Residential Exposure Assessments, which both assume that a child plays with a pet for two hours per day. However, none of these numbers reflect a "high-end scenario," which might involve a child who spends many hours with a pet (including sleeping) or multiple pets.

⁸ Ko, S, Schaefer, PD, Vicario, CM, and Binns, HJ. Relationship of video assessments of touching and mouthing behaviors during outdoor play in urban residential yards to parental perceptions of child behaviors and blood lead levels. *J. Exposure Sci. Environ. Epidemiol.* 2007 17, 47-57; Reed, KJ, Jiminez, M, Freeman, NCG, and Lioy, PJ. Quantification of children's hand and mouthing activities through a videotaping methodology. *J. Exposure Anal. Environ. Epidemiol.* 1999, 9, 513-520.

⁹ Ko, S, Schaefer, PD, Vicario, CM, and Binns, HJ. Relationship of video assessments of touching and mouthing behaviors during outdoor play in urban residential yards to parental perceptions of child behaviors and blood lead levels. *J. Exposure Sci. Environ. Epidemiol.* 2007 17, 47-57.

Previous EPA risk assessments have relied on the Freeman et al. study of nineteen children ages 3 years to 12 years to estimate hand-to-mouth frequency. This ignores the increased vulnerability of younger children, who have been found to have increased rates of hand-to-mouth activity. A 2007 EPA meta-analysis reported that the frequency of hand-to-mouth activity for 1- and 2-year-olds range from 19.6 times per hour for average behavior up to 63 times per hour for high exposure behavior.¹⁰

Furthermore, the N-Methyl Carbamate Cumulative Risk Assessment relied on the assumption that a child would touch the pet and get residue on the hand once per hour spent with the pet, and that during that hour, the frequency of hand-to-mouth activities was 13 times per hour. This assumption is not supported in the literature and contrasts with the methods utilized in the cumulative risk assessment for the organophosphates and the EPA Standard Operating Procedure for Residential Exposure Assessment where it is assumed that each time a child touches his or her mouth, the hand was equally contaminated with residues as if he or she had just touched the pet. Therefore, in this review of propoxur's registration, EPA needs to improve the estimation of non-dietary ingestion and dermal exposures from pet collar uses.

These comments are respectfully submitted for your consideration,

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¹⁰ Xue, J., Zartarian, V., Moya, J., Freeman, N., Beamer, P., Black, K., Tulve, N., and Shalat, S. "A Meta-Analysis of Children's Hand-to-Mouth Frequency Data for Estimating Nondietary Ingestion Exposure." *Risk Analysis*, 2007, Vol. 27, No.2.