



February 21, 2014

COMMENTS OF THE NATURAL RESOURCES DEFENSE COUNCIL ON THE VOLUNTARY CANCELLATION OF PROPOXUR-FORMULATED PET COLLARS

EPA-HQ-OPP-2009-0207

79 Federal Register 3586 (January 22, 2014)

The Natural Resources Defense Council (“NRDC”) is a national, non-profit environmental organization of lawyers, scientists, and other professionals. NRDC presents these comments on behalf of our 1.4 million members and online activists. NRDC does not have any financial interest in the topic of these comments. NRDC appreciates the opportunity to comment on the voluntary cancellation requests of Sergeant’s Pet Care Products, Inc. (“Sergeant’s”) and Wellmark International (“Wellmark”) (collectively, “registrants”) of their pet collars impregnated with the pesticide propoxur.

NRDC supports the immediate cancellation of propoxur-formulated pet collar product registrations in such a manner as to address the unacceptable risk posed to young children. However, we find that the conditions of the voluntary cancellation, agreed to in closed-door negotiations by the U.S. Environmental Protection Agency (“EPA”) and Sergeant’s and Wellmark, are unacceptable. The proposed cancellation will not adequately protect children from the risks of exposure to propoxur because it will allow the registrants to increase production prior to cancellation, potentially allow the registrants to simply substitute their registrations with different formulations of propoxur, and permit unsafe products to remain on the market indefinitely.

BACKGROUND

Propoxur is an insecticide that belongs to a category of pesticides call n-methyl carbamates. In addition to neurological toxicity, propoxur is a known carcinogen. EPA designated propoxur as a probable human carcinogen in 1996.¹ In August 2006, California added propoxur to a list of chemicals known to the state to cause cancer. (Health and Safety Code § 25249.5 et seq., commonly

¹ EPA Memorandum from Jess Rowland to Division Directors, Chemicals Evaluated for Carcinogenic Potential by the Office of Pesticide Programs (September 24, 2008).

known as Proposition 65.) The neurotoxic effects of this class of pesticides are due to their inhibition of an enzyme called cholinesterase. This enzyme is responsible for the timely deactivation of the nerve signaling protein acetylcholine.

Because of these toxicity concerns, NRDC petitioned EPA on November 26, 2007 to cancel the pet collar uses of propoxur. NRDC supplemented that petition on April 29, 2009 with the release of our *Poisons on Pets II* report. Our report found that the high levels of residues from pets wearing propoxur-formulated flea collars posed a risk of cancer and neurological damage far beyond EPA's acceptable levels. On April 7, 2010, EPA conducted an Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars ("2010 ORE"). EPA publicly released that risk assessment on July 23, 2010. Based on the findings in that ORE that the child incidental oral exposures were "of concern to the Agency," NRDC supplemented the petition again on January 18, 2011, reiterating our request that EPA immediately cancel the propoxur-formulated pet collar products.

On January 22, 2014, EPA publicly released another Occupational and Residential Exposure Assessment, which had been completed in September 12, 2013 ("2013 ORE"). Like the 2010 ORE, the 2013 ORE also found that there were exposures of concern to the agency from children's exposure to propoxur-formulated pet collars.

Also on January 22, 2014, EPA published notice of its receipt of voluntary cancellation requests by the registrants for propoxur-formulated pet collars. EPA also posted a series of communications between itself and Sergeant's and Wellmark regarding the conditions of cancellation. According to the Federal Register notice, the conditions of the voluntary cancellations are detailed in these correspondences. Among other things, the registrants may continue manufacturing these products through April 1, 2015; they may sell and distribute existing stocks through April 1, 2016, and other persons may sell and distribute the products until all the existing stocks are exhausted. The registrants are also permitted to increase the production of propoxur-formulated pet collars prior to cancellation.

EPA'S RISK ASSESSMENT SHOWS RISKS "OF CONCERN"

Both of the OREs conducted by EPA found levels of exposure to propoxur of concern. In the 2010 ORE, EPA found that the child incidental oral ingestion exposure from a treated pet is of concern (Margin of Exposure ("MOE") < 1000).² The MOE represents the ratio of the level at which no adverse effects are observed to the exposure amount. EPA sets a target MOE, and calculated MOEs that are lower than the target amount raise concerns about risk to human health. In the 2010 ORE, the MOEs ranged from 20 to 62. In the 2013 ORE, EPA lowered the target MOE to 100, by reducing

² U.S. Environmental Protection Agency. Propoxur: Occupational and Residential Exposure and Risk Assessment for Propoxur Formulated Pet Collars. April 7, 2010. Docket ID EPA-HQ-OPP-2009-0207-0015, p.10.

the FQPA 10X safety factor to 1X.³ Despite the lower target MOE, EPA still found that the non-cancer risk estimates for the oral ingestion route of exposure exceeded the level of concern for young children (from ages 1 to less than 2 years old).⁴ Specifically, EPA calculated MOEs of concern (< 100) for all sizes of Sergeant's cat collars and the small and medium sized dog collars with MOEs ranging from 37-85. For Wellmark collars, EPA calculated MOEs of concern for small and medium sized cat and dog collars with MOEs ranging from 47-74. Overall, EPA found that the "non-cancer risk estimates for the oral route of exposure results in risk estimates of concern (MOEs < 100) rang[ed] from 37 to 120" for children between 1 and 2 years old.

EPA's 2013 RISK ASSESSMENT STILL UNDERESTIMATES THE RISK

NRDC previously raised concerns that, in the 2010 ORE, EPA relied on inadequate and unsubstantiated exposure assumptions that substantially underestimate a young child's exposure to propoxur from flea collars. EPA repeated these problems in the 2013 ORE. As a result, although EPA found in the 2013 ORE that 9 out of the 12 propoxur-impregnated flea collar formulations resulted in exposures of concern for young children, correcting for some of the inadequate exposure assumptions reveals that none of these products are safe for use in the home.

For example, EPA failed to include an assessment of dermal dose in the residential post-application non-cancer risk assessment, despite acknowledging that there is both dermal exposure and absorption of propoxur. EPA failed to provide a description of the physiological or toxicological mechanism to support the claim that there are no toxicological effects from dermal exposures. This omission resulted in a significant underestimation of risk. Similarly, EPA failed to account for indirect hand-to-mouth exposure (toddlers touching objects or food with pesticide-contaminated hands and then putting those objects or food into their mouths), despite evidence that indirect hand-to-mouth exposure can be a significant route of exposure for young children.

EPA also failed to adequately assess exposure for children who have a high level of contact with their pet. In the 2013 ORE, EPA used the average exposure time (one hour) recorded in a 1996 study and summarized in EPA's 2012 Standard Operating Procedures for Assessing Residential Pesticide Exposures (2012 SOP).⁵ However, as depicted in table 8-5 in the SOP, half of the children observed in that study spent more than one hour per day with their pet and children who frequently interacted with their pet (95th percentile) spent more than twice this amount of time (2.3 hours per day). EPA also assumed children replenished the pesticide residue on their hands every 15 minutes while spending time with their pet. Therefore, EPA's assumptions in the 2013 ORE correspond to a limited amount of contact with a pet by assuming a child only touches the pet four times a day (equal to every 15 minutes, or 4 contacts per hour, multiplied by 1 hour per day). If the risk assessment better accounted for children who were at the high end of the study

³ U.S. Environmental Protection Agency. Propoxur. Occupation and Residential Exposure Assessment in Response to the Natural Resources Defense Council Petition for Pet Collars. September 12, 2013. Docket ID EPA-HQ-OPP-2009-0207-0190, p.4.

⁴ *Id.* at 13.

⁵ EPA 2012. Standard Operating Procedures for Residential Pesticide Exposure Assessment. http://www.epa.gov/pesticides/science/USEPA-OPP-HED_Residential%20SOPs_Oct2012.pdf

summarized in the SOP (2.3 hours per day), EPA would have estimated that children touch their pet 9 times per day (4 contacts per hour x 2.3 hours per day). If EPA accounted for children at the higher end of the spectrum (exposure time = 2.3 hours per day), the resulting MOEs (keeping all other values and equations constant) would range from 19-51 for Wellmark collars and 16-51 for Sergeant's collars.⁶

In calculating the quantity of pesticide on the skin, EPA used empirical values that were derived for liquid, not solid, products. This decision caused EPA to underestimate the risk in the 2013 ORE. EPA decided without explanation or substantiation that the active ingredient in the flea collars "is or behaves like a liquid" and selected exposure factors from the 2012 SOP for liquids, not solids. But, a Wellmark propoxur-formulated flea collar label states that the active ingredient is released as a "dust." According to EPA's 2012 SOP, dusts should be treated as solid formulations.⁷ Had EPA used the exposure factors (Transfer Coefficient and Fraction of active ingredient on hands) values for solid formulations, the MOEs would range from 0.0064 to 0.017 for Wellmark collars and 0.0053 to 0.017 for Sergeant's collars.⁸

EPA's cancer risk assessments for handlers and residential post-application exposures similarly underestimate adult exposures to propoxur-impregnated flea collars by failing to account for adults who have a high level of contact with their pet, omitting hand-to-mouth and inhalation exposures, and relying on the transfer coefficient value derived for a liquid product.

The inadequate assumptions in the 2013 ORE drastically underestimate risk and confirm EPA's 2010 finding that propoxur-formulated pet collars pose unacceptable risks to young children. In accordance with EPA's duty under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA should immediately cancel the registrations of propoxur-formulated pet collars.

SERGEANT'S AND WELLMARK WILL FLOOD THE MARKET WITH PROPOXUR-FORMULATED PET COLLARS

On January 22, 2014, EPA publicly released a series of correspondence between Sergeant's and EPA and one letter from Wellmark to EPA. In those letters, both companies separately indicated their intention to flood the market with their propoxur-formulated pet collars before the cancellation deadline.

In the letters between Sergeant's and EPA, Sergeant's agreed to voluntarily cancel its propoxur pet collars by April 1, 2015, as long as it could sell or distribute existing stocks until April 1, 2016, and as long as others would be allowed to sell and distribute those pet collars until all stocks are

⁶ MOEs calculated using the Treated Pets SOP spreadsheet available on EPA's website.

<http://www.epa.gov/pesticides/science/residential-exposure-sop.html>

⁷ EPA 2012. Standard Operating Procedures for Residential Pesticide Exposure Assessment.

http://www.epa.gov/pesticides/science/USEPA-OPP-HED_Residential%20SOPs_Oct2012.pdf

⁸ MOEs calculated using the Treated Pets SOP spreadsheet available on EPA's website.

<http://www.epa.gov/pesticides/science/residential-exposure-sop.html>

exhausted. EPA appears to have attempted to limit production of these pet collars leading up to April 1, 2015, but Sergeant's opposed it. Specifically, in response to a draft letter from EPA, Sergeant's "remove[d] the provisions regarding production limits and production volume data."⁹ Claiming that they were not aware of other voluntary cancellations with similar requirements, that similar requirements were not imposed on the other registrant (Wellmark), and that they were unaware of any "factual or legal basis" for these requirements, "Sergeant's cannot agree to them." About one month later, Sergeant's stated that it "intends" to produce no more propoxur pet collars in the next 18 months than it had sold during 2011 and 2012 combined.¹⁰ Moreover, there are no restrictions on Sergeant's production prior to the start of the 18-month period. NRDC opposes the protracted deadlines to cancel Sergeant's propoxur-formulated pet product registrations that allow Sergeant's to increase the amount of product on the market before the Release for Shipment deadline.

Worse still, propoxur-formulated flea collars will continue to be sold until all existing stocks are sold. Sergeant's letter indicates that the pet collars have a "typical shelf life of five years," meaning that consumers can still purchase these propoxur pet collars in April 2020 – or even later if retailers choose to stock products past the typical shelf life. These pet collars pose a risk to children, and these voluntary cancellations mean children can be exposed to these risks, without any warning, for at least the next six years and potentially longer.

Similar to Sergeant's intention to increase production of its propoxur pet collars, Wellmark's conditional voluntary cancellation allows it to produce 1.5 times the average annual production level for each propoxur pet collar from the calendar years 2010 to 2012. In other words, Wellmark will produce **more** propoxur flea collars in the year leading up to the cancellation of the products than it typically produces.

EPA should not allow Wellmark and Sergeant's to increase production of products EPA has determined to be "of concern." There should be an immediate withdrawal of these products from store shelves.

THE WELLMARK VOLUNTARY CANCELLATION MAY ALLOW PROPOXUR-FORMULATED PET COLLARS TO REMAIN ON THE MARKET

Wellmark's voluntary cancellation request is complicated, with terms and conditions that are difficult to understand. In its letter dated September 9, 2013, Wellmark outlines two situations under which it will conditionally request voluntary cancellation of its propoxur pet products. These complicated conditional requests for voluntary cancellation obscure the effect of Wellmark's request.

⁹ Letter from Donald McLean, Arent Fox, to Kaitlin Keller, EPA dated October 7, 2013. Docket ID EPA-HQ-OPP-2009-0207-0188.

¹⁰ Letter from Donald McLean, Arent Fox, to Kaitlin Keller, EPA dated November 1, 2013. Docket ID EPA-HQ-OPP-2009-0207-0189.

One condition appears to be based on Wellmark's ability to amend its current registrations by reformulating propoxur pet collars. Wellmark is to submit a "concept package" to EPA containing, among other things, "revised Confidential Statements of Formula (CSFs) [and] collar design specifications (i.e., collar weights & dimensions)...." But there are no conditions preventing Wellmark from reformulating its pet collars with a different amount of propoxur.

NRDC requests that EPA explain the conditions of Wellmark's conditional voluntary cancellation in plain terms so that the public can understand the possible effects on the market for propoxur-formulated pet collars. NRDC also requests that EPA require any product reformulation to not include propoxur. Again, these are products that EPA has already determined are of concern to children's health. EPA should be taking steps necessary to prevent continued exposure to these dangerous products, not accepting terms from the manufacturer that potentially allow propoxur-formulated flea collars to remain on the market.

CONCLUSION

NRDC opposes EPA's reliance on the voluntary cancellation process to leave dangerous pesticide products on the market long after EPA has determined that they are not safe. Children currently face unacceptable risks from exposure to propoxur-formulated pet collars. Even three years ago in its 2010 ORE, EPA acknowledged that these products expose children to risks of concern. But it took no immediate action to protect children from those risks.

Now, EPA is allowing Sergeant's and Wellmark to flood the market with more propoxur-formulated pet collars for the next year and for these products to be available to the public until all those products are sold. Given the typical five year shelf life of these products, this means that these dangerous products – which should never have been approved in the first place – will continue to pose a risk to children until at least the year 2020 and potentially indefinitely.

EPA must act to halt the flow of these products to consumers. EPA can require that Sergeant's and Wellmark stop the sale of these products immediately. Pesticide products that have risks of concern to the agency should not remain on the market for another six, or more, years. EPA should require that registrants of propoxur-formulated pet collars immediately cease the production, sale, and distribution of these products, and prohibit the use of existing stocks.

Respectfully submitted,

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