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July 15, 2011

Office of Pesticides Program (OPP) Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

RE: Petition Supplement Requesting Cancellation of Propoxur Pet Collar Uses; Availability
(Document ID EPA-HQ-OPP-2009-0207-0018)

Dear Administrator Jackson and EPA Staff:

Thank you for the opportunity to comment on the NRDC's petition supplement, which requests the cancellation of propoxur pet collars. BioSpotVictims, a non-profit organization which seeks to educate the public on the potential hazards of pet pesticide products, fully supports the NRDC's effort to remove tetrachlorvinphos and propoxur pet collars from the market.

The safety requirements for pet pesticide products continue to be a low priority at EPA

In 1996, the EPA's Occupational and Residential Exposure Branch (OREB) was asked to provide EPA's Special Review Branch (SRB) with an overview of pesticides registered for direct use on domestic animals:

<http://www.biospotvictims.org/004003-032.pdf>

Here are excerpts:

“It is our understanding that the issue of pet pesticide products has been on the SRB's unfunded list for several years.”

“The safety requirements for regulation of pet pesticide products have been ill-defined and inconsistently applied in the past.... They are available in grocery stores, pharmacies, feed stores, veterinary clinics and pet stores. They are often poorly labeled and lacking adequate instructions for their safe use.”

“The regulated industry has acknowledged that EPA's safety requirements for pet insecticides are less rigorous than those of the Food and Drug Administration for veterinary drugs (including topical preparations).”

Despite the passage of the Food Quality Protection Act in 1996, which required EPA to consider risks to infants and children from pesticide exposure, many pet pesticide products – including propoxur pet collars – have never been adequately assessed.

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EPA's safety requirements for pet insecticides remained inadequate for the next decade.

In 2009, after noticing a sharp increase in adverse incidents, EPA launched an investigation of pet spot-on products. Over 44,000 adverse incidents had been reported in 2008 – a 53 percent increase from 2007.

EPA's pet spot-on investigation concluded that the majority of incidents were due to inadequately labeled products and insufficient safety testing.

EPA failed to adequately assess residential exposures to propoxur pet collars in 1997

Propoxur pet collars were first registered in 1975, but the EPA did not begin to consider their risks to children until 1996.

In 1997, EPA's Reregistration Eligibility Decision for propoxur found:

“For the non-occupational uses of propoxur which include crack and crevice treatments, aerosols, tick and flea collars, and spot treatment, the Agency assumes that minimal exposure may occur.”

“The Agency concludes that aggregate risks to the general U.S. population, and to the population subgroups of infants and children, resulting from propoxur uses are not of concern.”

However, EPA-funded research, which quietly began in 1996 and ended in 1999, found that flea collars may expose children to potentially harmful levels of pesticide.

Dr. Janice E. Chambers, who headed the research at Mississippi State University, suggested that parents of young children use caution, especially during the first week after applying a new flea collar, when pesticide released tends to be highest. "Don't let the kid hug and sleep with the dog while the collar is fresh," Chambers advised in 1999. "The bottom line, for my current opinion, is that there is a potential concern regarding this source of insecticide exposure."

EPA found that propoxur pet collars may pose significant risks to children in 2005

In 2005, EPA published its preliminary cumulative risk assessment for N-methyl carbamate (NMC) pesticides. It stated:

“In particular, for the three routes considered in the residential assessment, exposure from hand-to-mouth activity by children and through the dermal route appear to be the most significant contributors to risk from residential exposures. Specifically, risks associated with crack and crevice uses of propoxur and those associated with pet collar uses of propoxur and carbaryl are the uses which are estimated to contribute the most to residential exposures.”

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However, with a nod to industry, EPA noted that there were “significant conservatisms” incorporated into their preliminary assessment which likely overestimated risk, and that EPA expected to revise this portion of the assessment after considering advice and suggestions from EPA’s Scientific Advisory Panel (SAP).

Data used by EPA to assess risks was insufficient in quantity and in quality

After reviewing the preliminary NMC assessment, one SAP panelist argued that “current data for assessing non-dietary oral ingestion are insufficient both in quantity and in quality, and are unlikely to be sufficient in the foreseeable future.”

That SAP panelist recommended that EPA run simulations with a deterministic model to learn whether hand-to-mouth activity contributes appreciably to the overall residential exposure assessment. If the estimated exposure from hand-to-mouth activity does represent a substantial portion of the total residential exposure, the panelist recommended making EPA’s assumptions more realistic.

EPA ignored that advice, and issued a revised NMC assessment in 2007, which stated that risks were “below OPP’s level of concern for all subpopulations.”

Once again, EPA finds that propoxur pet collars pose unacceptable risks to children

In response to the NRDC’s petition, EPA conducted an Occupational and Residential Exposure and Risk Assessment for Propoxur Pet Collars in April 2010. It found:

“A quantitative assessment of residential post-application exposure of a propoxur pet collar was conducted in the 1997 RED using surrogate data based on propoxur pest strips and dog aerosol spray treatment.... In addition, residential post-application risk was assessed in the 2007 NMC CRA for propoxur pet collars. Based on inputs, assumptions, and algorithms that were specific to the cumulative risk assessment, the propoxur pet collar dermal and incidental oral ingestion risk estimates were not of concern at that time...”

“HED has determined that exposure to propoxur is likely following residential pet collar use. Adults and children are likely to contact a previously treated pet, however, since no dermal endpoint was selected, only child incidental oral ingestion (hand-to-mouth) exposure was assessed. The incidental oral ingestion exposure scenario using default inputs and a 15 day average result in MOEs <62, this scenario exceeds the Agency’s level of concern (MOE <1000).”

A revised risk estimate was issued in July 2010, to account for an error, but the corrections did not alter the previous risk conclusions. However, with its customary nod to industry, EPA indicated that it anticipates more data from registrants which could reduce risk estimates.

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EPA's risk assessment failed to consider exposure to various sized pets

EPA risk assessments only consider the risk that “average” weight pets pose to “average” weight children. The actual risk may be significantly greater for younger children, or children who are exposed to small or large pets.

To address these concerns, EPA made a substantial revision to its Standard Operating Procedures (SOPs) for Residential Exposure Assessment, and submitted it to its Scientific Advisory Panel for review in October 2009. These draft guidelines state:

“For pet pesticide formulations which specify application rate in relation to animal weight (i.e., collars and top-spots), a rate should be quantified for small, medium and large weight classifications as assigned by the Agency. The weight ranges are as follows:

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).”

EPA has stated that its residential SOPs are currently undergoing further revision, and are not sufficiently developed for use in assessments, however, the above weight classifications were used by EPA last year to assess a spot-on product for cats (EPA Reg. No. 72642-9):

<http://www.biospotvictims.org/RELEASABLE-2.pdf>

EPA's risk assessment of propoxur pet collars must be conducted in a manner which is consistent with EPA policy, and consistent with risk assessments of similar scope.

EPA does not adequately protect pregnant women, fetuses and children

In its review of the revised residential SOPs, the Scientific Advisory Panel expressed concern that EPA's risk assessment methodology did not adequately protect pregnant women and fetuses. Furthermore, it was critical of EPA's definition of "toddlers" as children aged 3-6.

The Panel stated, "...using the toddler label for ages 3-6 is simply misleading and confusing. In addition, exposure factor data collected from 3-6 year olds might lead to underestimation of exposures to 2-3 year olds since hand-to-mouth and object-to-mouth behavior generally decline with age. Children with developmental delays, such as those with intellectual disabilities and/or autism, may still exhibit mouthing behavior at age 6. Finally, at least one Panelist is concerned that the Agency's questionable 'toddler' age selection is an indication that actual infant and toddler exposures have not been adequately examined."

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Sergeant's and Wellmark's response to EPA's risk assessment is deplorable

On June 22, 2010, a letter was submitted to the EPA on behalf of Sergeant's Pet Care Products and Wellmark International – the registrants of propoxur pet collars. It strongly objected to EPA's intention to release its risk assessment of propoxur pet collars to the public, and EPA's request to limit availability of the product while studies are being conducted, claiming that the release of the risk assessment and the proposed mitigation measures would “seriously damage, if not destroy, the market for Propoxur Pet Collars.” Furthermore, it requested a meeting with EPA and threatened legal action if the matter could not be resolved.

Sergeant's and Wellmark's transferable residue study is not credible

On July 12, 2011, a letter was submitted to the EPA on behalf of Sergeant's and Wellmark, disputing the assertions made in the NRDC's latest supplement, and made reference to a study that Sergeant's and Wellmark recently funded, which found there is “no reasonable basis for concern for the safety of children from exposure to propoxur residues transferred from pet fur.”

The study reported that transferable residues range from 0.0715% on Day 0 to 0.0033% on Day 28. These findings are in stark contrast with EPA-funded studies that were conducted by Dr. Janice E. Chambers.

The study from Sergeant's and Wellmark needs to be scrutinized for deficiencies. Was the study conducted in compliance with EPA Good Laboratory Practice Standards? What country was it performed in? Was the petting simulation performed in a manner which has been determined to mimic normal petting actions? It's bad enough that EPA relies on junk science to support pet safety – please do not use it to protect our children.

EPA must also consider influences, impacts or circumstances which might have impaired the integrity of the study. The fact is, without an acceptable study, Sergeant's and Wellmark would have to remove propoxur pet collars from the market.

Protecting children from pesticides is one of EPA's most important responsibilities

I urge EPA to stop coddling and catering to corporations that harm children, pets, and our environment. Please exercise your statutory obligation to protect children by canceling propoxur pet collars.

Sincerely,

James TerBush
Website Administrator