

BioSpotVictims.org

September 28, 2009

Information Quality Guidelines Staff (Mail Code 2811R)
U.S. EPA
1200 Pennsylvania Ave., NW
Washington, DC 20460

RE: Meeting of the FIFRA Scientific Advisory Panel, October 6-9, 2009; Request for comments; Federal Register Vol. 74, No. 141, P. 36708, July 24, 2009; Docket No. EPA-HQ-OPP-2009-0516

Ladies & Gentlemen:

For the past seven years, I have maintained a website that concerns adverse incidents in companion animals from the use of pet pesticide products. Each year, thousands of people find my website by searching for information on the adverse affects of these products, and many have taken the time to write to me about their tragic experiences. Their messages are posted on my website.

Most of the adverse incidents reported to me involve the use of pet spot-on treatments - a liquid that is applied as a spot or stripe to the back of the animal. These products often contain a high concentration of pesticide, and represent one of the most dangerous residential exposure scenarios for toddlers, as well as for pets. Spot-on treatments intended for large dogs often contain twice as much active ingredient as the dosage currently used to calculate risk assessments.

The EPA is currently investigating pet spot-on treatments because it has become increasingly concerned by the number of adverse incidents that are reported each year following the use of these products. Last year alone, the EPA received over 44,000 reports of adverse incidents - including hundreds of life-threatening reactions and deaths in pets. Unfortunately, the vast majority of adverse incidents from pet pesticide products are never suspected or reported to anyone.

I believe the 44,000 adverse incidents that were reported to the EPA last year are indicative of a failed regulatory system - one that consistently underestimates the risks that pet pesticide products pose to animals and humans (especially children). Several factors have contributed to this failure, including: companion animal safety studies that lack scientific integrity; the use of industry-backed probabilistic risk assessments (despite data gaps in the toxicity database); bowing to industry pressure by lowering the FQPA Safety Factor for pesticides; bowing to industry pressure by lowering the dermal absorption rate of pesticides; reliance on industry-backed studies and surveys for critical data; failure to consider maximum application rates of products when calculating residential post-application risk assessments; failure to consider aggregate and cumulative risks of pyrethroids; failure to consider the synergistic effect of active and other ingredients; inadequate warning statements on pesticide labels; inadequate adverse incident data from registrants; and inadequate post-market surveillance.

The above mentioned deficiencies will continue to exist, even if the Draft Technical Guidelines for the Standard Operating Procedures for Residential Pesticide Exposure Assessment are adopted.

BioSpotVictims.org

The Draft Technical Guidelines make use of probabilistic risk analysis, which is promoted as being a refinement over deterministic assessments. Probabilistic assessments are based on highly complex calculations. However, they require large amounts of data that are seldom available (according to a GAO report, Human Health Risk Assessment, May 2006). The results of these calculations are only as good as the modeling assumptions (according to Susan R. Poulter, Ph.D., 1997).

Unfortunately, the Draft Technical Guidelines concerning pet treatments rely on several incorrect assumptions, including: exposure scenarios involve only one pet; toddlers are assumed to touch a treated pet with only one hand; exposure time for toddlers is assumed to be only one hour per day (currently, exposure time is assumed to be 2 hours per day); toddlers are assumed to touch a treated pet only four times during the one hour period; the hand-to-mouth frequency data for toddlers is based on children 3 to <6 years old, which ignores the fact that children under 3 years of age are far more likely to engage in hand-to-mouth activity; it assumes that pet pesticide products dissipate at a rate of 14% per day (currently, residue dissipation is not considered); it also assumes that an even loading of residue across the entire surface of the pet occurs on the day of application, which greatly underestimates the acute risk posed by spot-on treatments. These assumptions have no basis in reality.

Several of the assumptions in the Draft Technical Guidelines are based on studies that are inadequate for risk assessment purposes. For example, the exposure time for toddlers with treated pets was based on an observational study of nineteen children who were interviewed and videotaped for four hours. In another example, the default transferable residue measurement for pet treatments was based on five dermal exposure studies that were submitted by pesticide registrants.

In the Draft Technical Guidelines, the EPA acknowledges that its Standard Operating Procedures concerning pets rely mainly on data submitted in support of pet pesticide product registration.

According to two internal EPA memorandums, which reviewed three of the dermal exposure studies, significant deficiencies were noted. These memorandums are publicly available on my website:

<http://www.biospotvictims.org/129121-113.pdf>

<http://www.biospotvictims.org/109701-2006-03-14a.pdf>

If credible data is not available for risk assessments, the EPA should not rely on industry-backed studies that lack scientific integrity as the best available information.

However, other dermal exposure studies were available that should have been considered. Here is a study titled, Human Exposure to Fipronil from Dogs Treated with Frontline:

<http://www.ncbi.nlm.nih.gov/pubmed/12361121>

It states, "Repeated exposure to such contamination can pose human health risks."

BioSpotVictims.org

Here is a study titled, Human Exposure to Imidacloprid from Dogs Treated with Advantage:

<http://www.informaworld.com/smpp/content~content=a725843883~db=all>

It states, “Repeated chronic exposure to imidacloprid may pose possible health risks to veterinarians, veterinary technologists, dog caretakers, and owners.

Here is a study titled, Assessing Levels of Intermittent Exposures of Children to Flea Control Insecticides from the Fur of Dogs:

http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/779

That study was funded by an EPA grant. Here are excerpts regarding it from the EPA’s website:

“There are reported insecticide residues present in food, water, and surfaces such as carpets treated for flea control. However, no studies (except those we currently have in place) have quantified the transferable flea control insecticide residues which occur on pets (the majority of which are dogs) that could be transferred to children. These dermal exposures could easily become oral exposures when children place their contaminated hands in their mouths. Organophosphorus insecticides or synthetic pyrethroids are among the most common types of insecticides used for flea control. Our calculations have estimated that transfer of these residues could result in exposure levels approaching the adult reference dose (RfD), which does not contain the 10-fold safety factor to account for the greater sensitivity of children. There are a very large number of dog-owning households in the United States (about 37%) and about half of pet-owning households have children in them. The opportunity for large numbers of children to contact flea control insecticides on pets is high. Because of this lack of information and the likelihood of appreciable insecticide residues being present on pet fur, we propose to test the following hypothesis: The residues of insecticides available for intermittent transfer to children from the fur of dogs treated by either a spot treatment or a collar for flea control will be appreciable and of a magnitude necessitating inclusion in cumulative risk assessments of pesticides to children; and, secondly, that the fur rubbing procedure developed to quantify transferable residues provides a useful estimate of insecticide residues which could be transferred from the fur of dogs to children.”

The above study reached the following conclusion:

“Overall, it appears that over-the-counter flea control remedies can result in dislodgable residues that have the potential to cause exposure of people. The likelihood of this resulting in internalization of the insecticide does not appear to be consistent among products. The exposure resulting from flea control products should be taken into account in aggregate and cumulative risk assessments. While there is insufficient information from these studies to accurately assess the actual exposure levels from these products, it is probably wise to exercise caution in contacting pets recently treated with similar products because apparently high levels of dislodgable residues occurred shortly after product application on some of the dogs.”

BioSpotVictims.org

Recently, the Natural Resources Defense Council conducted studies to determine the transferable residue from the fur of pets wearing flea collars, and published the results in a report titled, Poison on Pets II. It found, “Residue levels produced by some flea collars are so high that they pose a risk of cancer and damage to the neurological system of children up to 1,000 times higher than the EPA’s acceptable levels.”

Unfortunately, the EPA has informed the NRDC that its studies meet the definition of “research involving the intentional exposure of a human subject” in 40 CFR 26.1102(i), therefore it has refused to consider them in regulatory decisions under FIFRA.

The EPA’s rules prohibiting “research with human subjects” were created to protect humans from unethical experiments involving intentional exposure to pesticides. The pesticide industry had sought to perform such experiments on children to weaken pesticide regulations. These rules are now being used by the EPA to prohibit animal petting studies, thereby allowing dangerous pet treatments to remain on the market.

According to the National Pesticide Information Center, the average time spent indoors at home has been estimated from 60-90%. Many households have children and pets. That is why risk assessments based on credible data are so important. Deterministic assessments provide the most health protective estimate of exposure for children. If a deterministic assessment identifies risks of concern on the day of application, it should not be trumped by a probabilistic assessment.

Probabilistic methods, based on credible assumptions, may be a valuable tool in identifying risks not found by deterministic assessments. However, the assumptions found in the Draft Technical Guidelines, which rely extensively on studies and surveys provided by the pesticide industry, will betray the public trust by endangering the health of children and pets.

Sincerely,

James TerBush
Website Administrator