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Dear Ms. Christian,

This is submitted as a commentary for the upcoming FIFRA-SAP meeting October 6-9; *Evaluation of Updated Standard Operating Procedures for Residential Pesticide Exposure Assessment* [EPA-HQ-OPP-2009-0516].

I'm a practicing veterinarian, and my organization is a member of OPP's Pesticide Environmental Stewardship Program (PESP)—we are listed on their roster as the Hesperian Group. Our focus is the modern topical "spot-on" pesticides for pets, and our project will explore fundamental revisions in the protocols for these products. Our goal is to develop efficiency strategies for reductions in use and human exposure.

The steady rise of reported toxicities to spot-on products with pets underscores the potential health implications of chronic human exposure. We hope our insights will contribute to updated SOPs for assessing this source of pesticide exposure.

Sincerely,

Nicholas Halbach DVM
Director, PESP Hesperian Group

COMMENTS:

Over the past decade flea and tick control for dogs and cats has evolved to a dominant model of chemical use—the "spot-on" pesticides. Their dynamic is simple; the pet's skin and coat oils function as the reservoir for the products' active ingredients, and the point of their activity. The model has proven highly effective, and has replaced virtually all previous methods of pest control for pets, including premise treatments.

In reducing flea and tick control to that singular strategy, the spot-on model directs all pesticide usage to a single application target—the pet. The pet—specifically, its transferrable skin oil and associated active ingredient—becomes a persistent, focalized pesticide source which produces two exposure pathways;

- 1) direct and continuous human exposure via contact with the pet, and
- 2) collateral human exposure via contact with immediate (micro) environments shared with the pet.

Those pathways could be significant:

- Over 60% of U.S. households have one or more dogs and/or cats. Consequently, for many individuals spot-on treated pets may pose a single greatest source of chronic pesticide exposure.
- By extension, from their widespread usage, spot-on products may also pose the majority components in aggregate exposures for respective active ingredients in use.

Spot-on products present a novel use of novel chemicals with undetermined endpoints in health effects. The range of active ingredients includes chemicals listed as both possible carcinogens and suspected endocrine disruptors.

The NCEA *Exposure Factors Handbook* and *Child-Specific Exposure Factors Handbook* contain sections (listed on page 5) relevant to exposure assessment for topical pesticide-treated pets. The following are some observations:

- The *Exposure Factors Handbook* predates the spot-on products' general entry to the marketplace.
- Both handbooks are broad in scope, but lack specificity in addressing a plurality of exposure factors unique to spot-on use. Interaction time with pets is categorized under household chores (surrogate data), and amounts to only minutes per day as tabulated; consequently neither handbook appears to factor the extended contact intrinsic between owners and their pets.
- The *Child-Specific Factors Handbook* gives ample attention to dermal exposure and hand-to-mouth activity of children. As those routes are limiting factors in valid exposure assessments of the spot-on pesticides, children comprise the logical sentinel population.

In developing more critical SOPs for exposure assessments of the spot-on pesticides, it might be useful to isolate them as;

- 1) a distinct and ubiquitous pesticide exposure scenario, with
- 2) its own set of exposure factors (vs. surrogated factors)—derived from a combination of existing methodologies and field perspectives.

The following is an example:

Exposure Scenario: Spot-on Pesticide Use On a Dog or Cat:

Background: The spot-on model employs monthly topical application of a low-volume dose of solution comprising active pesticide ingredient in a lipid-soluble vehicle or "spreader". By a dynamic called "translocation", when focally applied to the animal's skin the pesticide-spreader solution diffuses steadily throughout oils of the skin, hair, and oil glands of the hair follicles. When translocation is complete the active ingredient persists within the skin oil of the animal's entire body surface at levels lethal to fleas and ticks by contact.

Spot-on products are marketed in arrays of fixed dose sizes for application to corresponding weight groups or dose bands of dogs and cats. This scheme is called banded dosing. The number of dose sizes/dose bands in a product's array typically ranges from one to four. This presentation renders coarsely-stepped dose curves with high variability in effective application rates throughout the treated populations. Transitions between dose bands are abrupt and steep; two animals of closely similar weights that fall into different bands can receive over two-fold differences in actual ml/lb dose rates. Greater disparities exist within individual dose bands; bands for cats and smaller dogs demonstrate dose rate variability in excess of 20-fold. One product's label protocol can compound that to 40-fold.

Exposure scenario: Animal skin oil containing pesticide from spot-on product application is continuously transferable by contact to humans and their immediate environments.

Factors In Human Exposure to Spot-on Pesticides

Dose rate:

- Varies up to 20-fold under existing banded dosing protocols.
- Higher dose rates within banded dosing schemes correlate with increase risk and severity of toxicities in pets (data analysis of reported incidences pending from OPP's Pet Incidence Team).

- Dose rate also correlates directly with the pet's potential as a source of chronic pesticide exposure for its owners:
 - Animals in lower ends of dose bands receive higher dose rates, and carry higher pesticide levels.
 - Smallest animals typically receive the highest dose rates within existing banded dosing schemes,
 - carry the highest pesticide levels, and
 - tend to be picked up and held for extended periods, increasing owner exposure.

Frequency of application:

- decreased application frequency due to;
 - owner error, or
 - non-compliance with standard monthly protocols
- increased application frequency due to;
 - owner error, or
 - intentional, or
 - per product protocol allowance

Dislodgement of active ingredient:

- Aberrant product solution dislodgement post-application—directly onto the owner or owner's immediate environment can occur by;
 - splash-off of solution at application
 - run-off from the applied area on the animal
 - shake off by animal
 - rub-off by animal
- Continuous dislodgement by transference of pesticide-containing skin oils;
 - directly to owner, and
 - owner's immediate environment;
 - bedding/pillows,
 - furniture,
 - car seats,
 - children's toys,
 - clothing,
 - food, food preparation/serving surfaces, kitchen areas
 - floors and carpets, or
 - other surfaces and effects with which the pet makes physical contact.
- Bathing
 - frequency (Some animals are bathed frequently, with variable losses of the skin oil-pesticide reservoir. Conversely, other animals—particularly cats—are seldom or never bathed).
 - shampoo type;
 - bland, non-oil stripping, or
 - medicated, anti-seborrhea/follicle-cleansing (remove skin oil/active ingredient)

Variables affecting active ingredient breakdown/presence on pet:

- outdoor activity of the pet/exposure to the elements
 - sun exposure (photodegradation of active ingredient)
 - moisture (hydrolysis of active ingredient); includes precipitation, bathing, swimming
 - widely variable, dependent on lifestyle of owner and pet
- pets confined indoors;
 - minimal breakdown of active ingredients from elements; expected higher pesticide levels.

Pet statistics:

- number of spot-on treated animals in household
 - correlates with intensity of direct and indirect (environmental) exposure
- spot-on products used, species and weights of treated animals;
 - actual applied dose rate equates to pesticide level on the pet, varies by up to 20-fold
- maintained indoors, outdoors, or ratio; per above, affects levels of pesticide on pet

Activities, interactions, and durations thereof between owner and pet (transference):

- petting, holding, hugging, carrying
- *sleeping (*many pets sleep on their owner's beds—extended exposure)
- contact while watching TV, reading, or relaxing (extended exposures)
- car travel
- playing and training
- grooming
- medical treatment
- tendency of an individual pet to interact with its owner (widely variable)

Child-specific tendencies—dermal and oral exposure:

- from pet's body surface;
 - skin-to-surface (dermal)
 - hand-to-surface-to-mouth,
 - mouth-to-surface
- from immediate environments shared with pet;
 - skin-to-surface (dermal)
 - hand-to-surface-to-mouth,
 - mouth-to-surface
- highly variable, when co-factored with activities and interactions listed above.

SUMMARY:

The spot-on model is a simplified and effective approach to comprehensive flea and tick control with companion animals. However, full assessment of this relatively new source of pesticide exposure appears challenging. The challenges include three main areas:

- 1) Applied dose rates under existing product banded-dosing protocols are highly variable in the field.
- 2) Dislodgement and transference of the pesticides to humans and their environments are subject to a wide variety of factors.
- 3) Valid transfer coefficients cannot be effectively developed and applied until variability in dosing precision and aberrant dislodgement are mitigated by refinements to existing spot-on product protocols.

A potential fourth challenge compounds the above: if endocrine disruption is determined as a health effect, the metric for tolerances could ultimately shift to parts per billion. That would mandate especially critical standards for exposure assessment.

RELEVANT SECTIONS FROM THE NCEA HANDBOOKS***EXPOSURE FACTORS HANDBOOK:***

- Chapter 7 - Dermal Exposure (p.11)
 - covers general physiological principles of dermal exposure
- Chapter 15 - Activity Factors (p.281)
 - Table 15A-1: Activity Codes and Descriptors Used for Adult Time Diaries (p.1019)
 - code 17 - Pet care; care of household pets including activities with pets; playing with the dog; walking the dog; (caring for pets of relatives, friends, code 42)
 - Code 42 – caring for pets of relative, friends (cross-referenced by code 17)
 - Table 15A-5: Pet care; minutes/day (p.1037)
 - Figure 1-2. Road Map to Exposure Factor Recommendations (p.351)
 - Activity Factors (all routes)
 - Consumer Products (all routes)
- Chapter 16 - Consumer Products

- Table 16-32. Number of Respondents Reporting Pesticides Applied by the Consumer at Home To Eradicate Insects, Rodents, or Other Pests at Specified Frequencies Total N Number of Times Over a 6-month Period Pesticides (p.1088)
- Table 16-33. Number of Minutes Spent in Activities Working with or Near Pesticides, Including Bug Sprays or Bug Strips (minutes/day) (p. 1089)

CHILD-SPECIFIC EXPOSURE FACTORS HANDBOOK:

- Chapter 2 - Variability and Uncertainty (p.72)
- Chapter 4 - Non-dietary Ingestion Factors (p. 118)
 - Table 4-1. Summary of Recommended Values for Mouthing Frequency and Duration (p.120)
 - Table 4-2. Confidence in Recommendations for Mouthing Frequency and Duration (p.121)
 - Table 4-3. New Jersey Children's Mouthing Frequency (contacts/hour) from Video-transcription (p.137)
 - Table 4-4. Survey-Reported Percent of 168 Minnesota Children Exhibiting Behavior, by Age (p.137)
 - Table 4-6. Variability in Objects Mouthed by Washington State Children (contacts/hour) (p.138)
 - Table 4-7. Indoor Mouthing Frequency (Contacts per hour), Video-transcription of 9 Children with >15 minutes in View Indoors (p. 139)
 - Table 4-8. Outdoor Mouthing Frequency (Contacts per hour), Video-transcription of 38 Children (p.139)
 - Table 4-9. Videotaped Mouthing Activity of Texas Children, Median Frequency (Mean • } SD) (p. 140)
 - Table 4-9. Videotaped Mouthing Activity of Texas Children, Median Frequency (Mean • } SD) (p. 140)
 - Table 4-11. Outdoor Hand-to-Mouth Frequency (contacts/hour) Distributions from Various Studies (p. 140)
 - Table 4-12. Survey Reported Mouthing Behaviors for 92 Washington State Children (p.141)
 - Table 4-13. Estimated Daily Mean Mouthing Times of New York State Children, for Pacifiers and Other Objects (p.141)
 - Table 4-14. Percent of Houston-area and Chicago-area Children Observed Mouthing, by Category and Child's Age (p.141)
 - Table 4-15. Estimates of Mouthing Time for Various Objects (minutes/hour) (p.142, 143)
 - Table 4-16. Mouthing Times of Dutch Children Extrapolated to Total Time While Awake, Without Pacifier, in Minutes per Day (p.144)

- Table 4-17. Estimated Mean Daily Mouthing Duration by Age Group for Pacifiers, Fingers, Toys, and Other Objects (hours:minutes:seconds) (p.145)
- Table 4-18. Outdoor Median Mouthing Duration (seconds per contact), Video-transcription of 38 Children (p.146)
- Table 4-19. Indoor Mouthing Duration (minutes per hour), Video-transcription of 9 Children with >15 minutes in View Indoors (p.146)
- Table 4-20. Outdoor Mouthing Duration (minutes per hour), Video-transcription of 38 Children (p.147)
- Table 4-21. Reported Daily Prevalence of Massachusetts Children's Non-Food Mouthing/Ingestion Behaviors (p.148)
- Chapter 7 - Dermal Exposure Factors (p. 245)
- Chapter 16 - Activity Factors (p.575)
 - Table 16-3. Mean Time (minutes/day) Children Under 12 Years of Age Spent in Ten Major Activity Categories, for All Respondents and Doers (p.591)

*Interaction with pets is not listed in any of the activities specifically; it is combined with household chores and activities.
- Chapter 17 - Consumer Products (p.649)
 - Table 17-1. Consumer Products Commonly Found in Some U.S. Households (continued) (p.656)
 - Table 17-10. Number of Minutes Spent in Activities Working With or Near Pesticides, Including Bug Sprays or Bug Strips (minutes/day) (p.663)
 - Table 17-15. Number of Respondents Reporting Pesticides Applied by the Consumer at Home To Eradicate Insects, Rodents, or Other Pests at Specified Frequencies (p.665)
 - Table 17-17. Number of Respondents Reporting Pesticides Applied by the Consumer at Home to Eradicate Insects, Rodents, or Other Pests at Specified Frequencies (p.665)
 - Table 17-18. Household Demographics, and Pesticide Types, Characteristics, and Frequency of Pesticide Use (p. 666)
