# **Hesperian Group EPA PESP Strategy** —Overview 2013

## EPA: *Describe Your Organization's 5-Year Goals Related to Pesticide Risk Reduction*

Our mission is to seek a careful balance of efficacy and safety in the use of pesticides with companion animals. Though the project's primary objective is to reduce human exposure, in close parallel it covers risk reduction for pets. Our strategy is comprehensive, specific in its tactics and performance measures, and aggressively geared for new standards of best practices. With cooperation from the EPA and stakeholder pesticide registrants our solutions are readily conveyable to the field.

## EPA: *What do you envision doing (broadly) to try to resolve your major issues?*

### INTRODUCTION

Over the past two decades flea and tick control for dogs and cats has evolved to a singularly dominant model of chemical use—the "spot-on pesticide."

The model is based on monthly topical application of a low-volume dose of solution comprising active pesticide ingredient in a lipid-soluble vehicle or "spreader." Through 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 in the skin oil of the animal's entire body surface at levels lethal to fleas and ticks by contact.

Spot-on products show generally good efficacy, and with over 60 versions on the market now account for the majority of pesticide use with pets. They are the main focus of this project.

### ISSUES

#### Human Exposure

For one of the U.S. population's largest segments—dog and cat owners—spot-on treated pets present a pervasive new source of chronic pesticide exposure. Skin oil containing active pesticide ingredient is directly and continuously transferable by touch from pet to owner and the variety of microenvironments they share: furniture, beds, floors and carpets, food areas, car interiors, etc. Indoor residues can accumulate and persist for years. Multiple pets compound the scenario.

Children are at greatest risk of exposure to spot-on pesticides. They have longer and closer interactions with pets and their shared environments, coupled with child-intrinsic tendencies that amplify the principal exposure routes to spot-on residues: mouth-to-surface (oral), hand-to-surface-to-mouth (oral), and body-to-surface (dermal). House dust adds another pathway and route (respiratory) to the aggregate, especially for toddlers at floor level (a study by the U.S. Geological Survey found that house dust contained sharply elevated pesticide levels in homes with spot-on treated animals).

Children and prenatal life are also most vulnerable to the risks of higher cumulative pesticide body burdens, including cancer, developmental and behavioral disorders, and the numerous possible endpoints of endocrine disruption.

As a novel use of relatively novel compounds, the spot-on formulations for pets have not yet been fully evaluated for human health effects at chronic low levels of exposure. Their range includes chemicals listed as both carcinogen and suspected endocrine disruptor.

**Technical**

Spot-on products are marketed as limited arrays of premeasured dose sizes for corresponding weight groups or "dose bands," a system called "banded dosing." Product protocols typically provide 3–5 dose sizes/dose bands to treat the entire range of dog weights, and 2–3 dose sizes for cats. Many of the feline products provide only one dose for all weights.

Though banded dosing is a successful marketing model for spot-on pesticides, as a clinical model it fails on fundamental technicalities: precision, efficiency, and overall controllability of treatment. The results are simplistic protocols embedded with markedly uneven dosing within and between dose bands, and dosing extremes to individual weights. Current labels direct owners to dose some pets by up to ten times the effective mL/lb rate of other animals in the same band; a 2 lb kitten or toy-breed puppy receives the same fixed quantity of pesticide as a 20 lb adult.

By that common design all present spot-on protocols force varying degrees of unnecessary higher dosing for the majority of animals treated. Higher dosing levels correlate with the incidence and severity of adverse spot-on reactions in pets reported to the EPA. Moreover, higher dosing correlates directly with the pet's potential as both a source and a vehicle for continuous pesticide transfer to its owners.

## STRATEGY

In addressing those issues our strategic approach embodies two tenets of pesticide risk reduction: selectivity for least-toxic chemicals, and greater control in their use.

The first phase of the strategy focuses on universal improvements to spot-on pesticide methods. It begins with stringent refinements to their baseline dosing precision, followed by design of hyper-efficient new protocols for the field:

**Goal 1—Precision Dosing of Spot-On Pesticides**
**Goal 2—New Protocols for Spot-On Pesticides**
**Goal 3—Cost Efficiency**

The new paradigms are better able to utilize spot-on formulations to their fullest clinical potential, while limiting their dosing variability, net usage, and human exposure to theoretical minimums. Qualitative measures are also integral to the total equation of risk reduction:

**Goal 4—Review Toxicological Profiles** of chemicals used for fleas and ticks, with emphasis on identifying safer options for pets around young children and pregnant women.

**Goal 5—IPM** This activity builds upon Goals 1–4, and will explore the spectrum of alternatives for pest control with pets. Our ultimate goal is to innovate robust and sustainable Integrated Pest Management (IPM) by combining modern biorational strategies with our models of lowered chemical use, and lowering the use still further.

The goals and their data will be detailed at hesperiangroup.org

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**Endocrine Disruption**

In the early 1990s scientists began to compare their observations of disturbing changes across a diversity of North American wildlife. New generations were exhibiting a variety of physical, metabolic, reproductive, and behavioral abnormalities: deformities, hermaphroditism, neonatal wasting, thyroid derangements, infertility, and diminished mating, migratory, and territorial drive. In some regions wildlife populations were in critical declines. In other areas species had already disappeared. The scientists converged on a central theory:

- that chemical pollutants were the underlying cause, and,
- that even infinitesimally low levels of those chemicals in a female's body could infiltrate the earliest life stages of her offspring—in the egg or in the womb—and there, via intricate mechanisms of hormone mimicking or hormone blocking, alter or interfere with normal gene expressions in the developing embryo or fetus.

Some of the abnormal gene activities and their effects were immediate. Others laid latent, manifesting later in life. If able to survive and reproduce, affected animals appeared to be passing the same anomalies and dysfunctions to their progeny (epigenetic transmission).

The collective syndrome was termed endocrine disruption.

Those findings in nature have catalyzed mainstream science's search for environmental links to analogous multigenerational trends in the human population, including a broad range of endocrine-related disorders:

- autism, attention deficit hyperactivity disorder (ADHD), learning disabilities,
- Parkinson's Disease, Alzheimer's Disease,
- diabetes (juvenile and adult), obesity,
- juvenile cancers,
- breast cancer, osteoporosis, endometriosis, polycystic ovary syndrome,
- prostate cancer, testicular cancer,
- Testicular Dysgenesis Syndrome, cryptorchidism, hypospadias, male infertility,
- thyroid disorders,
- asthma, and autoimmune diseases.

Relatively uncommon before 1950, many of those disorders began to rise significantly in the early 1970s when the first generation exposed in the womb to post-World War II chemicals reached maturity. New generations continue the trends.

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Pesticides are heavily represented in the current working lists of suspected endocrine disruptors. At the same time, spot-on pesticides for pets are represented in the first/priority groups of chemicals underway in the EPA Endocrine Disruptor Screening Program.

EPA faces a complex challenge; endocrine disruption's ultra-low effects thresholds could summarily shift parts-per-million metrics of existing toxicology to parts-per-billion, possibly parts-per-trillion, rendering present tolerances and safety factors for many pesticides grossly deficient and obsolete.

Until those gaps are filled, more careful and measured use of spot-on pesticides is indicated—particularly with pets around children and pregnant women. The Precautionary Principle applies.

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