EPA Evaluation of Pet Spot-on Products: Analysis and Plans for Reducing Harmful Effects

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The Analysis and Summary of Findings

In spring 2009, EPA noticed an increase in reports of pet incidents involving spot-on pesticide products. Spot-on flea and tick products are liquid pesticides applied to a "spot" on the pet's skin, usually around the back of the neck or shoulder area.

We received enhanced information on individual reported adverse effects from the companies that hold registrations for these products. We also received other information on these products.
We formed an expert veterinarian team to thoroughly analyse the data. We also partnered with the Food and Drug Administration's Centre for Veterinary Medicine and Health Canada's Pest Management Regulatory Agency, our counterpart agency in Canada, on the review of this analysis. The team

- studied incidents involving cats and dogs,
- looked at both active and inert ingredients,
- studied product labelling, and
- discussed data needs for the future to improve analyses and regulation.

We prepared Data Evaluation Records for products that represent the largest market share of the pet spot-on products. The DERs formed the basis of the analysis we conducted in 2009 and released in March 2010. They are intended to better characterize incidents received in aggregate incident summaries submitted by the manufacturers to the Agency under FIFRA Section 6(a)(2). The DERs are available from the EPA Data Evaluation Records of Spot-on Products Web page.

On March 17, 2010, we announced the results of our analysis: New Restrictions on Flea and Tick Products; Use Products with Extra Care. We also made available our report, Review of Enhanced Reporting of 2008 Pet Spot-on Incidents. Our expert team of veterinarians wrote this report based on their findings. The team had to deal with significant data limitations, which are described in the report.

Summary of findings

- **EPA found that the products could be used safely but that some additional restrictions are needed.** EPA's team of veterinarians learned that most incidents were minor, but unfortunately some pet deaths and "major incidents" have occurred. The Agency learned that the most commonly affected organ systems were skin, gastrointestinal (digestive), and nervous.

For more information, refer to Review of Enhanced Reporting of 2008 Pet Spot-on Incidents

Dog Findings:

EPA's expert veterinarian team found that

- small breed dogs were affected more than larger breeds for some products
- the amount of product in a single dose needed to vary more for small to large dogs; that is, how much the dog weighs matters a lot in deciding how much of a product should be used.

Cat Findings:

EPA's expert veterinarian team discovered that

- misuse or accidental exposure of cats to dog products was an important problem; cats can be harmed by dog products because they are more sensitive to certain pesticides; and
- label warnings against use of dog products on other animals, especially cats, are not working well enough, which appears to be a global concern.

Safety Testing: The team also found that the data we now require to determine the safety of these products for pets do not accurately predict the toxicity seen in the incidents that took place.

Changes Based on Evaluation of Pet Incidents

Based on the analysis, we determined that some changes need to be made in how

- we regulate the spot-on products,
- companies report data on pet incidents, and
- packages are labelled for cats, dogs, and size of animals to prevent unreasonable adverse effects and ensure the safety of these products.

The reported incidents demonstrated that many but not all pet incidents took place because the products were misused, bolstering the need for clearer labelling.

We are pursuing a series of actions to increase the safety of spot-on pesticide products for flea and tick control for cats and dogs. On March 17, 2010, we sought comment on the necessary changes, including how best to effectively implement these measures. Since EPA's report and plan for improving product safety were released for comment we have been in the process of reviewing the public comments.

In addition, we have been closely reviewing the DERs, the public comments, and product labelling to determine what product-specific changes are needed, including stronger and clearer labelling statements. In doing so, we identified some common issues with the pet spot-on products and some common changes that need to be made to pet spot-on product labels. We also are developing more stringent testing and evaluation requirements for both existing and new products. We expect these steps will help prevent adverse reactions from pet spot-on products.

We are coordinating with Health Canada and with the Food and Drug Administration's Centre for Veterinary Medicine on these actions. Canada identified similar concerns with incidents being reported from the use of spot-on products. The two countries have very similar products registered and some of the same registrants, and we often work together on review of data submissions. Some flea and tick products are drugs that are regulated by the FDA. We are collaborating with FDA as well because FDA regulates some similar products and it made sense for EPA to learn about FDA's processes and learn from its experience in post-market surveillance of incidents associated with animal drugs.

Recommendations to reduce harmful effects include:

Further Restrictions on Products

- **Dosing.** To address concerns about dosing, we are pursuing requiring label and/or packaging changes that would result in more narrow pet weight ranges per vial size. This means there will be more categories for the weights of pets so that small, medium, and large dogs get the right amount of product. Pet owners should always be aware of the weight of their pet and purchase and use the correct product for their pet's weight.

- **Improve labelling to avoid confusion between dog and cat products.** Because there were problems reported with cats exposed to dog products, we are pursuing the following actions:
  - Label changes that prohibit the use of the same brand names on cat and dog products; and
  - Requiring appropriate, clear label statements to address concerns with cat exposure to dog products as a result of direct application or interactions between cats and dogs in multi-pet households after the application of dog products.

- **Make labels more understandable.** To improve label clarity, we will pursue changes such as larger fonts and pictograms.

- **Make other label changes as needed.** We will meet with companies individually to review their products and discuss additional changes to labels or ingredients that the Agency feels are needed. These actions may include anything from adding a more complete list of potential side effects to product labels to cancelling products.

- **Inert Ingredients.** To address uncertainties about the "inert" (non-active) ingredients in these products and how they might contribute to toxicity, we will be pursuing the following actions:
  - No longer allow the interchangeable use of inert ingredients in these formulations;
  - Determine whether additional information is needed and, if so, require that information to evaluate certain inert ingredients; and
  - Disallow inerts that have suspected toxic effects when and if these are identified.

- **Conditions of Registration.** Based on what we currently know about these pet products, we expect to impose conditions of registration when granting amendments to existing products or granting new registrations. As with any registration action, we will review each application on a case-by-case basis to determine whether these conditions are appropriate and applicable to the product in question. The expected conditions are as follows:
  - A two-year registration time limitation from the date the product is released for shipment
  - Only one, basic confidential statement of formula
  - The submission of quarterly incident reports and an analysis of these report
  - The submission of quarterly sales information by doses sold

Tighter Regulation

- **Standardized reporting**. To be able to monitor these products better, we are pursuing more standardized reporting on adverse effects and sales. This will allow the Agency to more effectively review incidents, and if concerns are raised, give us information to act.

- **Pre-market clinical trials and post-market surveillance.** The Agency is taking steps to bring data requirements in line with FDA's requirements for similar products. This will allow us to be more consistent with how FDA regulates similar animal drugs, which includes pre-market clinical trials and a formal post-market surveillance program, and will allow us to more thoroughly assess the safety of the products.

- **Grant conditional registrations for new products.** Future pet spot-on registrations and amendments to new registrations will be restricted by appropriate conditions and time-limitations to allow us to continue to ensure the safety of these products after they are available to the public.

For more information, see mitigation plan and slides.

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Related Information

- Meetings with Manufacturers of Pet Spot-on Products
- EPA to Increase Restrictions on Flea and Tick Products: Cautions consumers to use products with extra care (News release, 3/17/2010)
- U.S. and Canada to Increase Scrutiny of Flea and Tick Pet Products (News release, 4/16/2009)
- Response to Comments on the Pet Spot-on Analysis and Mitigation Plan
- Pet Spot-on Analysis and Mitigation Plan, Data Evaluation Records for Products, and public comments on mitigation plan
- EPA posted a summary of the 3/17/2010 registrant meeting to the public docket
- List of EPA-Registered Spot-on Flea and Tick Products
- May 5, 2009 EPA spot-on meeting with registrants

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Last updated on March 16, 2014