

US EPA ARCHIVE DOCUMENT

OPP Updated Actions on Pet Spot-On

Flea and Tick Products

Due to a significant increase in adverse incidents, OPP is taking a series of actions to increase the safety of spot-on pesticide products for flea and tick control for cats and dogs. Immediately, OPP will begin reviewing labels to determine which ones need stronger and clearer labeling statements. Next, OPP will develop more stringent testing and evaluation requirements for both existing and new products. OPP expects these steps will help prevent adverse reactions. In dogs and cats that can include skin effects, such as irritation, redness, or gastrointestinal problems that include vomiting or diarrhea, or effects to the nervous system, such as trembling, appearing depressed or seizures—from pet spot-on products.

Following the 2008 increase in incident reports, OPP received additional information from the pet spot-on pesticide registrants and others and began an intensive evaluation of these products. OPP has reported the results of this evaluation, and taking steps to address the spike in reported incidents.

Among immediate actions that OPP is pursuing are:

- Requiring manufacturers of spot-on pesticide products to improve labeling, making instructions clearer to prevent product misuse.
- Requiring more precise label instructions to ensure proper dosage per pet weight.
- Requiring clear markings to differentiate between dog and cat products, and disallowing similar brand names for dog and cat products. Similar names may have led to misuse.
- Requiring additional changes for specific products, as needed, based on product-specific evaluations.
- When new products are registered, granting only conditional, time-limited registrations to allow for post-marketing product surveillance. If there are incidents of concern associated with the product, OPP will take appropriate regulatory action.
- Restricting the use of certain inert ingredients that OPP finds may contribute to the incidents.
- Launching a consumer information campaign to explain new label directions and to help users avoid making medication errors.

In addition, to improve the regulatory oversight of pet products, OPP will require more standardized post-market surveillance reporting on adverse effects, require submission of more sales information so the agency can better evaluate incident rates, and bring up-to-date the scientific data requirements on pre- and post-market testing so they are more in line with the Food and Drug Administration's requirements.

Flea and tick products can be appropriate treatments for protecting pets and public health because fleas and ticks can transmit disease to animals and humans. While most people use the products with no harm to their pets, the agency's analysis determined that smaller dogs tend to be disproportionately affected by some products and that the exposure of cats to some dog products is a concern.

OPP is coordinating these actions with Health Canada as Canada also identified similar concerns about the use of spot-on flea and tick products last year, and with the Food and Drug Administration's Center for Veterinary Medicine.

The agency is inviting public comment on how best to implement these new measures. A Federal Register notice was issued on March 19, 2010. The docket number is EPA-HQ-OPP-2010-0229.

EPA's report on the evaluation of products and incidents is available at:
<http://www.epa.gov/pesticides/health/petproductseval.html>.