I am working on a story about EPA incident data surrounding Seresto collars. It is my understanding that there have been a significant amount of incidents surrounding the pesticides in the collars, and I had some questions.

According to a records request of EPA documents, there have been at least 75,000 incident reports involving pets, including 1,698 deaths. Is this a high number? Why is it still sold? Is there any sort of threshold for removing the collar from the market?

Ex. 5 Deliberative Process (DP)

Background

FIFRA is the law under which EPA regulates products for pests of pets. Under the law, EPA must make a determination that the product will not cause "unreasonable adverse effects on the environment," defined in FIFRA 2(bb) as (in part) "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Thus, the benefits of a product must be weighed against the risks.

No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk. The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) Evaluations for pet products like shampoos, collars and spot-ons rely upon data on companion animal safety, efficacy and safety for humans who may be exposed as a result of product use. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

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Manufacturers are required under law to report adverse incident information to EPA. Individuals may report incidents potentially associated with use of an EPA-registered product by contacting the product manufacturer, their state lead pesticide agency, the National Pesticide Information Center, or by contacting EPA directly.

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It is my understanding that these incidents do not include the main incident reporting system, which likely has additional incidents. Do you have more information about the number of incidents?

Ex. 5 Deliberative Process (DP)

California toxicologists said the Bayer studies the EPA relied on to approve the collars underestimated the harm to adult dogs and cats. However, the EPA approved them. What science is there to support these registrations? How can customers know that these are safe to use?

Ex. 5 Deliberative Process (DP)

There have been at least 907 human-related incidents since 2013, according to EPA data. Is this a high number? Is there any sort of threshold for removing the collar from the market?

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) EPA also conducted a larger epidemiological analysis of human incident data associated with pyrethroids (Pyrethroids: Tier II Epidemiological Report, dated April 30, 2019) and found little substantive evidence to suggest a clear, associative, or causal relationship between exposure to pyrethroids and adverse effects. EPA will continue to evaluate incident data in future cycles of ~~Registration registration~~ rReview. EPA may initiate action at any time to address concerns if unreasonable adverse effects are identified. Such actions can range from mandatory label changes to cancellation of the registration.

It is my understanding that Bayer knew about these incidents for years, prior to selling dog collars to Elanco. Did Bayer make Elanco aware of these issues when selling the product to Elanco?

EPA does not have information on communications between Bayer and Elanco.

From my understanding talking with former EPA staff, Health Canada denied to approve Seresto because of the incident data. Do you have any response to this?

Ex. 5 Deliberative Process (DP)

Background

The law under which EPA regulates products for pests of pets is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under the law, EPA must make a determination that the product will not cause "unreasonable adverse effects on the environment," defined in FIFRA 2(bb) as (in part) "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Thus, the benefits of a product must be weighed against the risks.

No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk. The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.

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