All - Elissa says we cannot commit to adding a date now.

RD – would you be OK with, instead of a date, saying we would respond to the petition after a regulatory decision is made related to the 6a2 analysis?

Please let us know. Feel free to elevate to Marietta for clearance as needed.

Melanie L. Biscoe
Senior Regulatory Advisor, RMIB5
Pesticide Re-evaluation Division
US EPA Office of Pesticide Programs
202-566-0701
(She/Her)
From: Keigwin, Richard <Keigwin.Richard@epa.gov>
Sent: Wednesday, February 9, 2022 7:06 AM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Li, Jake <Li.Jake@epa.gov>
Subject: RE: FOR REVIEW: Press inquiry on Seresto

Two thoughts:
--If we have relative timeframe for responding to CBD’s petition or completing our analysis of the incident data, should we add that to the response?
--In the last paragraph, do we mean “informed” rather than “information”?

From: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Sent: Wednesday, February 09, 2022 6:50 AM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>; Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Li, Jake <Li.Jake@epa.gov>
Subject: FOR REVIEW: Press inquiry on Seresto

Hi all – Johnathan Hettinger from Investigate Midwest is working a story about Seresto. Last year, he had several questions about a FOIA release related to Seresto that we responded to. And, last week, this is the same reporter that asked FDA if they were taking over regulation of pet products. Now, he’s asking us for any updates since our last response to him in September (provided below for reference). This is the latest update from OPP since then. Thanks.

INCOMING:

I'm finalizing a story on Seresto for Investigate Midwest and USA Today that I reached out about previously. The story is about documents showing internal strife at the agency and years of repeated reviews that showed the high number of death reports filed about Seresto.

I just wanted to reach out before the story publishes to check in and see if there are any updates about Seresto. I would love to do an interview if you have any updates. It's always great to hear from the agency.

RESPONSE:

As part of EPA’s work to address concerns raised about pet collars, the agency asked for public comment on a petition from the Center for Biological Diversity requesting that the agency cancel the Seresto registration and to suspend the registration pending cancellation. The public comment period on the petition closed on September 10, 2021. EPA received comments from over 5,400 sources during the public comment period. After carefully considering public input and the requests of the petition, EPA will respond to the petition.

Additionally, EPA requested and is receiving support from the U.S. Food and Drug Administration (FDA) on the review of the incident data. EPA and FDA meet on a regular basis to discuss the regulation of animal products, and EPA has kept FDA information about the activities around the pet collars.

PREVIOUS RESPONSE FROM SEPTEMBER
- According to an email from Robert Miller, who I understand oversees incident reporting: "I ran some queries for Seresto pet incidents comparing the product to pet spot-on products well known to kill and maim pets. The queries suggest that Seresto is much more harmful to pets than many spot-on products combined. I'll have some bullet points, graphs and charts for you by Monday morning."

-What are these products "well known to kill and maim pets"? Is there any more information available about this analysis and what it showed?

EPA has now received the additional Seresto incident and sales information from Elanco and Bayer that it needs to conduct an in-depth analysis. No information is available on the analysis referred to in that email.

-The EPA has said it has not done an analysis of how Seresto compares to other pet products. This seems untrue, based on these documents and the documents I received last time. Do you have a response to that?

The staffer was routinely reviewing information and did not conduct formal analysis or produce a finalized report. General information was shared with colleagues in a regular staff meeting as part of ongoing discussions. The agency is currently in the process of reviewing additional incident and sales information from the Seresto registrants, Elanco and Bayer. In addition, EPA recently issued a Federal Register notice for proposed interim decisions for several pesticides requesting comments from the public on a proposal to request similar information for certain products registered for use directly on pets. These data would allow the agency to conduct a comparative assessment of pet incidents across registered pet products based on sales data to better determine whether any changes to the pet product registrations and labels are necessary.

-There also seems to be a delay in Elanco sending the reports after it purchased Seresto.

According to Miller's email, Elanco submitted other incident reports for other products but not Seresto. Is that true?

In mid-March, EPA informed registrants of pet spot-on products to hold their submissions for sales and incident data because EPA did not have mail service due to the pandemic. Elanco, interpreted this to mean all 6(a)(2) data should be temporarily held for all products, including for collars. This misunderstanding was quickly resolved, and the data were submitted by Elanco for Seresto upon request.
This summer, EPA informed industry to submit data electronically.

- **Senator Sanders sent a letter to the EPA about Seresto. Do you have a copy of that letter?**
  EPA would advise you contact the office of Senator Sanders for a copy of the letter.

- **The Canada PMRA analysis about Seresto said up to 80% of incidents are possibly related to the collar.** The PMRA analysis also found that Seresto could be harmful to humans, according to the emails. Would you be able to share this analysis? What did the causality analysis show?
  Health Canada conducted its analysis and reached its decision based on Canadian law. EPA follows the U.S. law –FIFRA, which requires that the benefits of a pesticide be weighed against its risks, for all analyses and decisions.
  As to the analysis conducted by Health Canada, EPA would advise that you speak to Health Canada’s Pest Management Regulatory Agency.

- **Is there anything else people need to know?**
  On July 13, 2021, EPA released for public comment a petition from the Center for Biological Diversity requesting that the agency cancel the registration of insecticide product PNR1427, more commonly known by its brand name Seresto (EPA Registration No. 11556-155), and to suspend the registration pending cancellation.
  The public comment period closed on September 10, 2021 and the agency received more than 5,000 comments. The petition is available in docket ID number EPA-HQ-OPP-2021-0409 at www.regulations.gov. After carefully considering public input and the requests of the petition, EPA will respond to the petition.