



OFFICE OF INSPECTOR GENERAL
U.S. ENVIRONMENTAL PROTECTION AGENCY

August 7, 2024

MEMORANDUM

SUBJECT: Response to Planned Corrective Actions for Office of Inspector General Report No. [24-E-0023](#), *The EPA Needs to Determine Whether Seresto Pet Collars Pose an Unreasonable Risk to Pet Health*, issued February 29, 2024

FROM: Sean W. O'Donnell, Inspector General 

TO: Michal Ilana Freedhoff, Ph.D.
Assistant Administrator for Chemical Safety and Pollution Prevention

Thank you for your April 30, 2024 memorandum, which outlines the Office of Chemical Safety and Pollution Prevention's planned corrective actions and estimated milestone dates to address one of the recommendations in the subject Office of Inspector General report. Based on the information and supporting documentation that you provided, we do not agree that the planned corrective actions meet the intent of Recommendation 1.

Recommendation 1 reads:

Issue amended proposed interim registration review decisions for both flumethrin and imidacloprid that include domestic animal risk assessments for the two pesticides, written determinations on whether the Seresto pet collar poses unreasonable adverse effects in pets, and an explanation of how the Office of Pesticide Programs came to its determinations. Allow for public comment by placing these documents in the applicable registration review dockets.

In the OCSPP's April 30, 2024 memorandum, you proposed the following corrective action for Recommendation 1:

At the completion of Corrective Action 2, OPP [the Office of Pesticide Programs] will prepare an analysis and briefing for the OCSPP Assistant Administrator, including an analysis of options for an appropriate timeframe for completing registration review for flumethrin that considers other program priorities and available resources.

This proposed corrective action does not meet the intent of Recommendation 1 for several reasons. As communicated in our report, the preliminary work plan that the EPA included in the registration review

dockets for both flumethrin and imidacloprid specified that the Agency would conduct domestic animal risk assessments. The final work plan for both pesticides reiterated the Agency's commitment to conducting domestic animal risk assessments. Pursuant to 40 C.F.R. § 155.53(b)(1), if, as part of a pesticide's registration review, the Agency finds that a new risk assessment of a pesticide is needed, the Agency will conduct an assessment based on existing data or information or after gathering additional data or information. Therefore, once the Agency concluded that a domestic animal risk assessment was necessary for each pesticide, it was obligated to conduct those assessments.

The OCSPP's April 30, 2024 memorandum recalls a portion of the OCSPP's response to our draft report. The response stated that, "On July 13, 2023, OPP [the Office of Pesticide Programs] released a comprehensive scientific review¹ of Seresto pet collars (the only pet product with both imidacloprid and flumethrin), which is equivalent to a 'domestic animal risk assessment.'" (Footnote in original.) However, we did not identify content in the "comprehensive scientific review" document whereby the EPA equates the review to a "domestic animal risk assessment."

Overall, the Agency's April 30, 2024 response does not adequately address the following issues for Recommendation 1:

- Provide support for the claim that the OCSPP's "comprehensive scientific reviews" of the Seresto pet collar as equivalent to the domestic animal risk assessments that the EPA identified the need for and committed to conduct in the pesticide registration reviews for flumethrin and imidacloprid.
- In the absence of such support, provide planned corrective actions to address the deficiencies of the flumethrin and imidacloprid registration reviews related to the EPA's commitment to conduct and include domestic animal risk assessments for both pesticides.
- Address the lack of opportunities for public comment, particularly for domestic animal risk assessments, for the flumethrin and imidacloprid registration reviews.

Specifically, the last deficiency is inconsistent with the Agency's public involvement practices. The EPA highlighted the importance of public involvement and the Agency's commitment to transparency in its *Meaningful Involvement Policy*, *Scientific Integrity Policy*, "Pesticide Program Public Involvement Opportunities" webpage, and "Opportunities to Participate in Pesticide Reevaluation" webpage.

We acknowledge that the OCSPP consulted with the U.S. Food and Drug Administration on its scientific review of Seresto pet collars. Additionally, we acknowledge that the OCSPP incorporated methodologies that the Food and Drug Administration uses, which may help the OCSPP establish and conduct domestic animal risk assessments during the flumethrin and imidacloprid pesticide registration reviews. We

¹ Canine and Feline Adverse Event Review for the Seresto Collar (EPA Reg No. 11556-155); <https://www.regulations.gov/document/EPA-HQ-OPP-2021-0625-0015>.

further acknowledge that the OCSPP recently implemented risk-mitigation measures; identified what scientific data it needs from the registrant to determine whether Seresto pet collars cause unreasonable risks to human health or to the environment when the collars are used as directed on the product label; and extended the Seresto pet collar registration for only five years.

We maintain that the EPA needs to address the domestic animal risk assessment and public involvement concerns that we described in our report. Recommendation 1 remains unresolved. EPA Manual 2750 requires that recommendations be resolved promptly. We look forward to future communication with you to reach resolution.

We will post this memorandum on our public website at www.epaoig.gov.

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