

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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July 18, 2022

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

The Honorable Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Administrator Regan and Commissioner Califf:

I am writing with an update on the status of the Subcommittee on Economic and Consumer Policy's investigation into Seresto flea and tick collars (EPA Reg. No. 11556-155), manufactured by Elanco Animal Health, Inc. (Elanco), which have been linked to tens of thousands of pet injuries and deaths. Consistent with the results of the Subcommittee's investigation and the recommendations in our staff report, I am calling on the Environmental Protection Agency (EPA) to (i) commence Notice of Intent to Cancel (NOIC) proceedings by providing the required notice to the Secretary of Agriculture, which would allow EPA to remove Seresto from the market; (ii) strengthen EPA's pre-registration scientific review process; and (iii) improve EPA's incident data collection system. I am also hopeful that EPA, consistent with its recognition that it lacks certain resources necessary to fully evaluate and monitor animal product safety, will engage the Food and Drug Administration (FDA)—which has extensive expertise in post-market monitoring and adverse event reporting—to assist in implementing my recommendations.

On June 15, 2022, the Subcommittee released a staff report entitled "Seresto Flea and Tick Collars: Examining Why a Product Linked to More than 2,500 Pet Deaths Remains on the Market," that details the findings of the Subcommittee's 16-month investigation into the safety of the Seresto flea and tick collar, a product manufactured by Elanco. Among other things, the report revealed that EPA under previous administrations was aware of the dangers of the Seresto collar as early as 2015 and failed to take action to protect pets and their owners. At a hearing held the same day that the report was released, the Subcommittee heard testimony from Faye Hemsley and Thomas Maiorino, owners of deceased pets; Jeffrey Simmons, President and Chief Executive Officer of Elanco Animal Health; Karen McCormack, former Scientist, Policy Analyst, and Communications Officer in the Office of Pesticide Programs at the Environmental Protection Agency; and Nathan Donley, Ph.D., Environmental Health Science Director at the Center for Biological Diversity. This letter summarizes the Subcommittee's findings and reiterates the recommendations contained in the staff report and examined at the hearing.

Investigation Summary

The Seresto flea and tick collar—a product advertised to provide eight months of flea and tick protection for dogs and cats for under \$70 and that is widely sold by pet specialty stores, online pet pharmacies, and large online retailers—received EPA approval in 2012 and was introduced to the market in 2013.¹ Since then, Bayer Animal Health, the original owner of the collar, and Elanco, which purchased the product in 2020, have sold more than 30 million collars.

The Subcommittee launched its investigation into the collar in March 2021, following the publication of an investigative report revealing that, as of June 2020, there had been more than 75,000 incidents and approximately 1,700 pet deaths linked to the Seresto collar.² Since then, the reported numbers have increased to more than 98,000 incidents and 2,500 pet deaths.³

During its investigation, the Subcommittee obtained documents from EPA, Elanco, and a whistleblower. These documents and other publicly available information demonstrated that EPA has been aware of the alarming incident numbers and the dangers caused by the collar since 2015. More specifically, documents and communications revealed that (i) EPA and the Canadian Pest Management Regulatory Authority (PMRA) independently determined that between 33% and 45% of reported pet deaths were “probably or possibly” caused by the Seresto collar; (ii) the PMRA refused to approve the collar for sale in Canada due to the extremely troubling results of its analysis; (iii) by 2017 at the latest, EPA officials began voicing frustrations over the Seresto collar remaining on the market; and (iv) neither EPA nor Elanco has taken action to address the safety of the collar. The Subcommittee’s staff report setting out these key findings and other results of our investigation in greater detail is attached to this letter.

Key Findings and Testimony

Evidence reviewed by the Subcommittee suggests that both EPA and Elanco have failed to act to protect consumers and their pets from the risks posed by the Seresto collar. Testimony

¹ *Popular Flea Collar Linked to Almost 1,700 Pet Deaths. The EPA Has Issued No Warning*, USA Today (Mar. 2, 2021) (online at www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/?gnt-cfr=1); Elanco Animal Health, *Comments of Elanco Animal Health, Inc.* (Sept. 10, 2021) (online at www.regulations.gov/comment/EPA-HQ-OPP-2021-0409-0282); Bayer Healthcare Introduces Seresto, *Offering Easy-to-Use Flea and Tick Control for Dogs or Cats That Lasts Eight Months*, PR Newswire (Jan. 20, 2013) (online at www.prnewswire.com/news-releases/bayer-healthcare-introduces-seresto-offering-easy-to-use-flea-and-tick-control-for-dogs-or-cats-that-lasts-eight-months-187650591.html); *Pet Owners Say Seresto Flea Collars Hurt, Killed Their Dogs*, WSB-TV Atlanta (Apr. 28, 2022) (online at www.wsbtv.com/news/local/atlanta/pet-owners-say-seresto-flea-collars-hurt-killed-their-dogs/YKCR3XSVJFCRAK3RL3WYU7PGU/).

² *Popular Flea Collar Linked to Almost 1,700 Pet Deaths. The EPA Has Issued No Warning*, USA Today (Mar. 2, 2021) (online at www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/?gnt-cfr=1).

³ Environmental Protection Agency, *US EPA Office of Pesticide Programs Incident Data System: Aggregate Incident Summary Report by Product* (Apr. 8, 2022) (online at www.biologicaiversity.org/programs/environmental_health/pdfs/Aggregate-Incident-Summary-Report-for-EPA-Reg-No-11556-155-Product.pdf).

provided at the Subcommittee’s hearing on June 15, 2022, further supported the staff report’s conclusions. The remainder of this section discusses key findings and testimony.

First, internal EPA documents demonstrate that EPA was on notice of potential issues with Seresto as early as 2015 but did little to address the many reported adverse incidents. In December 2015 an EPA presentation found that “Seresto ranked #1 by a wide margin” in terms of total adverse incidents among all flea and tick products registered with the EPA.⁴ After adjusting for sales figures, Seresto had nearly three times the rate of total incidents and nearly five times the rate of “Death” or “Major” incidents as the second most dangerous product. The collar had nearly 21 times the rate of total incidents and over 35 times the rate of “Death” or “Major” incidents as the third most dangerous product.⁵ Nevertheless, EPA resolved to “continue to monitor this situation” because it was aware that the Canadian PMRA was conducting a parallel analysis of the American incident data and wished to await the PMRA’s results.⁶

Second, based on information not previously available to the public, the Subcommittee’s investigation revealed that following its analysis of the U.S.-reported incident data, the Canadian PMRA refused to approve Seresto for sale in Canada. PMRA determined that, based on an analysis of 251 pet deaths, the Seresto collar “possibly or probably” caused either 33% of those deaths.⁷ As former EPA official Karen McCormack explained at the hearing, the PMRA concluded that, based on its analysis of the reported pet deaths and the toxicity of the Seresto collar, “the risks were too high to approve Seresto [in Canada], and they could not be mitigated by putting a label statement on the product or by issuing warning labels. So they refused to approve Seresto.”⁸

EPA conducted its own analysis of the same 251 pet deaths, and concluded that 45% were “possibly” or “probably” caused by the collar.⁹ Yet unlike the Canadian regulator, EPA failed to take action, deciding instead to continue to collect more data.¹⁰

Elanco continues to maintain, as confirmed at the hearing by the testimony of Chief Executive Officer Jeffrey Simmons, that—based on its own analysis and the analysis of third-party consultants paid by Elanco—just 0.51% of 2,340 reported pet deaths reported through mid-

⁴ Environmental Protection Agency, *Review of Seresto Pet Collar Incident Data* (Dec. 16, 2015) (ED_005739A_00100255-00026, ED_005739A_00100255-00028).

⁵ Environmental Protection Agency, *Review of Seresto Pet Collar Incident Data* (Dec. 16, 2015).

⁶ *Id.*

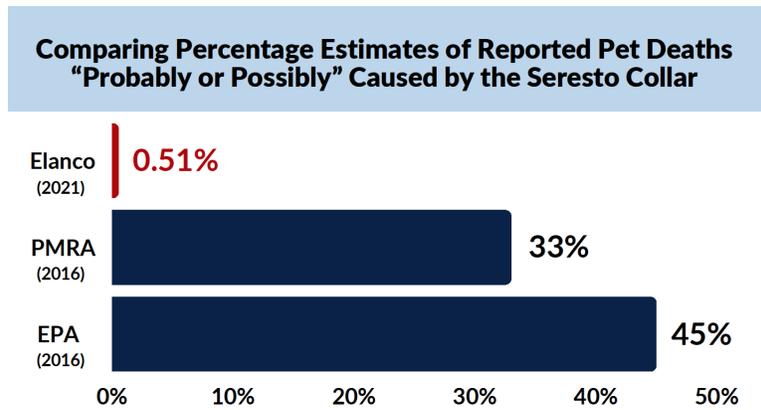
⁷ Environmental Protection Agency, *Seresto Briefing Document* (Sept. 22, 2016).

⁸ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Seresto Flea and Tick Collars: Examining Why a Product Linked to More than 2,500 Pet Deaths Remains on the Market* (June 15, 2022) (online at <https://oversight.house.gov/legislation/hearings/seresto-flea-and-tick-collars-examining-why-a-product-linked-to-more-than-2500>).

⁹ Environmental Protection Agency, *Seresto Briefing Document* (Sept. 22, 2016).

¹⁰ *Id.*

2021 (just 12 total deaths) were “probably or possibly” caused by the collar.¹¹ Elanco also claims that none of these 12 deaths were tied to the Seresto collar’s active ingredients.¹²



Compiled from data in Environmental Protection Agency, *Seresto Briefing Document*, September 22, 2016 and Elanco Animal Health Incorporated, *Form 8-K*, May 7, 2021.

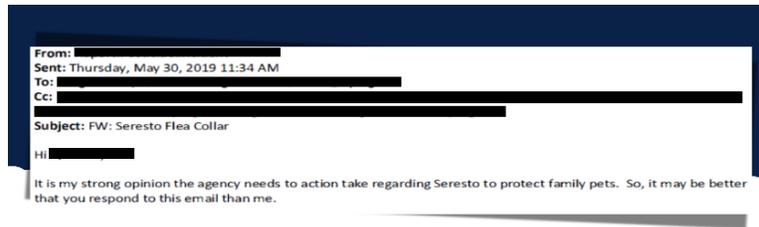
Third, internal EPA emails demonstrate that, by 2017 at the latest, EPA officials began raising concerns about Seresto but were rebuffed by supervisors. On one such occasion, an EPA scientist—apparently acting on orders from a senior EPA official—instructed two other EPA officials to stop expressing their concerns about Seresto over email.¹³ According to an EPA whistleblower, this incident took place in 2017. Later, in May 2019, an EPA official told a colleague that it was his “strong opinion” that EPA needed to “[take] action ... regarding Seresto to protect family pets”¹⁴:

¹¹ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Seresto Flea and Tick Collars: Examining Why a Product Linked to More than 2,500 Pet Deaths Remains on the Market* (June 15, 2022) (online at <https://oversight.house.gov/legislation/hearings/seresto-flea-and-tick-collars-examining-why-a-product-linked-to-more-than-2500>).

¹² *Id.*

¹³ See Email from Robert Miller, Environmental Protection Agency, to Maria Echevarria, Environmental Protection Agency (Mar. 4, 2021) (ED_005739A_00103710-00002) (describing an earlier incident in which a senior official in EPA’s Office of Pesticide Programs directed another EPA employee to “pull ... aside” two EPA officials “to tell [them] not to express [their] concerns about Seresto in emails”).

¹⁴ Email from Robert Miller, Environmental Protection Agency, to Quentin Borges-Silva, Environmental Protection Agency (May 30, 2019) (ED_005739D_00014094-00001).



“

It is my strong opinion the agency needs to [take] action...regarding Seresto to protect family pets.

(EPA Email, 5/30/19)

”

And in March 2021, after the release of the *USA Today* investigative report on Seresto, another EPA official wrote that they “ha[d] been screaming about [Seresto] for many years”¹⁵:



“

Looks like the sh** has hit the fan...Will be interesting seeing where this goes. I hope there is a FOIA for all communications on this so that our emails are made public. We have been screaming about [Seresto] for many years.

(EPA Email, 3/3/21)

”

Despite this evidence, neither EPA nor Elanco has taken action to address the safety of the Seresto collar, and the product remains on the market.

Recommendations

While the Subcommittee is encouraged that EPA’s Office of Inspector General has recently announced plans to evaluate the agency’s response to reported Seresto incidents, additional steps are needed to stem the harm that the Seresto collar continues to cause while Elanco refuses to act to protect consumers and their pets. As Mr. Simmons has confirmed, it remains Elanco’s position that “there’s no linkage [between] the active ingredients [and] a pet

¹⁵ Email from Nick Mastrota, Environmental Protection Agency, to Robert Miller and Colleen Rossmeisl, Environmental Protection Agency (Mar. 3, 2021) (ED_005739D_00014190-00001).

death.”¹⁶ During the hearing, Mr. Simmons acknowledged that Elanco—and its predecessor Bayer Animal Health—had refused EPA’s requests that it split the registration for dog and cat collars and make changes to the collar’s label because Seresto is a “safe product” and any “risk is reasonable.”¹⁷ Mr. Simmons admitted that Seresto’s label in the United States does not identify the risk of death—warning only about mild issues like skin irritation—despite the fact that the Seresto label in other countries describe it as “highly toxic” or “poison.”¹⁸ He also conceded that Elanco has no plans to change that label absent “data [that] warranted some need for a change.”¹⁹ Furthermore, Elanco has made clear that it will not voluntarily recall the product. Accordingly, as I summarized at the conclusion of the hearing on June 15, 2022, and as set out more fully in the staff report, EPA must take several critical steps to ensure that the failures related to the Seresto registration review and post-market surveillance do not happen again.

First and foremost, pursuant to its product cancellation authority, EPA should immediately commence administrative proceedings that would allow it to remove Seresto from the market in the United States. In the short term, this involves commencing NOIC proceedings by providing the required notice to the Secretary of Agriculture; this will ensure that a comprehensive review of Seresto and its risks is undertaken with an eye toward determining whether it should remain on the market long-term. In the meantime, I have also called on Elanco to institute a voluntary recall of the Seresto collar until the NOIC proceedings have concluded.

Second, to ensure that no product prematurely reaches the market in the future and endangers the well-being of pets and their owners, EPA must also strengthen its pre-registration scientific review process. Specific measures should include, among other things, updating EPA guidelines for companion animal and clinical studies to guarantee adequate sample sizes and representative testing conditions.

Third, EPA must improve its incident data collection system so that it can act more quickly and efficiently when facing alarming rates of incident reports. Steps include (i) requiring manufacturers to provide more comprehensive incident information, such as symptoms that animals experience, the circumstances in which the pesticide exposures occurred, and the species, sex, age, and health status of the affected animals and (ii) clearly marking products that fall under EPA’s jurisdiction and providing relevant contact information. It is especially in these areas where I believe that the FDA can provide helpful assistance.

Thank you for your attention to this important matter. The Subcommittee respectfully requests that your respective agencies respond to this letter by July 25, 2022, setting out the next steps that you intend to take concerning Seresto and explaining how you intend to implement the

¹⁶ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Seresto Flea and Tick Collars: Examining Why a Product Linked to More than 2,500 Pet Deaths Remains on the Market* (June 15, 2022) (online at <https://oversight.house.gov/legislation/hearings/seresto-flea-and-tick-collars-examining-why-a-product-linked-to-more-than-2500>).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

The Honorable Michael S. Regan

The Honorable Robert M. Califf

Page 7

recommendations set out above. Should you have any questions, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

A handwritten signature in black ink, appearing to read "Raja Krishnamoorthi", written over a horizontal line.

Raja Krishnamoorthi

Chairman

Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy