From:	Biscoe, Melanie
To:	Cyran, Carissa
Subject:	FW: Seresto House Hearing 6/15
Date:	Wednesday, June 15, 2022 4:52:00 PM
Attachments:	2022.06.15 ECP Seresto Staff Report FINAL.pdf

Heads up Carissa – here's the report from today's hearing. We're gonna be busy.

Melanie L. Biscoe
Senior Regulatory Advisor, RMIB5
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202-566-0701
(She/Her/Hers)

From: Fletcher, Rachel <fletcher.rachel@epa.gov>
Sent: Wednesday, June 15, 2022 3:57 PM
To: Reaves, Elissa <Reaves.Elissa@epa.gov>; Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>
Cc: Britton, Cathryn <Britton.Cathryn@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Khan, Matthew <khan.matthew@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Di Salvo, Paul <DiSalvo.Paul@epa.gov>; Stoner, Nora <Stoner.Nora@epa.gov>; Shuler, Jamey <Shuler.Jamey@epa.gov>
Subject: RE: Seresto House Hearing 6/15

Hi everyone,

Just wanted to send the June 2022 committee report along as an FYI.

Best,

Rachel

From: Reaves, Elissa <Reaves.Elissa@epa.gov>
Sent: Monday, June 13, 2022 2:05 PM
To: Biscoe, Melanie <Biscoe.Melanie@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>
Cc: Britton, Cathryn <Britton.Cathryn@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Khan, Matthew <khan.matthew@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Di Salvo, Paul <DiSalvo.Paul@epa.gov>
Subject: RE: Seresto House Hearing 6/15

Thank you. I had heard they were going to have a hearing but didn't know the date.

Elissa Reaves, Ph.D.
Director, Pesticide Re-evaluation Division

Office of Pesticide Programs
202-566-1925

From: Biscoe, Melanie <Biscoe.Melanie@epa.gov>
Sent: Monday, June 13, 2022 1:59 PM
To: Reaves, Elissa <Reaves.Elissa@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>
Cc: Britton, Cathryn <Britton.Cathryn@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Fletcher, Rachel <fletcher.rachel@epa.gov>; Khan, Matthew <khan.matthew@epa.gov>; Jones, Ricardo <Jones.Ricardo@epa.gov>; Di Salvo, Paul <DiSalvo.Paul@epa.gov>
Subject: Seresto House Hearing 6/15

FYI, Rachel brought this to my attention –

https://oversight.house.gov/legislation/hearings/seresto-flea-and-tick-collars-examining-why-a-product-linked-to-more-than-2500

Melanie L. Biscoe
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HOUSE COMMITTEE ON OVERSIGHT AND REFORM | SUBCOMMITTEE ON ECONOMIC AND CONSUMER POLICY

SERESTO FLEA AND TICK COLLARS: EXAMINING WHY A PRODUCT LINKED TO MORE THAN 2,500 PET DEATHS REMAINS ON THE MARKET

STAFF REPORT
JUNE 2022

EXECUTIVE SUMMARY

This staff report presents the findings of a 16-month investigation by the Committee on Oversight and Reform's Subcommittee on Economic and Consumer Policy into the safety of the Seresto flea and tick collar. Bayer Animal Health—the original owner and manufacturer of the collar—and Elanco Animal Health, which purchased Bayer Animal Health in 2020, have sold millions of Seresto collars since the product entered the market in 2013. Pet owners embraced the convenience of the eight-month flea and tick protection offered by the collar—for under $70—when many other flea and tick treatments must be re-applied monthly.

In March 2021, a report from *USA Today* revealed that, as of June 2020, there had been more than 75,000 incidents—what the Environmental Protection Agency (EPA) calls unexpected effects from the use of a pesticide—and approximately 1,700 pet deaths linked to the Seresto collar. Since the *USA Today* report was published, the reported numbers have increased to more than 98,000 incidents and 2,500 pet deaths.

The Subcommittee's investigation found that EPA knew about the dangers posed by the collar—and the many consumer complaints about the collars—for several years yet failed to take action. Documents and communications obtained and reviewed by the Subcommittee reveal:

- **EPA Rushed Seresto's Approval Through a Flawed Scientific Review Process.** An EPA Risk Manager wrote in 2016 that the agency "rushed" the Seresto collar's registration so that the CDC could use the collars in a study. The California Department of Pesticide Regulation found that key studies that tested the Seresto collar on adult dogs and cats were not acceptable because the studies "greatly under-estimated the exposures" to one of the collar's active ingredients. EPA's product manager for Seresto also observed that other required studies for pesticide products had small sample sizes and tested the pesticides on "hardy breeds," limiting the studies' usefulness.

- **EPA First Discovered Serious Issues with the Collar's Safety in 2015.** A 2015 EPA investigation found that "Seresto ranked #1 by a wide margin" in terms of total incidents and "Death" or "Major" incidents among flea and tick products. EPA found that, adjusted for sales figures, the Seresto collar 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 flea and tick 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.

- **Canada Refused to Allow the Collar to be Sold Due to Safety Concerns.** According to information obtained by the Subcommittee not previously available to the public, in 2016, Canada's Pest Management Regulatory Agency (PMRA) concluded—based on a review of U.S. incidents and toxicology studies—that the collar posed too great a risk to pets and their owners to be sold in Canada. PMRA expressed great concern over the "number and severity" of U.S. animal incidents linked to the Seresto collar. The Canadian agency reviewed enhanced data on

roughly 1,000 of the most serious "Death and Major" pet incidents linked to Seresto, and found that the collar probably or possibly caused 77% of these incidents.

- **EPA Allowed the Collar to Stay on the Market.** EPA's independent review of the complete incident data for Seresto "had largely the same overall impressions as PMRA's" analysis. Canada's PMRA reviewed 251 pet deaths linked to the Seresto collar and found that the collar probably or possibly caused 33% of those deaths. EPA independently reviewed the same 251 pet deaths and concluded that the collar probably or possibly caused 45% of those deaths. Yet EPA let the Seresto collar remain on the market—even after high incident numbers continued in recent years.

- **EPA Officials Voiced Frustrations Over the Seresto Collar Remaining on the Market.** Previously released documents show that, during internal deliberations over how to respond to an inquiry about the collar following the March 2021 *USA Today* investigative report, an EPA scientist stated that the substance of the agency's reply would "depend[] if you want the real answer or some talking points to cover our ass for doing nothing." The same scientist separately observed to other colleagues, "Looks like the sh** has hit the fan. There are lots of news and public advocate sites that have picked up on the Seresto story in *USA Today*. 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 this for many years." Another EPA official wrote that they hoped "this time someone can blow the lid off this travesty."

- **Reported Incident Figures May Understate the Harm Caused By the Seresto Collar.** By EPA's own admission, there "is undoubtedly some degree of underreporting in every incident database regularly used by" the agency's pesticide office. Many incidents go undetected or unreported because, as EPA has explained, the "[s]ymptoms associated with pesticide poisonings are often vague or mimic other causes leading to incorrect diagnoses." Further, EPA generally only requires companies to provide minimal pet incident data—total incident numbers, and whether the incidents were deaths, major, moderate, or minor incidents—with no information on pets' symptoms, age or health status, or length of exposure to the pesticide. EPA received only this minimal, aggregate data for Seresto from 2016 until 2020. From April 2020 until the *USA Today* report was published in March 2021—a period that included the closing of Elanco's August 2020 purchase of Bayer Animal Health (and, in turn, the Seresto collar)—EPA did not receive a single Seresto incident report from either company.

I. BACKGROUND

A. New, Long-Lasting Flea and Tick Collar Enters the Market

In January 2013, Bayer Animal Health began selling the Seresto flea and tick collar in the United States, stating that it provided safety and convenience to dogs, cats, and their owners. The collar—widely sold by pet specialty stores, online pet pharmacies, and large online retailers—offered eight months of flea and tick protection to dogs and cats for under $70. The convenience of eight-month flea and tick protection, when many other products must be re-applied monthly, made the Seresto collar hugely popular with pet owners. Since the collar entered the U.S. market, Bayer (the original owner and manufacturer of the collar) and Elanco (which purchased the collar in 2020) have sold nearly 34 million Seresto collars in the United States.[1]

B. Safety Concerns Emerge with a Hugely Popular Pet Collar

In March 2021, a report from *USA Today* revealed that, as of June 2020, there had been more than 75,000 incidents—unexpected effects from the use of a pesticide—and approximately 1,700 pet deaths linked to the collar. Since the *USA Today* report was published, the reported numbers have increased to more than 98,000 incidents and 2,500 pet deaths.[2]

According to documents obtained by the Subcommittee, as well as additional reporting from *USA Today* and internal EPA emails made public via a Freedom of Information Act (FOIA) request, EPA knew about the dangers posed by the Seresto collar for *years*, yet failed to take action to protect pets and their owners.

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[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/YKCR3XSVJVFCRAK3RL3WYU7PGU/).

[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); Environmental Protection Agency, *US EPA Office of Pesticide Programs Incident Data System: Aggregate Incident Summary Report by Product* (Apr. 8, 2022) (online at www.biologicaldiversity.org/programs/environmental_health/pdfs/Aggregate-Incident-Summary-Report-for-EPA-Reg-No-11556-155-Product.pdf); Environmental Protection Agency, *Introduction to Pesticide Incidents* (Apr. 28, 2022) (online at www.epa.gov/pesticide-incidents/introduction-pesticide-incidents).

C. The Subcommittee's Investigation

On March 17, 2021, the Subcommittee launched an investigation into deaths and injuries caused by the Seresto collar. As part of this investigation, the Subcommittee obtained internal documents from Bayer, Elanco, and EPA.[3]

II. EPA'S SCIENTIFIC REVIEW OF THE SERESTO COLLAR

Every pesticide product under EPA's jurisdiction must go through a Registration Review process—requiring a number of scientific studies showing the product's safety—before the product can be registered for sale to the public.[4] Bayer submitted its application for Seresto on September 23, 2010, and the subsequent registration review process resulted in EPA approval of the collar in March 2012.[5] However, according to a 2016 email from an EPA Risk Manager, the agency "rushed" the Seresto collar's registration so that the CDC could use the collars in a study.[6]

In internal documents recently released in response to a FOIA request, EPA's product manager for Seresto also raised concerns with the quality of the review process for pet products. In the wake of the 2021 *USA Today* report, the EPA product manager detailed various longstanding shortcomings with EPA's regulation of flea and tick products, including with the scientific studies supporting pet product registration. For example, the guidelines for required companion animal safety studies—which test a product on the animals that the product is designed for—had not been updated for approximately 20 years. Moreover, according to this EPA official, "these studies are usually negative for adverse effects"—meaning that the studies likely failed to detect products' potential harms to animals.[7] In the case of Seresto specifically, a separate review by the California Department of Pesticide Regulation's Medical Toxicology Branch did not find the collar's companion animal safety studies for adult dogs and cats to be acceptable, because the studies "greatly under-estimated the exposures" to one of the collar's two active ingredients.[8]

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[3] Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Jeff Simmons, Elanco Animal Health Inc. (Mar. 17, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-03-17.RK%20to%20Simmons-Elanco%20re%20Pet%20Collars.pdf); Letter from Chairman Raja Krishnamoorthi, Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, to Patrick Lockwood-Taylor, Bayer U.S. LLC (Mar. 17, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-03-17.RK%20to%20Lockwood-Taylor-Bayer%20re%20Pet%20Collars.pdf); Letter from Chairman Raja Krishnamoorthi, Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, to Hon. Michael S. Regan, Administrator, Environmental Protection Agency (Mar. 16, 2021).

[4] Seresto and EPA's Regulation of Pet Products (Mar. 31, 2021) (ED_005739A_00104527-00003).

[5] Environmental Protection Agency, *Review of Seresto Pet Collar Incidents Data* (June 9, 2016) (ED_OOS739A_00099909-00002); Seresto Incident Profile (July 16, 2019) (EAH-HOR-00003268).

[6] Email from Susan Jennings, Environmental Protection Agency, to Kable Davis, Environmental Protection Agency (Oct. 6, 2016) (ED_005739A_00098941-00001).

[7] Seresto and EPA's Regulation of Pet Products (Mar. 31, 2021) (ED_005739A_00104527-00003).

[8] California Department of Pesticide Regulation, *Flumethrin Study of Toxicology* (2012).

Other required studies on the efficacy and safety of pesticides used in pet products also had known flaws. EPA's Seresto product manager observed that the studies' "[s]mall sample sizes and use of known hardy breeds detract from the usefulness of these studies."[9] In addition, tests of ingredients are often conducted on animals such as rats and mice, but a 2017 EPA risk assessment found that dogs had sensitivity to imidacloprid—one of the two active ingredients in the Seresto collar—at doses seven times lower than the toxicity levels for rats and mice.[10] Meanwhile, EPA's risk assessment of flumethrin—the collar's other active ingredient—only studied the pesticide's effects on rats and mice.[11]

EPA does not require pre-market clinical trials of flea and tick products before registering them for sale. By contrast, the Food and Drug Administration (FDA), which also regulates certain animal products, requires a pre-market clinical trial of approximately 200 animals before approving the flea and tick products under its jurisdiction.[12] EPA's flawed review process ultimately led to a product hitting the market that would be linked to more harmful incidents than any other flea and tick product under EPA's jurisdiction.[13]

III. EPA'S REGULATION AND OVERSIGHT OF THE SERESTO COLLAR

A. <u>EPA Has Been on Notice of Seresto's Potential Dangers Since 2015</u>

EPA launched its first investigation into the Seresto collar in 2015 in response to an inquiry from NBC News.[14] According to an internal EPA presentation released (with redactions) pursuant to a FOIA request, EPA analyzed the number of incidents, or unexpected effects, associated with the Seresto collar and discovered serious potential safety issues. The agency concluded that of all flea and tick products in EPA's Incident Data System, "Seresto ranked #1 by a wide margin" in total incidents from January 2012 through July 2015.[15] The Seresto collar had nearly 4,000 more—or 58% more—incidents than the second most dangerous product, and over 7,000 more—or 235% more—incidents than the third most dangerous product.[16] Seresto

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[9] Seresto and EPA's Regulation of Pet Products (Mar. 31, 2021) (ED_005739A_00104527-00003).

[10] Center for Biological Diversity, *Petition to Cancel Registration of PNR1427 Insecticide (Brand Name Seresto)* (Apr. 8, 2021) (online at www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/2021-4-8-Petition-to-Cancel_SerestoCollarwExhs.pdf).

[11] Environmental Protection Agency, *Flumethrin: Human Health Risk Assessment for the Section 3 Registration Action for Cat and Dog Collars* (2016) (online at www.regulations.gov/document?D=EPA-HQ-OPP-2016-0031- 0005); Environmental Protection Agency, *Flumethrin: Draft Human Health Risk Assessment for Registration Review* (2018) (online at www.regulations.gov/document?D=EPA-HQ-OPP-2016-0031-0027).

[12] Seresto and EPA's Regulation of Pet Products (Mar. 31, 2021) (ED_005739A_00104527-00003). FDA regulates flea and tick products that are ingested or penetrate the skin. EPA regulates pesticide products that are applied to the skin. Seresto Evaluation—EPA Meeting (Mar. 23, 2021) (EAH-HOR-00000012).

[13] Environmental Protection Agency, *US EPA Office of Pesticide Programs Incident Data System: Aggregate Incident Summary Report by Product* (Mar. 19, 2021).

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

[15] *Id.*

[16] *Id.*

also had 570—or 163%—more incidents labeled either "Death" or "Major" than the second most dangerous product, and 745—or 428%—more than the third most.[17] Notably, Seresto ranked first in incidents "by a wide margin" even though the collar was not yet on the market in 2012, the first year of the time period analyzed.[18]

From this incident data, EPA calculated the odds of "fatal or high severity" incidents for Seresto compared to all other flea and tick products. The agency found that Seresto was one of the top three most dangerous products by this metric, along with versions of two other Bayer products—K9 Advantix and Frontline.[19]

In a portion of the presentation not previously made public but obtained by the Subcommittee, EPA then factored in sales data obtained from Bayer for these three products to compare the rate at which incidents occurred for each product. EPA discovered that Seresto had the highest rate of total incidents as well as "Death" or "Major" incidents. Compared to the second most dangerous product, Seresto had nearly three times the rate of total incidents, and nearly five times the rate of "Death" or "Major" incidents. Compared to the third most dangerous product, the Seresto collar had nearly 21 times the rate of total incidents, and over 35 times the rate of "Death" or "Major" incidents.[20]

Faced with this data showing Seresto to be far more hazardous than other flea and tick products, EPA resolved to "continue to monitor this situation" as the agency waited for the results of an analysis of Seresto incident data from Canada's Pest Management Regulatory Agency (PMRA). PMRA was then studying Seresto—including the collar's U.S. incident data—to decide whether the collar was safe enough to be approved for sale in Canada. PMRA was also investigating the question of whether the collar caused harmful incidents in pets, a key factor in EPA's decision-making. The Seresto incident data that EPA had collected and analyzed showed a link between collar use and harmful incidents, but did not prove that the collar caused

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[17] *Id.*

[18] *Id.*; *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). In the agency's guidelines for incident severity classification, EPA states that a "major" animal incident occurred if the animal "exhibited or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability." Environmental Protection Agency, *Pesticide Registration Notice 98-3* (Apr. 3, 1998) (online at www.epa.gov/sites/default/files/2014-04/documents/pr98-3.pdf); *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).

[19] K9 Advantix and Frontline are "spot-on" treatments—liquid products applied to a dog or cat's skin to repel fleas and ticks. Food and Drug Administration, *Safe Use of Flea and Tick Products in Pets* (June 22, 2021) (online at www.fda.gov/consumers/consumer-updates/safe-use-flea-and-tick-products-pets); Environmental Protection Agency, *Review of Seresto Pet Collar Incident Data* (Dec. 16, 2015).

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

the incidents. Canada's analysis of U.S. Seresto incidents would help EPA answer this question.[21]

B. EPA Learned in 2016 That the Seresto Collar Was Deemed Too Dangerous to Be Sold in Canada

PMRA's Seresto report—which EPA received in July 2016 and which has not been made public prior to this Report—contained a number of striking findings. PMRA closely reviewed 961 "Death and Major" pet incidents using enhanced data provided by Bayer, and found that the Seresto collar probably or possibly caused 737—or 77%—of them. More broadly, PMRA expressed great concern over the "number and severity" of animal incidents linked to the Seresto collar. The PMRA report revealed that from 2012 through 2015, there were over 19,000 reported pet incidents in the United States, including 381 deaths and 1,342 major incidents.[22]

Category		Number of Incidents
Human	Major	13
	Moderate	125
	Minor	219
	Total Human	*357*
Domestic Animal	Death	381
	Major	1 342
	Moderate	4 605
	Minor	12 883
	Total DA	*19 211*
Total		**19 568**

Source: Health Canada's Pest Management Regulatory Agency, *Seresto Collar for Large Dogs (2013—1614); Seresto Collar for Small Dogs (2013—1616); and Seresto Collar for Cats (2013—1618)* (Apr. 15, 2016).

Adjusted for sales figures, these incident numbers were still concerning under PMRA's standards. PMRA used the threshold of one incident per 10,000 collars sold as an indicator of a potential problem and a trigger for investigation. The Seresto collar had an incident rate of 36 to 65 incidents per 10,000 collars sold, and three to five "Death and Major" incidents per 10,000 collars sold. By comparison, the 15 pet collars registered for sale in Canada at the time averaged 0.07 incidents per 10,000 collars sold. Seresto's incident numbers were also trending in the wrong direction: PMRA expressed "additional concern" over the fact that Seresto's total incident numbers had nearly doubled every year since 2013.[23]

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

[22] Health Canada's Pest Management Regulatory Agency, *Seresto Collar for Large Dogs (2013—1614); Seresto Collar for Small Dogs (2013—1616); and Seresto Collar for Cats (2013—1618)* (Apr. 15, 2016).

[23] *Id.*

	Incident Rate (# incidents /10,000 units of product sold)	
Product	All Incidents	Death + Major Incidents
Seresto Large Dog (>7weeks old and >8kg)	36	4
Seresto Small Dog (>7weeks old and <8kg)	46	3
Seresto Cat (>10weeks old)	65	5

Source: Health Canada's Pest Management Regulatory Agency, *Seresto Collar for Large Dogs (2013—1614); Seresto Collar for Small Dogs (2013—1616); and Seresto Collar for Cats (2013—1618)* (Apr. 15, 2016).

i. <u>Animal Symptoms from Collar Use</u>

PMRA analyzed the symptoms experienced by pets in the 737 cases probably or possibly caused by the collar. Skin effects—including lesions and reddened, dry, and irritated skin—were the most common symptoms in the sample. Among the 737 cases, nearly 80% of the animals suffered from at least one skin effect. Most of these skin effects were serious—they covered large areas of the body, did not resolve after the collar was removed, or required medical treatment.[24]

Other frequently reported symptoms from the sample of the 737 cases included lethargy, abnormal behavior, excessive grooming and vocalization, vomiting, diarrhea, and anorexia. Over one-third of cases reported effects in multiple organ systems. Of these, 5% to 10% of cases involved convulsions, muscle tremors, and loss of control of bodily movements.[25]

These troubling symptoms appeared shortly after use of the Seresto collar began, mostly within the first month. Many pet owners reacted by removing their pets' collars early, "likely...due to the adverse effects experienced by the animals." Half of the dog owners who reported the duration of their pets' use of the Seresto collar removed it after two months of use or less, even though the collar is meant to be worn for eight months. Cat owners acted even sooner. Half of them removed the collar after a month of use or less.[26]

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[24] *Id.*

[25] *Id.*

[26] *Id.*

Unfortunately, PMRA found that the "progression of effects is difficult to mitigate—it appears that removal of the collar does not occur in time…despite early removal." In other serious non-skin incidents, harmful effects continued to worsen even after collar removal.[27]

Most alarmingly, 10% of pets in the sample of the 737 cases died or were euthanized after wearing the collar.[28] In 8% of the cases PMRA examined, animals displayed what the agency called "systemic effects," involving their internal bodily systems. These included kidney, liver, blood, lymphatic, and immune system disorders.[29] PMRA found these disorders to be "of particular concern" because they are so difficult for pet owners to spot. Pet owners only tend to notice and report obvious, external symptoms, such as hair loss, vocalization, and trembling. Systemic effects, however, are not visible to the owner unless the pet undergoes testing and diagnosis by a medical expert—testing which, according to PMRA, is "frequently not done." As such, PMRA considered even the 8% of cases showing systemic disorders to be worrisome given how difficult they are to uncover.[30]

ii. <u>Human Symptoms from Collar Exposure</u>

PMRA also found that some pet owners suffered notable harms from their pets' collar use. From 2012 through 2015, there were 357 human incidents linked to the Seresto collar. As with pet incidents, PMRA obtained additional details from Bayer concerning the most serious human incidents. This information comprised 106 human incidents—nine major and 97 moderate. Of these 106 incidents, PMRA found 88—or 83%—were probably or possibly caused by exposure to the Seresto collar.[31]

As with pets, symptoms among pet owners often appeared quickly, typically the same day the individual was exposed to the collar. Roughly 40% of affected individuals experienced symptoms simply from opening the collar and putting it on their pet. Nearly 45% experienced symptoms through contact with a pet who wore the collar, while the rest of the affected owners were exposed in both ways.[32]

Half of affected individuals reported skin and immune disorders, with common symptoms including hives and dermatitis. In addition, about 15% of individuals experienced respiratory, neurological, and digestive effects, with throat irritation, breathing difficulty, dizziness, and nausea among the most common symptoms. Overall, about 40% of affected individuals from this sample experienced what PMRA considered to be serious effects, often requiring medical treatment. As with the pet incidents, affected individuals removed the collar early—25% of the time.[33]

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[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] *Id.*

Notably, these observed effects on humans were consistent with clinical studies into imidacloprid—one of the collar's main active ingredients—which have found that "[r]epeated chronic exposure to imidacloprid may pose possible health risks to veterinarians, veterinary technologists, dog caretakers, and owners."[34]

C. PMRA Determined the Only Way to Stop Seresto's Harms Was to Stop Bayer from Selling the Collar

PMRA found that the symptoms experienced by pets, as well as the onset of their symptoms, were consistent with the toxicology studies of the Seresto collar's two active ingredients—imidacloprid and flumethrin. PMRA noted that "such consistency occurs infrequently."[35]

With a mountain of data showing the dangers posed by the Seresto collar to both animals and humans, and the consistency of these dangers with the toxicology studies of the collar's active ingredients, PMRA considered whether any preventive measures could mitigate the risks the collar posed. PMRA considered adding to the collar's label symptoms that could develop from use of or exposure to the collar. The agency also considered issuing a press release to warn people to report symptoms, or requiring that Bayer decrease the concentration of the collar's active ingredients. However, PMRA concluded that updating the label would not prevent symptoms from occurring; a press release would only help provide more data, when PMRA already had enough data to assess the collar's risks; and it was not known what rate of active ingredients would actually be safe.[36]

Mitigation Option	Effectiveness	Reasons
1. Add symptoms to label	Low	Labelling symptoms will not prevent them from occurring. European labels indicate collar should be removed if signs worsen.
2. Press release to warn to report symptoms	Low	Simply provides more data; PMRA has sufficient data to characterize risks
3. Decrease concentration of active ingredients	Unknown	Unknown what rate would be a safe dose.
4. Reject submission	High	Prevent incidents from occurring

Source: Health Canada's Pest Management Regulatory Agency, *Seresto Collar for Large Dogs (2013—1614); Seresto Collar for Small Dogs (2013—1616); and Seresto Collar for Cats (2013—1618)* (Apr. 15, 2016).

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[34] M.S. Craig et al., *Human Exposure to Imidacloprid from Dogs Treated with Advantage*, Toxicology Mechanisms and Methods (2005) (online at https://pubmed.ncbi.nlm.nih.gov/20021094/).

[35] Health Canada's Pest Management Regulatory Agency, *Seresto Collar for Large Dogs (2013—1614); Seresto Collar for Small Dogs (2013—1616); and Seresto Collar for Cats (2013—1618)* (Apr. 15, 2016).

[36] *Id.*

Ultimately, PMRA concluded that only preventing the Seresto collar from being sold in Canada could effectively protect pets and humans from the collar's harms. Accordingly, the PMRA report recommended rejecting Bayer's application to register Seresto for sale in Canada. PMRA management followed the report's recommendation and decided not to approve Bayer's application.[37]

D. EPA's Own Analysis Matched PMRA's Findings, Yet EPA Took No Action

According to unreleased portions of documents previously made only partially available to the public, the Subcommittee has learned that, after receiving PMRA's report, EPA conducted a peer review of PMRA's causality analysis. PMRA had reviewed 251 pet deaths linked to the Seresto collar and concluded that 33%—or 84—of the pet deaths were probably or possibly caused by the collar. EPA independently reviewed the same 251 pet deaths and found an even stronger connection between Seresto collar use and deaths. EPA concluded that 45%—or 113—of the deaths were probably or possibly caused by the collar.[38]

EPA's independent review of the complete incident data for Seresto, in turn, "had largely the same overall impressions as PMRA's Incident Report." The Agency again compared Seresto's incident numbers to those of other Bayer flea and tick products by factoring in sales data, as it had in December 2015. Once again, Seresto was found to have "had significantly higher incidence rates for *Deaths* and *Deaths or Majors* than the overall incidence rates of all other Bayer products during the 2014-2015 period."[39] EPA concluded that "the death incidence rate of Seresto was about 70% higher than the overall death incidence rate of" the other Bayer products studied, while "the death + major incidence rate of Seresto was 150% higher than" that of the other Bayer products.[40]

EPA now had overwhelming evidence of the dangers posed by the Seresto collar. The collar was linked to more incidents—including more "Death and Major" incidents—than any flea and tick product the agency tracked. Moreover, there was strong evidence that the collar caused a significant portion of these incidents. Yet EPA decided to continue collecting more data before deciding whether to take any additional action.[41] The product remained on the market, unchanged, causing further harm to pets and their owners.

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[37] Health Canada's Pest Management Regulatory Agency, *Seresto Collar for Large Dogs (2013—1614); Seresto Collar for Small Dogs (2013—1616); and Seresto Collar for Cats (2013—1618)* (Apr. 15, 2016); Environmental Protection Agency, *Seresto Briefing Document* (Sept. 22, 2016) (ED _ 005 739A_ 00099214-00001).

[38] Environmental Protection Agency, *Seresto Briefing Document* (Sept. 22, 2016).

[39] *Id.*

[40] *Id.*

[41] *Id.*

E. EPA Tried to Minimize Discussion of Seresto During the Trump Administration, Despite Continuing Harms

According to an internal EPA document released via a FOIA request and a Subcommittee staff interview with an EPA whistleblower, under the Trump Administration, at least one senior agency official tried to tamp down discussions of concerns about Seresto. Acting on orders from a senior EPA official, an EPA scientist instructed two other EPA officials to stop expressing their concerns about Seresto over email.[42] According to the EPA whistleblower, this incident took place in 2017.

In September 2018, according to documents released via a FOIA request, an EPA scientist reported 125 pet deaths linked to the Seresto collar in the second quarter of that year—"the highest number we have seen." The scientist added that there had been 361 deaths linked to Seresto from August 30, 2017, to April 1, 2018, reflecting a trend of increasing death incidents.[43]

The news later in the year was even worse. In advance of a November 2018 EPA briefing on Seresto, another EPA scientist shared incident data for the third quarter of 2018. That quarter yet again set a new record as "the highest quarter we have ever seen for [pet] deaths"—148. This compared to 87 pet deaths reported in the same quarter a year before, a 70% year-over-year increase. This scientist calculated that there were more pet deaths linked to Seresto through the first three quarters of 2018 than in all of 2017 combined. The scientist observed that the Seresto collar "is the only product where we are seeing this trend," and suggested that EPA management should be made to understand the Seresto data.[44]

After more troubling information came in about the collar, the Director of EPA's Office of Pesticide Programs (OPP) wrote in June 2019 that EPA needed to call in Bayer for another discussion about "what can be done to reduce the number of incidents."[45] The Director of OPP's

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[42] *See* Email from R. Miller, Environmental Protection Agency, to M. 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." According to a whistleblower, this interaction took place in 2017. Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy Majority Staff, Meeting with EPA Whistleblower (May 12, 2021). EPA produced all emails from ten key officials mentioning "Seresto" and similar identifying terms in response to a FOIA request. Complaint for Declaratory and Injunctive Relief, 6 (Apr. 13, 2021), *Center for Biological Diversity v. Environmental Protection Agency,* D.D.C. (No. 21-cv-1015).

[43] Email from N. Mastrota, Environmental Protection Agency, to S. Snyderman, Environmental Protection Agency (Sept. 17, 2018) (ED_005739A_00103845-00001).

[44] Email from C. Rossmeisl, Environmental Protection Agency, to S. Snyderman, Environmental Protection Agency (Nov. 19, 2018) (ED_005739D_00001470-00001).

[45] Email from R. Keigwin, Environmental Protection Agency, to M. Goodis, Environmental Protection Agency (June 21, 2019) (ED _005739D _00003676-00001).

Registration Division supported this idea, observing that "there does appear to be some consistency among the narrative descriptions of the major incident reports for this product."[46]

F. Bayer Refused to Make Changes to Address the Safety of the Collar

EPA met with Bayer and Elanco several times over the years to discuss the safety profile of the Seresto collar. Even as the collar amassed the most incidents and deaths of any flea and tick product under EPA's jurisdiction, the agency proposed only limited actions to address the product's safety.[47] EPA and Bayer met in July 2019, but the meeting again resulted in no regulatory action.

During and after the July 2019 meeting, EPA proposed that Bayer pursue separate registrations for the Seresto dog and Seresto cat collars, to better allow EPA to analyze the incident data for the different collars. Bayer opposed this option on the grounds that it would lead to added fees and a greater administrative burden.[48] EPA's product manager for Seresto accepted Bayer's rationale, writing to Bayer: "I understand the complexity of splitting out the registrations; thank you for considering it and for your explanation of the difficulty such an action would have at this time."[49]

Alternatively, EPA proposed that Bayer update the Seresto warning label. EPA noted that the Seresto collar's U.S. label had not been updated since 2014, even though Bayer had updated the collar's label in Germany to note neurological risks.[50] EPA characterized the Agency's relationship with Bayer as a "partnership," and asked Bayer to consider a label update "in the spirit of stewardship."[51] However, Bayer responded that the data on neurological incidents did not support an update to the U.S. label. The label remained unchanged.[52]

G. Elanco Finalized Its Purchase of Bayer Animal Health in August 2020

In the midst of rising concerns about the safety of the Seresto collar, Elanco acquired Bayer Animal Health in August 2020 for $6.89 billion, having agreed to a Share and Asset

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[46] Email from M. Goodis, Environmental Protection Agency, to E. Reaves, Environmental Protection Agency (June 22, 2019) (ED_005739D_00003711-00001). Consistent symptoms among incidents provide evidence that the incidents were caused by a pesticide product, and did not occur randomly.

[47] Seresto Incident Profile (July 16, 2019) (EAH-HOR-00003270).

[48] Email from D. Keil, Bayer, to W. Heeb, Bayer (Aug. 8, 2019) (EAH-HOR-00004506-7); Email from J. Schofield, Bayer, to C. Aubee, Environmental Protection Agency (Sept. 4, 2019) (EAH-HOR-00003998).

[49] Email from J. Herrick, Environmental Protection Agency, to J. Schofield, Bayer (Oct. 8, 2019) (EAH-HOR-00003997).

[50] Email from D. Keil, Bayer, to W. Heeb, Bayer (Aug. 8, 2019) (EAH-HOR-00004506-7); EPA Meeting (July 16, 2019) (EAH-HOR-00003362).

[51] Email from D. Keil, Bayer, to W. Heeb, Bayer (Aug. 8, 2019) (EAH-HOR-00004506-7).

[52] *Id.*

Purchase Agreement in August 2019.[53] Seresto immediately became Elanco's "top product globally."[54] EPA indicated in a letter to the Subcommittee that, in discussions with Bayer and Elanco in the course of investigating unexpected incidents, Bayer confirmed in writing that it had provided Elanco with "all relevant data" about the collar, apparently including incident reports and other similar data concerning reported unexpected events.[55]

H. Elanco, Like Bayer, Refused to Make Changes to Improve the Collar's Safety

According to internal EPA meeting notes obtained by the Subcommittee, in the wake of the March 2021 *USA Today* report, EPA met with the collar's new registrant, Elanco, and drew attention to warnings about neurological risks that had been added to the collar's European Union label—but not to the U.S. label. However, Elanco insisted that the data did not support an update to the U.S. label. The label stayed the same.[56]

In between these 2019 and 2021 meetings, Bayer officials noted—in a February 2020 company meeting—that Seresto's Colombian label classified the collar as highly toxic, and that the Australian label had similar language.[57] The collar's Australian label contains a simple warning: "POISON."[58] Yet both Bayer and Elanco insisted that the U.S. label required no modifications.

Even if Bayer and Elanco had accepted EPA's proposed adjustment to the U.S. label, this change likely would not have solved the problem. As noted above, in 2016, the Canadian PMRA concluded that adding symptoms to the label would have low effectiveness, because merely listing the health conditions that could develop through exposure to the Seresto collar would not prevent them from occurring. PMRA decided that only preventing sales in Canada could keep pets safe.[59]

I. Elanco Offered Flawed Defenses of the Collar and Appears to Have Met Little EPA Pushback

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[53] Elanco, *Elanco Closes Acquisition of Bayer Animal Health* (Aug. 3, 2020) (online at https://investor.elanco.com/press-releases/press-releases-details/2020/Elanco-Closes-Acquisition-of-Bayer-Animal-Health/default.aspx).

[54] *Id.*

[55] Letter from Radha Adhar, Deputy Associate Administrator, Environmental Protection Agency to Chairman Raja Krishnamoorthi, Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy (May 24, 2021).

[56] Discussing Seresto Incident Profile (Mar. 23, 2021) (EAH-HOR-00002259.)

[57] Seresto TF Meeting (Feb. 27, 2020) (EAH-HOR-00004742)

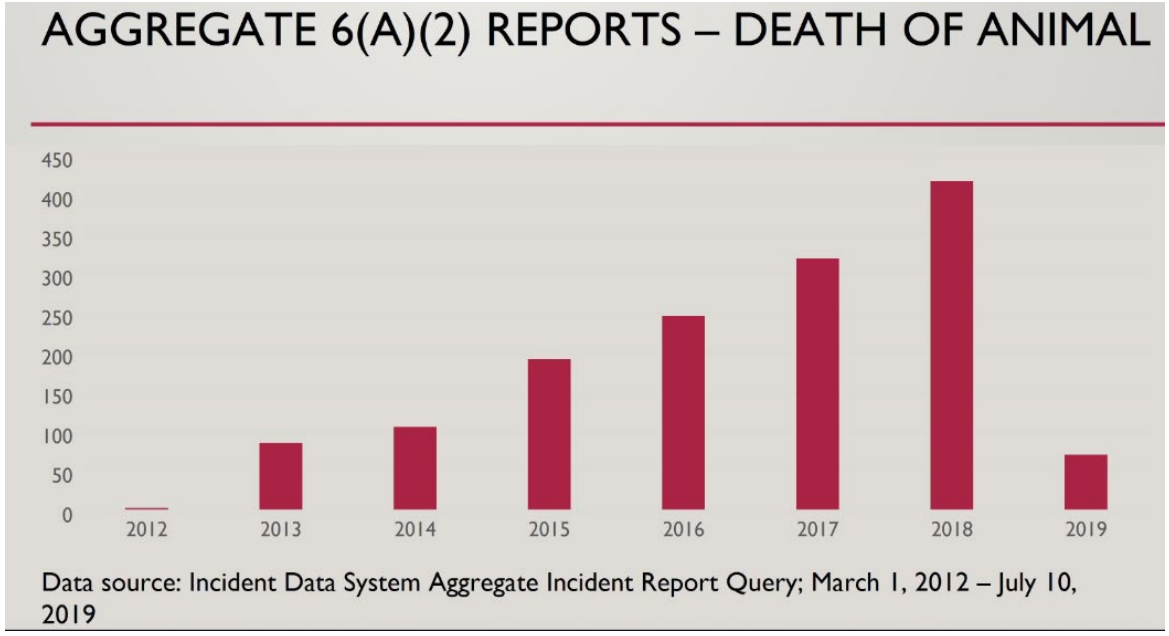
[58] INFOPEST, *Seresto for Kittens and Cats Fleas and Tick Collar* (online at websvr.infopest.com.au/LabelRouter?LabelType=L&Mode=1&ProductCode=80642).

[59] Health Canada's Pest Management Regulatory Agency, *Seresto Collar for Large Dogs (2013—1614); Seresto Collar for Small Dogs (2013—1616); and Seresto Collar for Cats (2013—1618)* (Apr. 15, 2016).

Documents obtained by the Subcommittee show that Bayer and Elanco relied on dubious justifications to explain adverse incidents caused by the Seresto collar.

For example, as far back as October 2015, Bayer justified the Seresto collar's high number of incidents through reference to the so-called "Weber Effect."[60] The Weber Effect posits that the number of incidents linked to a product will peak at the end of the second year after regulatory approval, followed by a steady decline as the market becomes familiar with the product.[61] In December 2015, an EPA presentation noted that "Seresto is no longer brand new (Weber effect non-issue)."[62]

Even so, at the July 2019 meeting between EPA and Bayer—seven years after the collar received regulatory approval—a third-party consultant hired by Bayer still cited the Weber Effect to explain the collar's incident numbers.[63] At the time, reported animal deaths had increased each year the collar had been on the market.[64] Yet meeting notes and email communications obtained by the Subcommittee do not indicate that EPA pushed back on this faulty justification.



*Note: 2019 data only reflected Q1 of that year.

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[60] Email from D. Miller, Environmental Protection Agency, to K. Davis, Environmental Protection Agency (Oct. 7, 2015) (ED_005739D_00000460-00006-7)

[61] Keith B. Hoffman et al., *The Weber Effect and the United States Food and Drug Administration's Adverse Event Reporting System (FAERS): Analysis of Sixty-Two Drugs Approved from 2006 to 2010*, Drug Safety (Apr. 2014) (online at https://pubmed.ncbi.nlm.nih.gov/24643967/).

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

[63] Discuss Seresto Incident Profile (July 16, 2019) (EAH-HOR-00000001).

[64] Seresto Incident Profile (July 16, 2019) (EAH-HOR-00003270).

Source: Seresto Incident Profile (July 16, 2019) (EAH-HOR-00003270).

The same consultant, now working for Elanco, again referenced the Weber Effect in a March 2021 meeting with EPA—nine years after the collar received regulatory approval. In this case, the representative pointed to a decline in reported pet deaths—from 384 in 2019 to 165 in 2020—to argue that the collar's mortality data had finally stabilized.[65] In March 2021 alone, however, with the increased public awareness from that month's *USA Today* article, Elanco received over 200 reports of pet deaths.[66]

Elanco also made dubious claims about another central issue: the number of deaths the Seresto collar had caused. Of the 2,340 pet deaths linked to Seresto as of June 30, 2021, Elanco claims that only 12—or 0.51%—of them were "probably or possibly" caused by the collar. The company further denied that the active pesticide ingredients in the Seresto collar were responsible for any of those pet deaths.[67] The company has taken the position that the safety and toxicity studies of the collar's active ingredients do not support the claim that the collar could cause serious harm to animals.[68] However, as noted above, PMRA's and EPA's independent analyses of 251 pet deaths linked to Seresto found that from 33% to 45%—or 84 to 113—of these deaths were probably or possibly caused by the collar.[69]

J. <u>After the *USA Today* Report, EPA Officials Expressed Frustration over the Agency's Inaction</u>

On March 2, 2021, *USA Today*'s reporting highlighted the lack of regulation for what EPA's internal data showed may be the most dangerous flea and tick product on the market.[70] On that day, as revealed by documents released via a FOIA request, an official from the California Department of Fish and Wildlife wrote to EPA asking for reassurance that the collars were safe to use on the endangered San Joaquin kit foxes. The Department had been using the Seresto collar on the foxes for the previous five years. When an EPA official asked for the best person to answer this question, an EPA scientist replied, "It depends if you want the real answer or some talking points to cover our ass for doing nothing."[71] The scientist separately observed:

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[65] Discuss Seresto Incident Profile, (Mar. 23, 2021) (EAH-HOR-00002257).

[66] Letter from Elanco to Environmental Protection Agency (Apr. 26, 2021) (EAH-HOR-00005685).

[67] In March 2021, Elanco presented a study to EPA of 405 pet deaths linked to the collar. The study did not find the collar responsible in 99% of these deaths. Seresto Evaluation—EPA Meeting (Mar. 23, 2021) (EAH-HOR-00000017, EAH-HOR-00000019).

[68] Elanco Animal Health, *Comments of Elanco Animal Health, Inc.* (Sept. 10, 2021) (online at www.regulations.gov/comment/EPA-HQ-OPP-2021-0409-0282).

[69] Environmental Protection Agency, *Seresto Briefing Document* (Sept. 22, 2016).

[70] *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).

[71] Email from N. Mastrota, Environmental Protection Agency, to C. Wire, Environmental Protection Agency (Mar. 3, 2021) (ED_O0ST38A_U0103833-00001).

> Looks like the sh** has hit the fan. There are lots of news and public advocate sites that have picked up on the Seresto story in USA Today. 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 this for many years.[72]

In reaction to the same query concerning the endangered foxes, EPA's pesticide incident coordinator wrote internally, "I will respond if you like, but I may lose my cool. Why is Seresto even registered? At the very least Seresto should not be used on the endangered" foxes.[73] A senior EPA official responded: "You are correct that it would be inappropriate to respond in your official capacity and express your personal opinions. If you need guidance on how to respond appropriately to inquiries, or how to respond professionally to your internal colleagues...we can discuss."[74] Another EPA employee—a former pesticide incident coordinator—wrote separately to the two agency officials who voiced their frustrations to express the hope that "this time someone can blow the lid off this travesty."[75]

IV. EPA'S PESTICIDE INCIDENT REPORTING SYSTEM HAS BEEN PLAGUED WITH PROBLEMS FOR DECADES

By EPA's own admission, the incident reporting system the Agency uses to assess product safety has been plagued by underreporting for many years.

A. A 1995 Government Accountability Office Report Highlighted Problems with EPA's Incident Reporting System

The problems with the EPA's system for collecting incident data have been known for decades. In 1995, a Government Accountability Office (GAO) report catalogued the shortcomings of EPA's system for collecting pesticide incident data. GAO highlighted incident underreporting as a key issue, affecting both the quality and quantity of reports. An important factor contributing to underreporting was the voluntary nature of incident reporting for all entities except the company that made the product. EPA did not require state agencies, private organizations, or individual customers to report incidents. Only if the product's manufacturer learned of an incident—for example, through a customer voluntarily reporting the incident to the company—was a report required to be made to the agency.[76]

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[72] Email from N. Mastrota, Environmental Protection Agency, to R. Miller, Environmental Protection Agency (Mar. 3, 2021) (ED_005739D_00014190-00001).

[73] Email from R. Miller, Environmental Protection Agency, to N. Berckes, Environmental Protection Agency (Mar. 3, 2021) (ED_005739A_00103710-00002).

[74] Email from M. Echevarria, Environmental Protection Agency, to R. Miller, Environmental Protection Agency (Mar. 3, 20201) (ED_005739A_00103710-00002).

[75] Email from Y. Hopkins, Environmental Protection Agency, to N. Mastrota, Environmental Protection Agency (Mar. 4, 2021) (FOIA ED_005739D_00014201-00001).

[76] Government Accountability Office, *Pesticides: EPA's Efforts to Collect and Take Action on Exposure Incident Data* (July 1995) (GAO/RCED-95-163) (online at www.gao.gov/assets/rced-95-163.pdf).

In addition, GAO observed that companies were not required to provide EPA with essential context about incidents, including information about the circumstances in which a pesticide exposure occurred, the amount of exposure, and the symptoms a victim experienced. Absent this crucial information, EPA had no way of knowing exactly how severely people or animals were harmed from pesticide exposures, or how much danger the pesticide posed.[77]

The GAO report also emphasized the medical community's "incomplete understanding or recognition of pesticide" incidents as a major cause of underreporting.[78] As noted by the Canadian PMRA, the types of internal symptoms—such as organ damage—that can only be discovered by a medical professional tend to be more serious, and more harmful, than the external symptoms—such as a rash—that pet owners notice.[79] When medical professionals fail to diagnose these serious harms, or to connect them to pesticide exposure, the incident reports that EPA ultimately receives may not include many of the most serious incidents. This creates a skewed, incomplete picture of a product's safety.

Given these significant flaws, GAO concluded at the time that the agency's pesticide incident reporting system did "not currently ensure that EPA has sufficient information to determine whether action to protect public health is necessary." However, GAO expressed optimism that a new reporting rule then being developed by EPA could mitigate the problem of incident underreporting, giving the agency more of the key information it needed to protect the public from harmful pesticides.[80]

B. <u>EPA's 1997 Reporting Rule Did Not Fix the Problems Identified by GAO</u>

Unfortunately, the new reporting rule that EPA issued in 1997 did not address the important shortcomings identified by GAO. Notably, the new rule required only aggregate reporting of domestic animal incidents. This meant that companies generally only needed to report two pieces of data from incidents linked to their pesticide products: the total number of incidents, and whether the incident was a death, major, moderate, or minor incident. That is, rather than provide any description of symptoms, the companies were permitted to categorize the adverse effects that animals experienced as major, moderate, or minor.[81] The rule failed to address the primary shortcoming GAO identified three years earlier: without a description of symptoms, or the circumstances in which the exposure occurred, it would be difficult for EPA to decipher exactly how much danger a pesticide product posed.

Ultimately, under the aggregate reporting system, if a dog experiences vomiting and a skin rash after wearing a pet collar for a week, and the dog's owner reports these symptoms to

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[77] *Id.*

[78] *Id.*

[79] Health Canada's Pest Management Regulatory Agency, *Seresto Collar for Large Dogs (2013—1614); Seresto Collar for Small Dogs (2013—1616); and Seresto Collar for Cats (2013—1618)* (Apr. 15, 2016).

[80] *Id.*

[81] Environmental Protection Agency, *Reporting Requirements for Risk/Benefit Information*, 62 Fed. Reg. 49370 (Sept. 19, 1997); Environmental Protection Agency, *Pesticide Registration Notice 98-3* (Apr. 3, 1998) (online at www.epa.gov/sites/default/files/2014-04/documents/pr98-3.pdf).

the collar's manufacturer, the company is only required to report this incident—along with all others over a three-month period—simply as a major, moderate, or minor incident, depending on how the company itself chose to classify the dog's symptoms. By the time the incident arrives on EPA's radar, it is stripped of useful context.

C. EPA's 2007 Report Acknowledged the Continuing Flaws with the Agency's Incident Reporting System

Almost a decade after issuing the updated reporting rule, EPA acknowledged continued flaws in a 2007 report on the agency's pesticide incident reporting system. EPA recognized that there "is undoubtedly some degree of underreporting in every incident database regularly used by" the agency's pesticide office.[82] The factors contributing to this underreporting—several of which GAO identified a dozen years earlier—included:

- No universal, mandatory legal duty to report;
- No central reporting point for all incidents;
- No requirement for active monitoring of incidents;
- Symptoms associated with pesticide poisonings are often vague or mimic other causes leading to incorrect diagnoses;
- Physicians may also misdiagnose due to a lack of familiarity with pesticide effects;
- Incidents are often not investigated adequately enough to identify the pesticide that caused the observed effects;
- Difficulty in identifying and tracking chronic effects; and
- Reluctance or inability to report.[83]

EPA also noted several clinical studies of human pesticide poisoning cases finding that only 4% to 25% of human pesticide poisoning cases were ultimately reported to poison control centers. This finding raises the concern that even fewer animal cases may be reported.[84]

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[82] Environmental Protection Agency, *OPP Report on Incident Information: The Baseline* (2007) (online at archive.epa.gov/pesticides/ppdc/web/pdf/session10-finalrpt.pdf).

[83] *Id.*

[84] *Id.*

D. EPA's Flawed Reporting System Has Contributed to Problems with Seresto Collar Oversight

Despite acknowledging these key flaws over a decade ago, the agency's reporting system has not been updated since 1997. The incident data that EPA received on the Seresto collar exemplifies the structural shortcomings of the agency's reporting system.

For instance, when an EPA Ombudsman asked, in August 2020, for a rundown of all Seresto incident reports from the prior year, EPA's pesticide incident coordinator explained that companies are not required to provide EPA "much data" for pet incidents. The incident coordinator instead directed the Ombudsman to a folder of individual reports that EPA had received directly from pet owners—with a warning that "[s]ome of these reports are graphic." The incident coordinator explained that the individual reports contained "much more information than aggregate reports" from companies.[85]

However, EPA received only a small number of individual reports from pet owners about the Seresto collar. From the product's registration in 2012 through the beginning of 2019, EPA received only eight reports of animal deaths directly from pet owners and veterinarians.[86] Over this same period, the agency received more than 1,300 reports of animal deaths from Bayer.[87] For several years, Bayer reported these deaths to EPA in aggregate form, with no information about the deceased pets' age, health status, symptoms, or length of exposure to the collar.[88]

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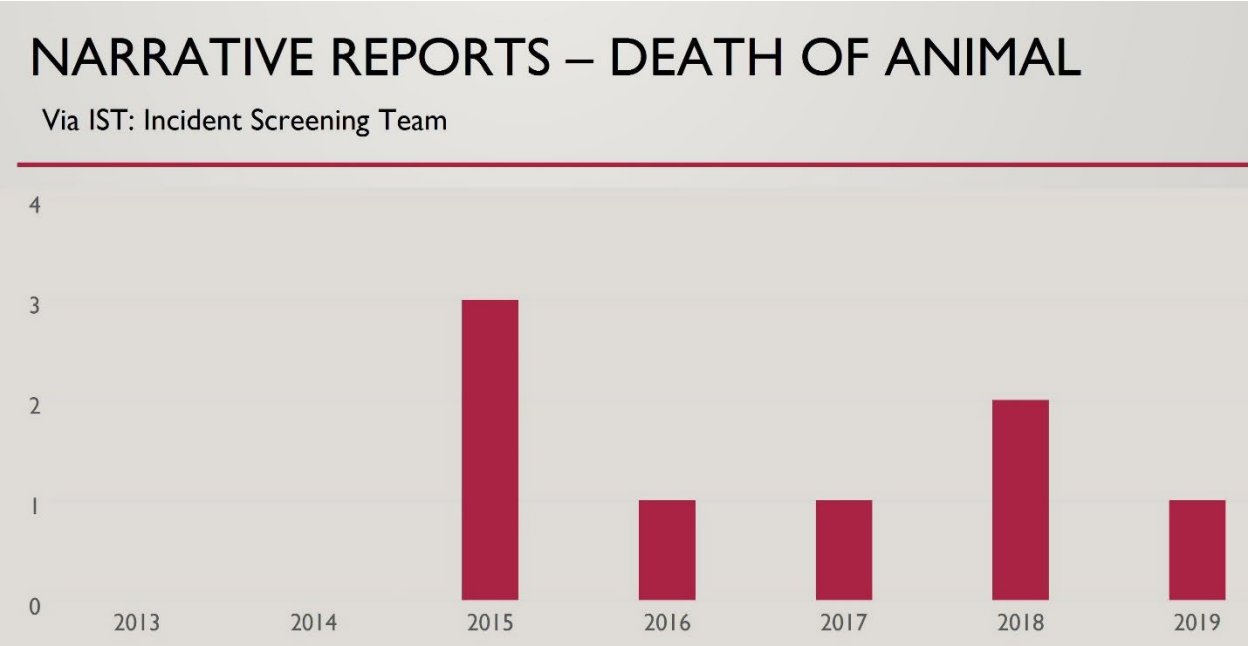
[85] Email from R. Miller, Environmental Protection Agency, to N. Berckes, Environmental Protection Agency (Aug. 4, 2020) (ED _ 005 739A_ 00423726-00001).

[86] Seresto Incident Profile (July 16, 2019) (EAH-HOR-00003269).

[87] Seresto Incident Profile (July 16, 2019) (EAH-HOR-00003270).

[88] At EPA's request, Bayer provided enhanced incident reporting—including case narratives—for all Seresto incidents that occurred from the collar's registration in 2012 until either 2015 or 2016. Afterwards, Bayer only provided aggregated incident reporting to EPA until the sale of the collar in August 2020. Environmental Protection Agency, *Flumethrin Preliminary Work Plan* (Sept. 29, 2016) (EAH-HOR-00004257). EPA also received a smaller number of reports from the National Pesticide Information Center, which receives reports from pet owners and veterinarians. Email from S. Ozmen, Environmental Protection Agency, to E. Messina, Environmental Protection Agency (Mar. 18, 2021) (ED_005739A_00103909-00002); Elanco Animal Health, *Comments of Elanco Animal Health, Inc*. (Sept. 10, 2021) (online at www.regulations.gov/comment/EPA-HQ-OPP-2021-0409-0282).



Source: Seresto Incident Profile (July 16, 2019) (EAH-HOR-00003269).

In April 2020, these aggregate incident reports from Bayer stopped arriving altogether. Bayer did not provide any further incident reports to EPA before the closing of Elanco's purchase of Bayer Animal Health in August 2020. From August 2020 to March 2021, Elanco failed to provide Seresto incident reports to EPA—despite sending incident reports for other products to the agency. Only after the release of the *USA Today* report in March 2021 did Elanco report to EPA the thousands of incident reports that had accrued since April 2020.[89]

Shortly before Elanco finally provided these long overdue incident reports, EPA's pesticide incident coordinator complained in an internal email that Facebook likely receives more reports of pet incidents than EPA.[90] To keep tabs on the collar in the absence of company reporting, an EPA scientist began following a Facebook group where pet owners shared their issues with the Seresto collar. This scientist observed to colleagues that the majority of these reports involved "very consistent symptoms: seizures, tremors, vomiting, and anorexia." The scientist made a post to the Facebook group encouraging pet owners to report Seresto incidents to EPA at Report.Pesticide.Incident@epa.gov.[91]

[89] The delayed reporting took place due to a misunderstanding over how and when to submit reports during the pandemic. Email from K. Smith, EPA, to R. Miller, EPA (Mar. 3, 2021) (ED_ 005 739D 000 14253-00001-2); Email from R. Miller, EPA, to R. Fletcher, EPA (Mar. 12, 2021) (ED_005739A_00104273-00001).

[90] Email from R. Miller, Environmental Protection Agency, to M. Rust, Environmental Protection Agency (Mar. 3, 2021) (ED_005739A_00423787-00001).

[91] Email from N. Mastrota, Environmental Protection Agency, to R. Miller, Environmental Protection Agency (Mar. 19, 2021) (ED_005739D_00001043-00001)

V. RECOMMENDATIONS

For too long, the Seresto collar has harm to many pets, and their owners. Despite Seresto's unprecedented incident numbers, the collar's manufacturer, Elanco, has refused to voluntarily recall the collar.[92] EPA's Office of Inspector General (OIG), meanwhile, has recently announced plans to evaluate the agency's response to reported Seresto incidents.[93] In light of the information obtained in this Investigation, the Subcommittee makes the following recommendations:

- **Recall Seresto Collars and Begin Proceedings to Cancel the Seresto Collar's Registration:** Canada's PMRA concluded in 2016—based on U.S. incident data—that the Seresto collar posed too great a risk to animals and humans to be safe for use. EPA agreed with PMRA's underlying findings and analysis, and EPA officials have expressed concerns about the collar's safety for years. Accordingly, EPA should initiate a Notice of Intent to Cancel proceedings, which will ensure that a comprehensive review of Seresto and its risks is undertaken. In the meantime, to protect pets from further harm, Elanco should institute a voluntary recall of the Seresto collar until comprehensive safety testing can be completed.[94]

- **Strengthen the Scientific Review Process:** EPA should revamp and strictly follow its Registration Review process for pesticide products. The Agency should update its guidelines for companion animal safety studies so that they are better able to detect adverse effects. Likewise, EPA should require that scientific studies have adequate sample sizes and use animals that are as similar as possible to the animals that will ultimately be exposed to the pesticide product.

- **Improve Incident Data Collection:** EPA must improve its data collection to better understand the risks posed by the pet products it regulates. This should include information on the symptoms that animals experience, the circumstances in which the pesticide exposures occurred, and the species, sex, age, and health status of the affected animals. EPA should consider placing its contact information on all pet products under the Agency's jurisdiction, so that consumers can directly make detailed reports to EPA when an incident occurs. In turn, EPA

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[92] *Elanco Defends Seresto Safety, Refuses Recall*, dvm360 (Mar. 19, 2021) (online at www.dvm360.com/view/elanco-defends-seresto-safety-refuses-recall); Environmental Protection Agency, *US EPA Office of Pesticide Programs Incident Data System: Aggregate Incident Summary Report by Product* (Mar. 19, 2021).

[93] Environmental Protection Agency Office of Inspector General, *Notification of Evaluation: The EPA's Response to Reported Incidents of Unintended Effects from Pet Collar Pesticides* (May 19, 2022) (online at www.epa.gov/system/files/documents/2022-05/Notification%20Memo_Seresto_OSRE.FY22.0120.pdf).

[94] Health Canada's Pest Management Regulatory Agency, *Seresto Collar for Large Dogs (2013—1614); Seresto Collar for Small Dogs (2013—1616); and Seresto Collar for Cats (2013—1618)* (Apr. 15, 2016); Letter from Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Elanco (Mar. 17, 2021).

should ensure that the relevant offices in the Agency have the resources necessary to collect, document, and analyze these reports.