UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 9, 2021

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

On behalf of the U.S. Environmental Protection Agency, I am responding to your letter dated March 16, 2021, regarding EPA's registration of Seresto flea and tick collars and EPA's Incident Data System (IDS).

Pursuant to section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136d(a)(2), "if at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the [EPA] Administrator." A registrant must report adverse effect information, whether derived from scientific studies or from reports of harmful effects allegedly resulting from the use of the registrant's pesticide product.

IDS is maintained by EPA's Office of Pesticide Programs (OPP) and incorporates data submitted by registrants under FIFRA section 6(a)(2), as well as other incidents reported directly to EPA. EPA has compiled pesticide-related incident reports in the IDS since 1992. The IDS includes reports collected from various sources, including mandatory section 6(a)(2) reports from registrants and reports from other federal and state health and environmental agencies and individual consumers, on incidents involving humans, plants, and wild and domestic animals where there is a claim of an adverse effect.

EPA collects and evaluates the data from the IDS and identifies potential patterns with respect to the extent and severity of the health effects due to pesticides exposure. While IDS reports are broad in scope and can in some cases contain detailed information, the system does not consistently capture details about incident events, such as exposure circumstances or medical outcome. Five levels of severity rankings for incidents are specified in 40 CFR § 159.184(c)(5), ranging from death to symptoms being unknown, unspecified or alleged to be of a delayed or chronic nature that may appear in the future. Symptom information is sometimes included in the narrative portion of the incident, but generally only for the higher-severity rankings for humans. This information is usually not validated or confirmed by a healthcare professional and represents anecdotal reports or allegations only, unless otherwise stated in the report. IDS reports can sometimes also include narrative information on exposure scenario and

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hazard information, but generally only for the more severe human incidents.

EPA does not routinely investigate or follow up on incidents, but may do so on a case-by-case basis and/or monitor the situation.[1] Data submitters, likewise, are not required to follow up or investigate incidents under section 6(a)(2), and their obligation is limited to reporting these incidents to the Agency. Instead, incident information is generally used as part of the Agency's pesticide re-evaluation process, conducted once every 15 years,[2] and provides post-marketing feedback following initial registration of the product. During registration review, EPA evaluates information from all kinds of sources, including adverse effect data reported to IDS.

IDS incidents of a severe nature or a suggested pattern or trend among less severe incidents can prompt the Agency to further investigate a particular chemical or product. Because IDS has such extensive coverage, it can assist in providing temporal trend information and determining whether risk mitigation has helped reduce potential pesticide exposure and decreased the number of potential incidents reported to IDS. Overall, IDS provides good information about national trends and frequency of incidents for pesticides and can provide valuable insights into the hazard and/or exposure potential of a pesticide.

Additional information on incidents and incident reporting can be found at https://www.epa.gov/pesticide-incidents with details on incident reporting by pesticide manufacturers available at https://www.epa.gov/pesticide-incidents/incident-reporting-pesticide-manufacturers-registrants.

Enclosed, please find information responsive to your request related to EPA's IDS. The Agency queried the IDS database for pet products in IDS with incidents of pet death or injury and human death or injury, including flea and tick collars and flea and tick spot-on treatments. Enclosed are PDF aggregate summary reports for 132 active products. These aggregate summary reports include pet and human minor incidents submitted by the registrant as required under section 6(a)(2). Each incident is given an exposure severity code, which is identified in the reports. A document describing each exposure severity code is attached for guidance. In addition, section VIII of Pesticide Registration Notice (PRN) 98-3, also enclosed, provides further details on each exposure severity code. Finally, the reports include:

1. the number of reported incidents involving pet death;
2. the number of reported incidents involving pet injury;
3. the number of reported incidents involving human death; and
4. the number of reported incidents involving human injury.

EPA receives information from a variety of sources about incidents where adverse effects appear to have been caused by pesticides. EPA's High-Priority Incidents Screening Process (HPISP)—also managed within OPP—is intended to ensure that potential high-priority incidents are identified, screened, and disseminated in a timely manner. Once a potential high-priority incident is identified, it is reviewed by

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[1] To ensure that potential high-priority incidents are identified in a timely manner, an Incident Screening Team (IST) meets biweekly to review incidents determined to be high priority. The IST screens each incident, assigns a tier level, and disseminates the incident information to the appropriate individuals within OPP.

[2] Pursuant to FIFRA section 3(g), EPA must review each currently registered pesticide product at least once every 15 years to ensure that products continue to meet the FIFRA standard for registration. This process, known as "registration review," replaced the older registration evaluation process known as "re-registration." EPA's regulations at 40 CFR Part 155 provide standards and procedures for registration review. During registration review, EPA evaluates information from all kinds of sources, including adverse effect data reported to IDS. *See* 40 CFR § 155.50(a)(5) (requiring the inclusion of summaries of incident data in the registration review case docket).

OPP's Incident Screening Team (IST) and placed in categories ranging from Tier 1 – Tier 3, signifying the level of concern and priority for further attention and review.

During registration review,[3] EPA evaluates information from many sources, including adverse effect data reported to IDS. Pursuant to 40 CFR § 155.50(a)(5), the registration review docket must include summaries of incident data.

EPA's regulations at 40 CFR Part 159 provide additional requirements for compliance with section 6(a)(2). EPA maintains information, including guidance documents, on its website concerning what, when, and how registrants must report adverse effect information to the Agency. Enclosed, please find three Pesticide Registration Notices (PRN) outlining registrants' obligations under section 6(a)(2) and Part 159:

- PRN 98-3: Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrations
- PRN 98-4: Additional Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrations
- PRN 2000-8: Reportability of Attorneys' Opinions and Conclusions Under 40 CFR Part 159 and FIFRA Section 6(a)(2)

When EPA receives adverse effects information pursuant to section 6(a)(2), it reviews, summarizes, and enters that information into a database for use in the Agency's regulatory functions concerning the registration of pesticide products. Although this database was not developed with a primary goal of informing the public, information about pesticide adverse effects can be obtained by the public through the Freedom of Information Act (FOIA). Although disclosures of section 6(a)(2) information under FOIA include summaries grouped by pesticide category and registrant, many of the supporting documents used by OPP to create the summaries consist of personal, medical, and similar files that are exempt from disclosure.

EPA considers incident information when evaluating the risks from exposure to a pesticide. Incident reports help EPA determine whether a pesticide product's application directions need to be clarified, the uses of the product should be restricted, or additional protective safety equipment should be required.[4] If at any time EPA learns that a pesticide product does not comply with the requirements of FIFRA, the Agency may initiate a proceeding under FIFRA section 6(b) to either cancel or change the classification of the product registration. In order to initiate cancellation based on unreasonable adverse effects on the environment, EPA must determine that the risks are unreasonable in light of the benefits associated with continued registration and use of the product at issue. When EPA issues a Notice of Intent to Cancel, the registrant or another adversely affected person may request an administrative hearing; EPA's regulations at 40 CFR Part 164 provide procedures for cancellation proceedings.

EPA understands the importance of Congress' need to obtain information necessary to perform its legitimate oversight functions, and we are committed to working with your staff to accommodate

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[3] Footnote 2, *supra*.

[4] For example, in 2009, EPA noticed an increase in reports of pet incidents involving pet products applied to the pet's skin, typically for flea and tick control. EPA's review culminated in mitigation for these products including enhanced incident reporting, label changes to avoid confusion between dog and cat products, and a 2-year, time-limited registration. More information is available at https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects.

Congress' interests. If you have any further questions, please contact me, or your staff may contact Kristien Knapp in EPA's Office of Congressional and Intergovernmental Relations at Knapp.Kristien@epa.gov.

Sincerely,

Robin H Richardson

Robin H. Richardson
Acting Associate Administrator

Enclosures

cc: The Honorable Michael Cloud, Ranking Member