August 20, 2020

Robert Little
OPP Docket
Environmental Protection Agency Docket Center (EPA/DC) (28221T)
1200 Pennsylvania Ave., NW
Washington, DC 20460–0001

Subject: Novaluron – Draft Ecological Risk Assessment for Registration Review (EPA-HQ-OPP- 2015–0171)

Dear Mr. Little:

On behalf of the Bay Area Clean Water Agencies (BACWA), we thank you for the opportunity to comment on the Draft Ecological Risk Assessment (ERA) for novaluron. BACWA's members include 55 publicly owned wastewater treatment facilities ("POTWs") and sewer collection system agencies serving 7.1 million San Francisco Bay Area residents. We take our responsibilities for safeguarding receiving waters seriously. BACWA is especially interested in pesticides that are used in manners that have transport pathways to the sanitary sewer, as even the most sophisticated wastewater treatment plants cannot fully remove complex chemicals like pesticides.

Every day, BACWA members treat millions of gallons of wastewater that is then discharged to fresh or salt water bodies, including local creeks and rivers, bays, and the Pacific Ocean. These waterways provide crucial habitat to a wide array of aquatic species and waterfowl. In some cases, waters receiving POTW discharges ("receiving waters") may be effluent-dominated in that there is little to no dilution, either because the receiving water is small or there is a lack of mixing at certain times due to thermal or saline stratification.

BACWA has a strong interest in novaluron due to identified pathways to sewers and its high toxicity to aquatic invertebrates. The primary purpose of this letter is to request that the ERA be expanded to include an evaluation of risks associated with indoor pest control products, which can be used for pet flea control. In addition to commenting on the Draft ERA, we are also taking this opportunity to share information about pet flea control alternatives, to support the risk/benefit evaluation that will be necessary if EPA identifies significant risks from sewer discharges of novaluron. We are providing this input at this time because we understand that the next opportunity for public comment will be after EPA has prepared its proposed decision.

BACWA appreciates that the Office of Pesticides Programs (OPP) has started to conduct evaluation of risks associated with pesticide discharges to the sewer system ("down the drain" risk assessments). Omitting evaluation of the sewer discharge environmental exposure pathway can be harmful to the environment and prove costly for POTWs, as detailed below.

In almost every U.S. state – including California – state law precludes any local regulation of pesticide sales or use. We have no local option to control use of pesticides consumer products. Therefore, it is essential to us that OPP's Draft ERA adequately evaluates potential impacts to wastewater quality, and results in mitigation measures ensuring that detrimental impacts to the beneficial uses of the receiving water are *prevented*. This is not just a California issue – the Federal Clean Water Act (CWA) toxicity standards drive our interest in how novaluron affects POTWs across the entire nation.

For these reasons, it is of utmost importance to BACWA that all indoor uses with pathways to the sewer be carefully and thoroughly evaluated.

Thank you for this opportunity to present our input on each of these topics.

Background – Pesticide discharges to the sewer can harm the environment and be costly

Pesticide discharges to the sewer system can prove costly for POTWs, due to the potential for pesticides to cause or contribute to wastewater treatment process interference, NPDES permit compliance issues, adverse impacts to receiving waters, degradation of recycled water quality and/or ability to reuse biosolids, in addition to exposing POTWs to the potential for third party lawsuits under the CWA.

Of particular concern is the ability of a specific pesticide to cause exceedance of a POTW's effluent toxicity limits. One universal water quality standard in the U.S., which stems directly from the CWA, is that surface waters cannot be toxic to aquatic life. NPDES permits require POTWs to demonstrate that they meet this standard by evaluating acute and chronic toxicity using EPA standard methods (set forth in 40 CFR Part 136). To evaluate toxicity, every POTW must (1) conduct toxicity screening tests with a range of species, (2) select the most sensitive species, and (3) perform routine monitoring (typically monthly or quarterly). These monitoring data are used to determine whether the discharge has a *reasonable potential* to cause or contribute to toxicity in the receiving water. If it does, the CWA requires that numeric effluent limits be imposed, otherwise POTWs may be given numeric effluent triggers for further action. In the event that routine monitoring *does exceed* a toxicity limit or trigger, the POTW must perform accelerated monitoring (e.g., monthly); and if there is still evidence of consistent toxicity, the discharger must do a Toxicity Reduction Evaluation (TRE) to get back into compliance. The TRE requires dischargers to evaluate options to optimize their POTWs and conduct a Toxicity Identification Evaluation (TIE), the cost of which can vary from $10,000 to well over $100,000 depending on complexity and persistence of the toxicant. The goal of the TIE is to identify the substance or combination of substances causing the observed toxicity. If a POTW's effluent is toxic because of a pesticide, it may not have any practical means to comply with CWA-mandated toxicity permit limits.

Once identified, the cost to treat or remove the toxicity causing compound(s) can vary dramatically. Often, there are few ways for a discharger to mitigate the problem other than extremely costly treatment plant upgrades. Upgrading POTWs is often ineffective for organic chemicals like pesticides that appear at sub microgram per liter concentrations, largely because sewage is a complex mixture of natural organic compounds. Regardless of this, the discharger

must comply with its CWA permit limits. If a discharger violates a toxicity limit, it can be subject to significant penalties (in California up to $10/gallon or $10,000 per day).

In addition, when surface water bodies become impaired by pesticides, wastewater facilities may be subject to additional requirements established as part of Total Maximum Daily Loads (TMDLs) set for the water bodies by EPA and state water quality regulatory agencies. A number of pesticide-related TMDLs have been adopted or are in preparation of being adopted in California. The cost to wastewater facilities and other dischargers to comply with TMDLs can be up to millions of dollars per water body per pollutant. This process will continue as long as pesticides are approved for uses that result in water quality impacts; it is therefore imperative that EPA conducts an ERA addressing water quality impacts and for EPA to take action to ensure that any impacts are prevented or fully mitigated.

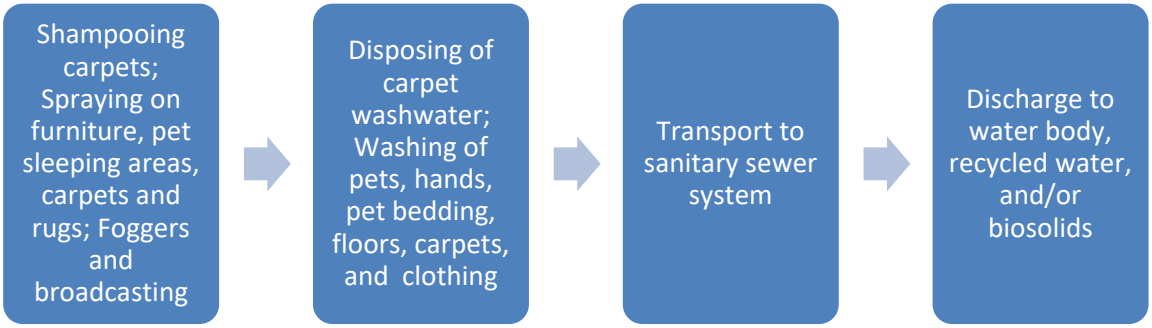
Effluent toxicity is regulated throughout the U.S. It is Federal law – the CWA – that requires that surface waters cannot be toxic to aquatic life and requires the establishment of effluent limitations as necessary to achieve this standard. When addressing currently used pesticides, California water regulators must implement the CWA toxicity standard. As EPA has acknowledged in other settings (e.g., see EPA's Pyrethroids Ecological Risk Mitigation Proposal [Docket ID # EPA-HQ-OPP-2008-0331-0096]), failure to meet this nationwide standard imposes burdensome costs on POTWs.

BACWA requests that OPP conduct an evaluation of sewer discharges of novaluron from indoor pest control treatments

BACWA is concerned that risks associated with indoor novaluron use were not evaluated in the Draft ERA and respectfully asks EPA to include this analysis (a "down-the-drain" risk assessment) in the revised assessment. EPA has POTW predictive modeling tools which are suitable for conducting this assessment and has conducted similar assessments for many other pesticides.

As explained in Appendix 1, indoor uses of insecticides can be subsequently transported within a home to an indoor drain that flows to a POTW via the pathways illustrated in Figure 1. This pathway can be both direct (application to drains and drain traps, and discharge of carpet shampoo washwater into the sink) or indirect (such as after transfer onto human hands, socks, or clothing that are subsequently washed).

Figure 1. Novaluron Pathway: From Indoor Pest Control to Wastewater Discharge



Based on reviews of novaluron product labels, for several indoor applications the user is directed to use crack, spot or perimeter application. These application methods are not expected to result in measurable transport to the sewer, compared to that of general spraying or fogging, given scientific evaluations of fate and transport of insecticidal applications (Appendix 1).

However, for flea and tick control, novaluron is applied to carpets, furniture, pet sleeping areas, and throw rugs via low-pressure sprayers and carpet shampoo equipment, per the EPA-approved label language, such as the label excerpt below.[1]

Use Sites	Application Method	Application Rate	Use Directions
General Surface Application	Low-pressure Sprayer	Dilute spray solution: 1 oz. per gal. of water Spray rate: 1 gal. per 1,500 ft^2	For use on carpets, furniture, pet sleeping areas & throw rugs, etc. Repeat treatment every 7 months as necessary. If needed, repeat treatments may be made 21 days after previous treatment.
Carpet Shampoo	Non-Heat Extracting Carpet Shampoo Equipment	Dilute instructions on carpet shampoo: 1 oz. per gal. (7.8 ml/L) of diluted shampoo Application rate: 1 gal. of diluted shampoo per 1,500 ft^2 (139 m^2)	May also be used with a liquid, non-heat extracting carpet shampoo application. Allow carpet to completely dry and vacuum thoroughly.
Kennels and Doghouses (building, resting areas, walls, floor, animal bedding & run areas)	Adjustable Hose-End Sprayer, Tank Type Sprayer, Sprinkling Can or Low Pressure Sprayer	Dilute spray solution: 1 oz. per gal. of water Spray rate: 1 gal. per 1,500 ft^2	Treat pets and their bedding with EPA registered flea and tick control products, flea or flea and tick collar, pet powder, pet spray, pet dip, pet shampoo, flea shampoo or flea and tick pet shampoo, in conjunction with this application as part of a complete flea control program. Repeat N + P Regulator application at 7 month intervals or as needed, but not more than every 21 days. Follow use directions for other EPA registered products that are used in conjunction.

[1] Label Amendment, Label Language Revisions to Make DFU and Restrictions Easier to Read, N+P Regulator, EPA Registration Number: 53883-335, November 22, 2017.

Novaluron is also applied via general surface broadcast treatments and foam application for the control of flying insects. The foam application includes drains, sink traps, bathtub traps, and in-floor drains (below). [2]

Use Sites	Application Method	Application Rate	Use Directions
Interior Applications to Residential, Commercial, Public, Industrial and Agricultural Buildings	General Surface (including Broadcast, Spot and Crack and Crevice)	1 oz. per gal. of water per 1,500 ft^2 or 1,000 linear feet for crack and crevice	Treat all areas where flying insects may collect, rest or breed. Apply solution as a coarse, wetting spray to breeding and harborage sites. For drains, apply dilution into and around the drain and catch basin area. When possible, treat vertical surfaces surrounding breeding sites, where small flies tend to alight. If needed, repeat 14 days after previous treatment or if heavy rainfall occurs.
Fly breeding sites such as drains, traps of sinks, bathtubs and in-floor drains	Foam application	1 oz. per gallon of diluent To convert to foam, add foaming agent at the manufacturer's recommended rate.	Using a professional foam applicator, apply finished foam to areas of fly breeding sites such as drains, traps of sinks, bathtubs and in-floor drains. For best results, foam should be applied thoroughly ensuring all void areas and fly breeding material is treatment. Follow the requirements of the foam equipment manufacturer.

Lastly, for what the label calls "pests of stored products," a fogger application is described on the label (below). [3]

Use Sites	Application Method	Application Rate	Use Directions
General Surface Application, and Crack and Crevice in Food and Non-Food Areas	Pressurized spray system capable of delivering a pin-point or variable spray pattern Low Pressure Sprayer	Dilute spray solution: 1.5 ozs. per gal. of water (11.7 ml/L) Spray rate: 1 gal. per 1,500 ft^2 (27 ml/m^2)	For treatment of food processing and food handling establishments and in food and nonfood storage warehouses repeat application in 90 days. (Places other than private residents in which food is held, processed, prepared, or served) **Crack and Crevice applications** may be made directly to cracks and crevices, baseboards, floors, ceilings, walls, expansion joints, molding, areas around water and sewer pipes, voids where pests can hide and similar areas. **Spot treatments** may also be made to storage areas, closets, around water pipes, doors and windows, behind and under refrigerators, cabinets, sinks, stoves and other equipment, shelves, drawers and similar areas. Contact as many insects as possible.
Fogging Appl.	ULV equipment, mechanical misting sprayers, aerosol generators, or thermal foggers	Follow the equipment manufacturer's solution preparation instructions. N + P Regulator may be diluted with water or petroleum distillate. Application rate: 1.5 ozs. (44.3 ml) per 12,000 cubic feet (340 m^3)	Close area to be treated and shut off all ventilation Systems. Apply the product in the air and direct fog or mist toward all areas that may harbor target pests. After treatment, leave the room closed for 30 minutes or longer as recommended by the equipment manufacturer or the labels of other products applied in tank mixing. Do not remain in treated area. Ventilate thoroughly before reentry.

[2] Ibid.
[3] Ibid.

Given the high invertebrate toxicity as well as these pathways to POTWs and surface waters, the ERA should be expanded to evaluate sewer discharges from indoor applications that include sprayers, foggers, and broadcast applications as well as direct applications to drains and drain traps.

BACWA suggests mitigation strategies for EPA to consider specific to flea and tick control

Given the direct applications to drains and traps as well as evidence for an exposure pathway for other indoor uses, the "down-the-drain" risk assessment for novaluron may conclude that risk mitigation is warranted to reduce POTW novaluron discharges and associated invertebrate toxicity. Because 100 percent of POTWs must comply with the CWA 100 percent of the time, whenever EPA identifies significant risks from pesticides discharged to POTWs, BACWA believes that a robust exploration of risk mitigation is imperative.

With respect to flea and tick control, our review of control options detailed in Appendix 2 identified many alternatives that are likely far less environmentally problematic than indoor spray treatments. The new generation of FDA-approved orals seems to be more convenient, equally or more effective, and well accepted by pet owners and veterinarians. In addition, mechanical controls (vacuuming) is also highly effective. We do <u>not</u> believe that spot-on products with fipronil, imidacloprid, indoxacarb, or pyrethroids are acceptable alternatives. Further, as described in Appendix 2, tick biology differs from fleas, therefore it is unlikely that their life cycle warrants indoor treatments.

In light of these findings, BACWA requests that OPP conduct its risk-benefit evaluation for novaluron's pet flea/tick control uses in the context of pest biology and the broad range of available non-pesticide alternatives, including FDA-approved oral medications.

Further, *non-pesticidal* carpet shampoos may provide some flea and tick control, as recognized by EPA's FIFRA Science Advisory Panel, which noted, "even non-pesticidal soaps may have a mortality factor against fleas and ticks."[4] If the carpet shampoo additive is proposed for re-registration, BACWA requests that EPA ask registrants to conduct an efficacy evaluation of novaluron-containing carpet shampoo to determine the minimum application rate and the efficacy versus non-pesticidal carpet shampoos and other mechanical controls (i.e., frequent vacuuming).

Thank you for the opportunity to provide this feedback regarding both the Draft ERA and subsequent mitigation strategies. We ask that OPP evaluate novaluron discharges to POTWs and the subsequent potential impacts to effluent toxicity. If significant risks are identified, we request that EPA explore mitigation options.

[4] FIFRA Scientific Advisory Panel Meeting Minutes and Final Report No. 2019-02, EPA-HQ-OPP-2019-0161-0037, Page 17.

If you have any questions, please contact BACWA's Project Managers:

Karin North
City of Palo Alto
(650) 329-2104
Karin.north@cityofpaloalto.org

Autumn Cleave
San Francisco Public Utilities Commission
(415) 695-7336
ACleave@sfwater.org

Respectfully Submitted,

Lorien Fono, Ph.D., P.E.
Executive Director
Bay Area Clean Water Agencies

cc: Elissa Reaves, Acting Director, Pesticide Re-Evaluation Division
Tracy Perry, EPA OPP Pesticide Re-Evaluation Division
Rick P. Keigwin, Jr., Director, EPA OPP
Andrew Sawyers, Director, EPA Office of Water, Office of Wastewater Management
Tomas Torres, Director, Water Division, EPA Region 9
Kevin Costello, Branch Chief, Pesticide Re-Evaluation Division
He Zhong, Environmental Fate and Effects Division
Sujatha Sankula, Environmental Fate and Effects Division
Greg Orrick, Environmental Fate and Effects Division
Christopher M. Koper, Environmental Fate and Effects Division
Kristina Garber, Environmental Fate and Effects Division
Nicole Zinn, EPA OPP Pesticide Re-Evaluation Division
Marietta Echeverria, Director, Environmental Fate and Effects Division
Debra Denton, EPA Region 9
Patti TenBrook, EPA Region 9
Karen Mogus, California State Water Resources Control Board
Philip Crader, California State Water Resources Control Board
Rich Breuer, California State Water Resources Control Board
Tom Mumley, California Regional Water Quality Control Board, San Francisco Bay Region
Janet O'Hara, California Regional Water Quality Control Board, San Francisco Bay Region
James Parrish, California Regional Water Quality Control Board, SF Bay Region
Debbie Phan, California Regional Water Quality Control Board, SF Bay Region
Jennifer Teerlink, California Department of Pesticide Regulation
Chris Hornback, Chief Technical Officer, National Association of Clean Water Agencies
Cynthia Finley, Director, Regulatory Affairs, National Association of Clean Water Agencies
Kelly D. Moran, Urban Pesticides Pollution Prevention Partnership
BACWA Executive Board
BACWA Pesticides Workgroup

Appendix 1
Indoor Pest Control Treatments:
Evidence for the Pathway to the Sewer

There is mounting evidence that pesticides from indoor foggers and sprays have exposure pathways to the sewer, with spot/crack applications preferable to broadcast spraying and fogging.

A UC Riverside study from 2010 sought to better understand the human health consequences of indoor insecticidal treatments, comparing a fogger, a perimeter spray, and both crack-and-crevice sprays, and spot sprays.[5] Researchers selected registered commercial products and applied per label instructions in rooms of unoccupied homes. They then evaluated the deposition of active ingredients, which included permethrin, chlorpyrifos, cyfluthrin, cypermethrin, and deltamethrin. They found that:

> *"Each application type produced a surface residue, but the residues differed sharply in deposition and distribution. Relative to the general distribution of residue following fogger applications, perimeter, crack-and-crevice, and spot applications resulted in less total chemical residue and limited distribution to within 0–40 cm of the wall."*
>
> *"…fogger applications differ from all other methods of application that rely on directed sprays examined in this paper. This supports our proposal that deposition and spatial distribution are principally determined by the type of pesticide application (i.e. fogger vs. crack-and-crevice) and the actions of the applicator (i.e. heavy vs. light applications)."*

In 1990, the California Department of Food and Agriculture published a dermal contact study presenting findings regarding the transfer of residue to people and their clothing following a chlorpyrifos/allethrin fogger treatment in carpeted rooms.[6] The rooms were all located in a new hotel so as to eliminate background pesticide residue and to provide repeatability from room to room. The foggers were set up per label instructions and were activated for two hours followed by ventilation of the room. Male and female participants later conducted a standardized exercise routine in specific locations in the room. Shirts, tights, gloves and socks were subsequently collected for analysis. Both allethrin and chlorpyrifos were detected in all exposed samples exceeding the minimum detection limits. Had these garments been placed in the laundry, this would have resulted in discharge to the sewer. Similarly, when the volunteer participants showered, the residue on their heads and other bare skin transferred to the sewer.

Based on the data from these studies characterizing the transfer of sprayer and fogger active ingredients to room occupants, it appears that washing of hands, clothing, carpets and floors could be significant sources of pesticides to POTWs.

---

[5] Keenan, James J., John H. Ross, Vincent Sell, Helen M. Vega, Robert I. Krieger, "Deposition and spatial distribution of insecticides following fogger, perimeter sprays, spot sprays, and crack-and-crevice applications for treatment and control of indoor pests," Regulatory Toxicology and Pharmacology 58 (2010) 189–195.

[6] Ross, J., T. Thongsinthusak, H.R. Fong, S. Margetich, R. Krieger, California Department of Food and Agriculture, "Measuring Potential Dermal Transfer of Surface Pesticide Residue Generated from Indoor Fogger Use: An Interim Report," Chemosphere, Vol.20, Nos.3/4, pp 349-360, 1990.

Appendix 2

Indoor Flea and Tick Control Alternatives and Mitigation

Rather than using insecticidal spray for indoor flea and tick control, one should first examine the pest biology and evaluate alternative treatment strategies. Tick biology is different than fleas and therefore requires different measures of control. Unlike fleas, ticks require three hosts to complete their cycle from egg to adult, and thus are typically found in wooded areas or in brush. Perhaps for that reason, American Veterinary Medical Association (AVMA) advises on-pet tick control but does not advise any type of indoor tick control, either pesticidal or non-pesticidal. [7]

Meanwhile, the fleas found on a pet are estimated to represent only 1-5% of the flea cycle in a home; the other 95% are found as eggs, larvae, pupae, and adult fleas throughout the home and surrounding environment. Therefore, to avoid repeat infestations, one must address all stages of this flea cycle including flea eggs, larvae and pupae.[8] The AVMA recommends non-pesticide mechanical controls, including frequent indoor vacuuming, washing of pet bedding, and use of an on-pet flea comb. In particular, vacuuming needs to be both thorough and frequent. It should include the pet sleeping area, floors, furniture and all upholstered or carpeted surfaces, including under cushions, furniture and in other hard to reach places. Regarding frequency, it turns out that during the pupal stage, the flea is encased in a shell that is not penetrated by pesticides. The act of vacuuming can speed up the process. Specific guidance from one study notes the following:

> *"The vibration also stimulates adult fleas to emerge from their cocoons so that they can be collected in the vacuum machine. Therefore, frequent vacuuming, during a flea infestation, can reduce the overall flea burden in the home. It should be ensured that vacuum bags are disposed of properly, to prevent recolonization of the home with flea stages previously removed by vacuuming."* [9]

Although topical pet products currently dominate the on-pet flea control market, new oral medications have recently become available. The table on the following page summarizes the current state of available oral medications for pets. The new pills, which are registered by U.S. FDA rather than U.S. EPA, appear to eliminate aquatic (and human) exposure pathways and should be equally or more convenient for pet owners, once they have obtained a prescription from a veterinarian. The involvement of the veterinarian has the added benefit of providing pet specific guidance on flea control approach and safe dosage. Some studies indicate that oral medications may be more effective than topical spot treatments possibly because there is less reliance on proper application by the owner.[10]

---

[7] https://www.avma.org/resources/pet-owners/petcare/external-parasites

[8] Flea Control Failure? Myths and Realities," Halos, L., et al., Trends in Parasitology, May 2014, Vol. 30, No. 5.

[9] "Biology, Treatment, and Control of Flea and Tick Infestations," Blagburn, B., and Dryden, M., Vet Clin Small Anim, 2009, Vol 39, pp 1173-1200.

[10] "Flea blood feeding patterns in cats treated with oral nitenpyram and the topical insecticides imidacloprid, fipronil and selamectin," McCoy, c., et al., Veterinary Parasitology, Vol. 156, pp 293-301, 2008.

Table A1: List of Currently Available Oral Pet Treatments for Fleas and Ticks (Alphabetical)

Active Ingredient	Example Product Names and Manufacturers	Dogs, Cats or Both?	Flea, Tick, Both	Dose Schedule	Adulticide?	Insect Growth Regulator?	Chemical Family	Year Registered
Afoxolaner	Nexgard (Merial)	Dogs only	Both	1 month	X	No	Isoxazoline[11]	2013
Fluralaner	Bravecto (Merck)	Dogs only	Both	2-3 months	X	No	Isoxazoline	2014
Lotilaner	Credelio (Elanco)	Dogs only	Both	1 month	X	No	Isoxazoline	2018
Lufenuron	Program (Novartis) and Sentinel (that also includes a heartworm pharma)	Both	Flea eggs, as well as hookworms, roundworms	1 month	No	X	Benzoylurea	1995 (for dogs)
Nitenpyram	Capstar (Novartis), Capguard (Sentry)	Both	Flea	A few hours only (meant for immediate infestation control)	X	No	Neonicotinoid	2000
Sarolaner	Simparica (Zoetis, a subsidiary of Pfizer)	Dogs only	Both	1 month	X	No	Isoxazoline	2016
Spinosad	Comfortis and Trifexis (Elanco)	Both	Flea	1 month	X	No	Spinosyn, macrocyclic lactone	2007 (approx.)

[11] Flea products from the isoxazoline chemical family are new to the marketplace; therefore, pet health insights are largely limited to the studies conducted by the manufacturers and the packaging text required by the FDA. There appears to be no published information about health and safety beyond the manufacturer guidance in the MSDS. Due to the application method (pill), human exposure is likely small, though no data are available to verify this assumption.