July 6, 2020

Mr. Darius Stanton
Office of Pesticide Programs
Regulatory Public Docket Center (28221T)
U.S. Environmental Protection Agency (EPA)
1200 Pennsylvania Ave., NW.
Washington, DC 20460–0001

**Subject: Fipronil – Draft Risk Assessment (EPA-HQ-OPP-2011–0448)**

Dear Mr. Stanton:

On behalf of the Bay Area Clean Water Agencies (BACWA), we thank you for the opportunity to comment on the Draft Risk Assessment for fipronil. BACWA's members include 55 publicly owned wastewater treatment facilities ("POTWs") and 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.

**Summary**

BACWA was surprised and disappointed that despite detailed scientific evidence shared with EPA Office of Pesticide Programs (OPP) on multiple occasions, EPA's fipronil risk assessment does not even mention the scientific fact that fipronil is discharged to municipal wastewater systems, pass through POTWs, and result in discharges that pose ecological risks. Based on the scientific data, we have substantial reason to believe, and come to the logical conclusion, that pet treatments will cause widespread non-compliance with the Federal Clean Water Act. Because 100% of POTWs must comply with the Federal Clean Water Act 100% of the time, risk mitigation for fipronil is imperative.

We request EPA please lay out a specific plan that addresses the primary source of fipronil in municipal wastewater – topically applied pet treatments (pet "spot-ons" and sprays). A first step, using the soon to be completed updated efficacy testing guidelines, would be to implement a program to eliminate unnecessary use of fipronil in pet treatments and to minimize POTW discharge quantities.

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

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Central Contra Costa Sanitary District • East Bay Dischargers Authority • City of San Jose • East Bay Municipal Utility District • City & County of San Francisco

**Contents of this letter**
Below – and in multiple enclosed scientific papers – we again share the scientific evidence around fipronil in municipal wastewater, highlighting the concentrations in municipal wastewater effluent and comparing the fipronil concentrations in these continuous discharges to aquatic toxicity endpoints used in EPA's fipronil risk assessment.

In addition to commenting on the draft risk assessment, we are also taking this opportunity to provide input on mitigation strategies for EPA to discuss with fipronil registrants. We provide below more detail about our mitigation request, which parallels the mitigation request made for neonicotinoid and pyrethroids-containing pet treatments. We are providing this input at this time because mitigation measures are essential and we understand that the next opportunity for public comment will be after such discussions and after EPA has prepared its proposed decision.

**Summary Background**
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 fipronil due to its high aquatic toxicity and proven ability to pass through POTWs and appear in our effluent. The primary purpose of this letter is to request that the ecological risk assessment be expanded to include an evaluation of sewer discharges from pet flea control products. Multiple scientific studies, including 2017 study involving several of our member agencies and a 2017 dog-washing study conducted by California Department of Pesticide Regulation, provide strong evidence that pet flea control products are the primary source of fipronil discharges to municipal wastewater treatment plants.

BACWA appreciates that OPP has started to conduct evaluation of risks associated with pesticide discharges to the sewer system ("down the drain" risk assessments). OPP's fipronil risk assessment did not include a down-the-drain assessment. Omitting evaluation of the sewer discharge environmental exposure pathway can prove costly for POTWs, as detailed below.

In almost every US state – including California – state law precludes any local regulation of pesticide sales or use. As municipal wastewater treatment facilities have no local option to control use of pesticides consumer products, it is essential to us that EPA implement mitigation measures ensuring that impacts to the beneficial uses of the receiving water are prevented. This is not just a California issue – the Clean Water Act toxicity standards that drive our interest in neonicotinoid insecticides affect POTWs across the entire nation.

**Pesticide Discharges to the Sewer Can 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, impacts to receiving waters, recycled water quality and/or biosolids reuse, in addition to exposing POTWs to the potential for third party lawsuits under the Clean Water Act.

Of particular concern is the ability of a specific pesticide to exceed effluent toxicity limits. One universal water quality standard in the U.S., which stems directly from the Federal Clean Water Act, is that surface waters cannot be toxic to aquatic life. NPDES permits require POTWs to demonstrate that they meet this standard by evaluating 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 discharger 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 treatment plants 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 Clean Water Act-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 treatment plants is an extremely expensive and slow process; for example, the Sewer System Improvement Project of the San Francisco Public Utilities Commission is a 20-year and $2+ billion undertaking. Upgrading treatment plants is also 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 Clean Water Act 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).

Case in point, a POTW in San Rafael, California, serving a community of 30,000 residents with a discharge of about 3 million gallons a day, observed toxicity in 21 of 28 samples several years ago. In one sample, the toxicity was 8 times the threshold to be considered toxic. The facility conducted a TIE and identified that the likely cause of the toxicity was pesticides – specifically pyrethroid insecticides. Follow-up investigations identified that the pesticide permethrin was present at low concentrations in the wastewater. EPA (in its Clean Water Act oversight role) subsequently required that toxicity limits be imposed upon reissuance of the permit. The cost to this small community and the resources required of the local water regulatory agency are precisely what we seek to avoid in the future for all pesticide chemicals.

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 U.S. EPA and state water quality regulatory agencies. A number of pesticide-related TMDLs have been adopted or are in preparation 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 a Registration Review focusing on water quality impacts and for EPA to take action to ensure that any impacts are prevented or fully mitigated.

This is a nationwide issue. Effluent toxicity is regulated throughout the U.S. It is Federal law – the *Federal* Clean Water Act – 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 neonicotinoids and other currently used pesticides, California water regulators must implement the Federal Clean Water Act 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.

**Background – Fipronil in POTW Influent and Effluent**

As summarized below and detailed in attached scientific papers, fipronil is frequently detected in POTW influent and effluent. Available data suggest that typical municipal wastewater treatment processes do not substantially reduce fipronil concentrations, i.e., that fipronil and its degradates pass through POTWs, as illustrated in Figure 1 (on the next page). Concentrations reported in undiluted, continuously discharged POTW effluents exceed the aquatic invertebrates chronic toxicity endpoints used in the draft risk assessment. Since our effluents flow into the San Francisco Bay estuary, we find it particularly notable that most available POTW effluent data significantly exceed the EPA fipronil risk assessment salt water ("estuarine and marine") invertebrate chronic toxicity endpoints for fipronil (7.5 ng/L), fipronil sulfide (4.6 ng/L), <u>and</u> fipronil sulfone (2.6 ng/L).

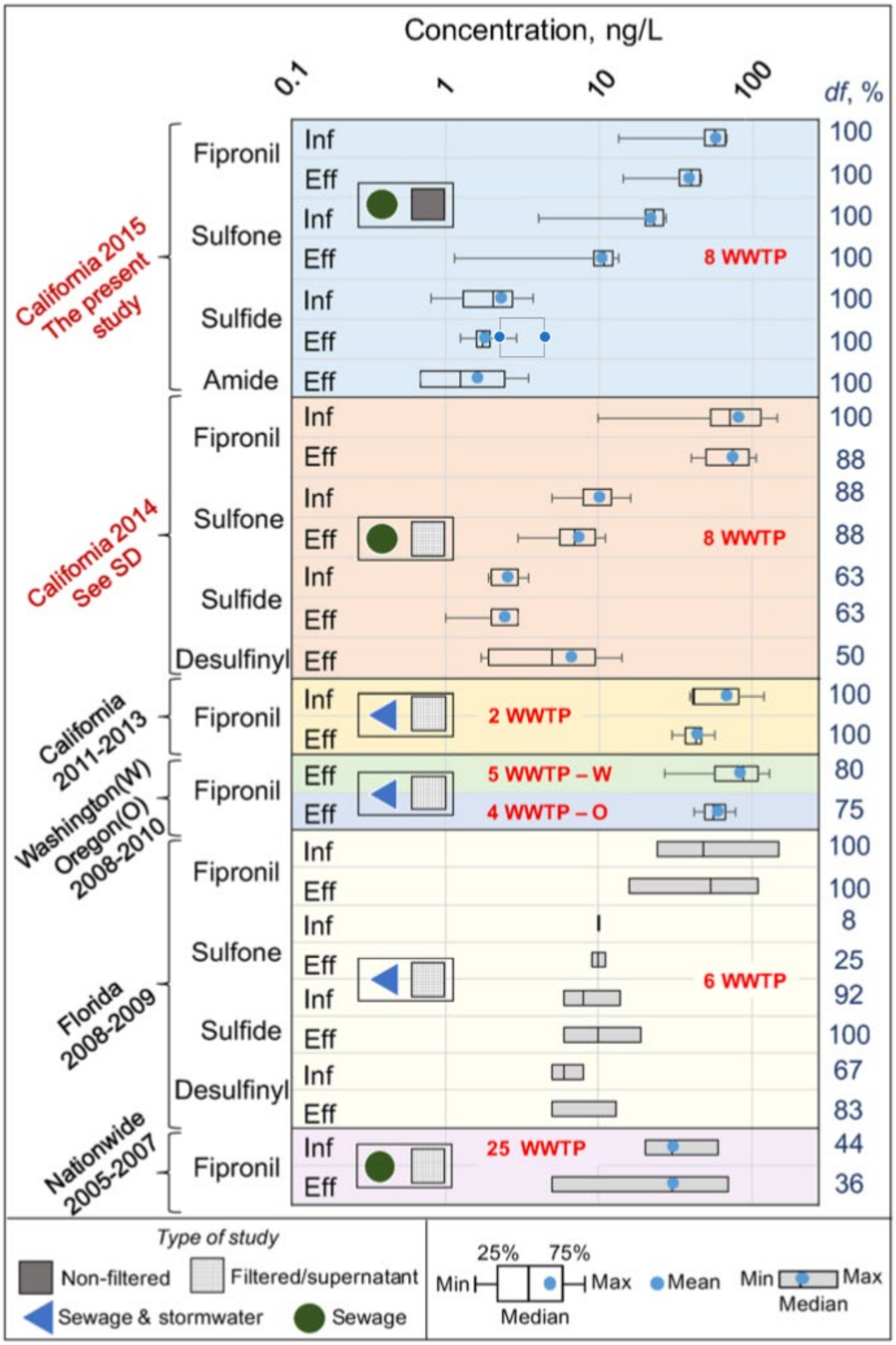
Recent scientific studies have measured fipronil in POTW influent and effluent, and have examined sources, per-capita loadings, and the reasons that fipronil and its degradates pass through POTW treatment processes. We enclose three key papers detailing the presence of fipronil in municipal wastewater:

(1) Sutton et al (2019; enclosed) completed a state-of-the-science review of occurrence and fate of fipronil, its degradates, and other current-use pesticides in North American wastewater, finding that at 40 sampled POTWs, both fipronil and its sulfone degradate were detected in treated wastewater effluent at levels exceeding EPA OPP chronic invertebrate aquatic life benchmarks. Reported median fipronil concentrations, from 30-104 ng/L, all exceeded the EPA risk assessment's invertebrate chronic toxicity endpoints for both fresh water (11 ng/L) and salt water (7.5 ng/L).

(2) A study conducted by the San Francisco Bay Regional Monitoring Program in collaboration with California Department of Pesticide Regulation and Arizona State University (Sadaria et al. 2017; enclosed) measured imidacloprid and fipronil, as well as fipronil degradates, in the influent and effluent of 8 urban California POTWs. The results indicated that fipronil, its degradates, and imidacloprid were ubiquitous in the influent sewage and final treated effluent of all 8 participating POTWs, and suggested that pet flea control products may be the primary source of both chemicals in wastewater. Pet washing is likely a major discharge pathway for fipronil from pet flea control products (Teerlink et al. 2017; enclosed). Based on data from Bigelow Dyk et al (2012; enclosed) characterizing topical flea control active ingredient transfer to owners' hands and per capita pet population data, study authors found that owner hand washing could

potentially explain the entire influent load of POTWs sampled in their study, suggesting that indirect transfer is also likely to be a discharge pathway.

**Figure 1. (from Sadaria et. al. 2017) Summary of detected concentrations of fipronil (ng/L) in wastewater treatment plant effluent**




df = detection frequency; data sources in Sadaria et al. 2017 (enclosed)

(3) Sadaria et al (2019; enclosed) conducted the first U.S. nationwide, longitudinal study of sewage sludges for fipronil and its degradates, which revealed fipronil's ubiquitous occurrence in US municipal wastewater. A geospatial analysis showed fipronil and degradate levels in municipal sludges are uncoupled from agricultural use of fipronil on cropland surrounding sampled municipalities, thus pointing to urban uses (e.g., pet flea control) as the major source of fipronil loading to wastewater. Fipronil sewage sludge concentrations increased significantly between 2001 and 2006-2007, the time period when fipronil spot-on products developed significant market share as replacements for chlorpyrifos pet flea shampoos.

Additionally, EPA scientists reported that municipal wastewater was the primary pathway by which fipronil flows to surface water in North Carolina (McMahen et al. 2016, enclosed). Heidler and Halden (2009, enclosed) and Supowit et al. (2016 enclosed) also documented fipronil and degradate presence in municipal wastewater and fate and pass through at POTWs.

California Department of Pesticide Regulation has completed two studies that confirm the linkage between companion animal topical treatments and POTWs:

(1) Washing fipronil-treated dogs. Dogs were washed at 2, 7, or 28 days after application of a fipronil-based topical flea treatment (Teerlink et al. 2017, enclosed). The rinse water was analyzed for fipronil and its degradates. The mass of fipronil and its degradates in the rinse water ranged up to 86% of the mass applied. Average percentage of fipronil and its degradates detected in the rinse water generally decreased with increasing time from initial application: 21 ± 22, 16 ± 13, and 4 ± 5% respectively for 2, 7, and 28 days after application. Results confirm a direct pathway of pesticides to municipal wastewater through the use of spot-on products on dogs and subsequent bathing.

(2) A collection system ("sewershed") study with the City of Palo Alto's Regional Water Quality Control Plant. Results from the pet-grooming sampling site contained elevated concentrations of active ingredients like fipronil in pet flea control treatments, providing evidence that pet washing is a pathway for fipronil discharges to sewer systems.[1] We encourage OPP to obtain the final results of this study, which should be published soon.

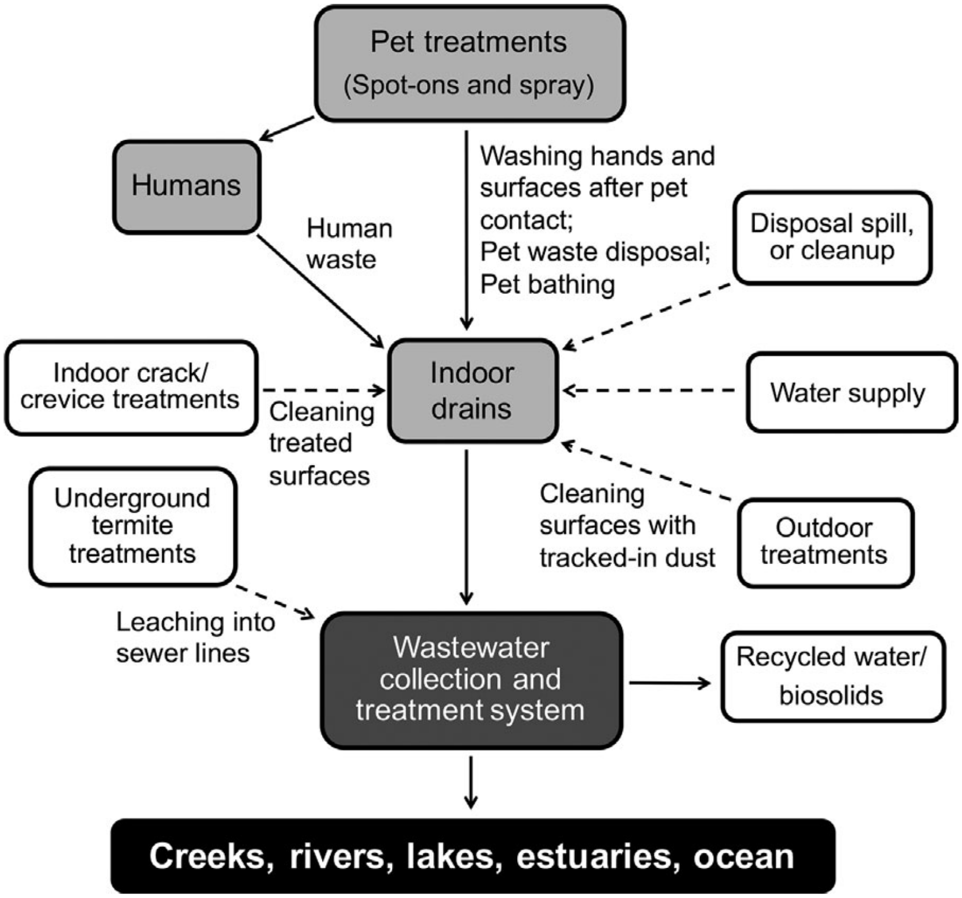
**1) BACWA requests that the fipronil risk assessment be expanded to include an evaluation of sewer discharges from pet flea control treatments**

BACWA is concerned that risks associated with pet flea control treatments were not examined in the risk assessment and respectfully asks the U.S. EPA to include this analysis (a "down the drain" risk assessment) in the revised assessment. U.S. EPA has POTW predictive modeling tools to suitable for conducting this assessment and has conducted similar assessments for many other pesticides.

Based on product labels and information in the literature, Sadaria et al 2017 developed a detailed conceptual model linking fipronil's very limited urban use patterns and the transport pathways by which fipronil reaches the wastewater collection system, as shown in Figure 2.

[1] https://www.cdpr.ca.gov/docs/emon/surfwtr/presentations/presentation_155_wastewater_flea_tick_topical_waters.pdf

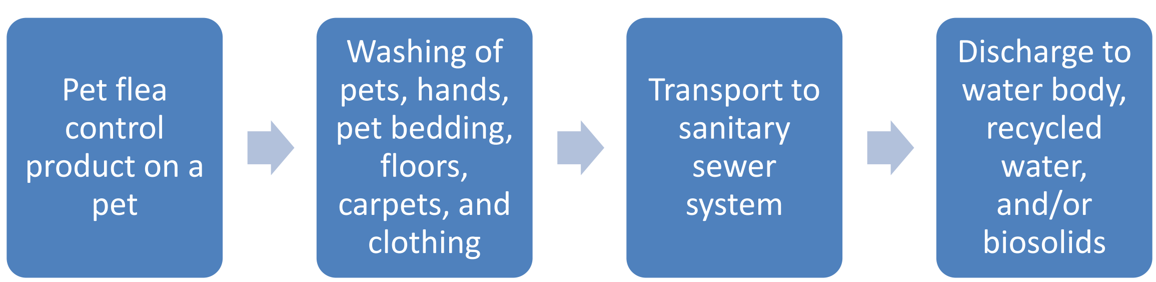
**Figure 2. (from Sadaria et. al. 2017)**
**Conceptual Model of Sources of Fipronil in Municipal Wastewater**




Dashed lines denote pathways assessed to be relatively small in the Sadaria et al 2017 study. Uses without a clear pathway (e.g., containerized baits) and with unlikely pathways (e.g., air transport and deposition) are excluded from the figure.

As explained in Appendix 1, pet flea control products contribute to POTW influent pesticides loads. Pet flea control chemicals are transported within a home to an indoor drain that flows to a POTW via the pathways illustrated in Figure 3.

**Figure 3. Fipronil Pathway: From Pet to Wastewater Discharge**




Scientific studies described above and those detailed in Appendix 1 examined the pathways that transport active ingredients from pet flea control products to the sewer system, both directly (through dog washing) and indirectly (such as after transfer onto human hands or socks that are subsequently washed). Based on the data from these studies and pet population data, it is clear that pet flea control products are significant sources of pesticides to POTWs that should be accounted for in the risk assessment.

The slightly higher concentrations reported in northern California POTWs reported by Sadaria et al. likely reflect real differences between these communities and those monitored in the nationwide study. The northern California study was conducted during a severe drought that triggered water use restrictions throughout the study area and significant reductions in POTW influent flows. Its September timing coincides with what may be the peak pet flea control season in the study area. According to Sadaria et al 2017:

> "*Higher overall concentrations and detection frequencies in effluent from northern California may reflect regional, seasonal, and/or climate-related differences from other sampled facilities, such as lower dilution caused by drought-related water use reductions, presence of pests during all seasons because of the mild coastal climate, and pesticide use responding to regional pest pressures (e.g., high flea populations in California coastal areas)*."

BACWA requests that U.S. EPA fipronil modeling and mitigation approaches account for these factors. Please see BACWA's comments on the Preliminary Ecological Risk Assessment for the Pyrethroid Insecticides (enclosed), where we detailed potential approaches for addressing these factors within U.S. EPA's current POTW model.

**2) BACWA Requests that U.S. EPA Pursue Risk Mitigation for Fipronil**

Because fipronil concentrations reported in undiluted POTW effluents exceed the aquatic invertebrates chronic toxicity endpoints used in the risk assessment, we expect that the "down-the-drain" risk assessment will likely conclude that risk mitigation is warranted to reduce POTW fipronil discharges. Because 100% of POTWs must comply with the Federal Clean Water Act 100% of the time, whenever U.S. EPA identifies significant risks from pesticides discharged to POTWs, BACWA believes that a robust exploration of risk mitigation is imperative.

In response to the finding that pet flea control products are major sources of pesticides to POTWs, BACWA completed an assessment of pet flea control alternatives. This assessment, which is summarized in Appendix 2, identified multiple practical, effective, non-pesticide alternatives.

In light of these findings, BACWA requests that OPP conduct its risk-benefit evaluation for pet flea control products as a group (i.e., considering pyrethroids and neonicotinoids, which are also undergoing Registration Review) and in the context of the broad range of available non-pesticide alternatives, including FDA-approved oral medications and mechanical controls (e.g., vacuuming, washing of pet bedding).

While we agree that pet flea and tick control has societal benefits, our review of control options detailed in Appendix 2 identified plentiful alternatives that are far less environmentally problematic than fipronil. For example, the new generation of FDA-approved orals seems to be more convenient, equally or more effective, and well accepted by pet owners and veterinarians.

Mechanical controls (vacuuming, washing of pet bedding) offer lower cost and greater long-term control as these are the sole option that addresses all life cycle stages of fleas. Finally, we emphasize that we do not believe that neonicotinoids or pyrethroids are good alternatives to fipronil.

BACWA suggests that U.S. EPA also consider the following additional risk mitigation strategies for fipronil products:

- Add the same product stewardship label elements that are proposed for the pyrethroid insecticides, i.e., stewardship statements and indoor and outdoor drain discharge prohibition pictograms prohibiting discharge to any drain, label clarifications, Spanish language translations, and indoor/outdoor use clarifications
- Determine the minimum application rate necessary to achieve pest control. This would eliminate unnecessary overuse and minimize POTW discharge quantities.
- Address washing treated pets by requiring removal of all label language on pet spot-on products that encourages washing and water exposure of treated pets (e.g., delete "waterproof") and adding language to dissuade owners from washing their pets for at least 2 weeks after treatment.

Thank you for the opportunity to provide this feedback regarding both the risk assessment and subsequent mitigation strategies. We ask that OPP evaluate fipronil discharges to POTWs and fully explore mitigation options for pet flea control products. BACWA requests that EPA coordinate with California Department of Pesticide Regulation (which has extensive relevant information and expertise), veterinarians, and registrants; bring in the latest scientific information – including scientific studies and modeling that are currently underway; and develop mitigation strategies for fipronil.

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

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Respectfully Submitted,

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Enclosures:


1. Sadaria, A.M. et al. 2017. Passage of Fiproles and Imidacloprid from Urban Pest Control Uses Through Wastewater Treatment Plants in Northern California. *Environmental Toxicology and Chemistry*. 36 (6), 1473-1482. (Both paper and the author's supporting information are enclosed).
2. Sutton, R., Xie, Y., Moran, K., & Teerlink, J. (2019). Occurrence and Sources of Pesticides to Urban Wastewater and the Environment. In K. Goh (Ed.), *Pesticides in Surface Water: Monitoring, Modeling, Risk Assessment, and Management* (pp. 63-88). Washington, DC: American Chemical Society.
3. Sadaria, A. M., Labban, C. W., Steele, J. C., Maurer, M. M., & Halden, R. U. (2019). Retrospective nationwide occurrence of fipronil and its degradates in U.S. wastewater and sewage sludge from 2001 - 2016. *Water Res*, 155, 465-473.
4. Bigelow Dyk, M. et al. (2012). Fate and distribution of fipronil on companion animals and in their indoor residences following spot-on flea treatments, *Journal of Environmental Science and Health, Part B: Pesticides, Food Contaminants, and Agricultural Wastes*, 47(10): 913-924
5. Halos, L. et al. 2014. Flea Control Failure? Myths and Realities. *Trends in Parasitology*, 30:5 228-233.
6. Blagburn, B., and Dryden, M., Biology, Treatment, and Control of Flea and Tick Infestations, *Vet Clin Small Anim,* 2009, Vol 39, pp 1173-1200.
7. Litchfield et al., Safety Evaluation of Permethrin and Indoxacarb in Dogs Topically Exposed to Activyl® Tick Plus, *J Veterinar Sci Technology* 2015, 6:2.
8. Teerlink, J., J Hernandez, R Budd. 2017. Fipronil washoff to municipal wastewater from dogs treated with spot-on products. Sci Total Environ 599-600: 960-966. (Both paper and the author's supporting information are enclosed).
9. McMahen, R. L., Strynar, M. J., McMillan, L., DeRose, E., & Lindstrom, A. B. (2016). Comparison of fipronil sources in North Carolina surface water and identification of a novel fipronil transformation product in recycled wastewater. *Sci Total Environ*, 569-570, 880-887. (Both paper and the author's supporting information are enclosed).
10. Supowit, S. D., Sadaria, A. M., Reyes, E. J., & Halden, R. U. (2016). Mass Balance of Fipronil and Total Toxicity of Fipronil-Related Compounds in Process Streams during Conventional Wastewater and Wetland Treatment. *Environ Sci Technol*, 50(3), 1519-1526. (Both paper and the author's supporting information are enclosed).
11. Jennings, K. A., Canerdy, T. D., Keller, R. J., Atieh, B. H., Doss, R. B., & Gupta, R. C. (2002). Human Exposure to Fipronil from Dogs Treated with Frontline. *Vet Human Toxicol*, 44(5), 301-303.
12. Cochran, R. C., Yu, L., Krieger, R. I., & Ross, J. H. (2015). Postapplication Fipronil Exposure Following Use on Pets. *J Toxicol Environ Health A*, 78(19), 1217-1226.
13. Heidler, J., & Halden, R. U. (2009). Fate of organohalogens in US wastewater treatment plants and estimated chemical releases to soils nationwide from biosolids recycling. *J Environ Monit*, 11(12), 2207-2215.
14. Bay Area Clean Water Agencies (BACWA). February 3 2020 and July 7, 2017.Comment Letters on U.S. EPA Preliminary Ecological Risk Assessment for the Pyrethroid Insecticides.


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## Appendix 1

## On-Pet Flea Treatments:
## Evidence for the Pathway to the Sewer

### Part I – Evidence for the Pathway to the Sewer

There is mounting evidence that pesticides from pet flea control products (spot-ons and collars) have exposure pathways to the sewer. The research summary below is organized first by the consumer use, followed by specific studies throughout a sewage collection system and at POTWs.

Pet Flea Control Products - Background
The pesticidal mode of action for fipronil topical companion animal treatments is topical in nature, not systemic.[2] These topical treatments are designed to impact one or more stages of the flea cycle through direct contact with the pesticide (rather than an adult flea biting the pet and obtaining the pesticide systemically with the consumed blood). Therefore, pesticides in topicals and collars are not meant to enter the pet's bloodstream but rather are meant to stay on the pet's fur in order to be effective.

Pet Flea Control Products – Sewer Discharge Pathways
Several scientific studies have examined the transport of active ingredients from pet flea control products onto surfaces, such as human hands, that are subsequently washed, completing a transfer pathway to the sewer system.

- *Spot-on treatment product to glove (hands) pathway:* A 2012 study by Bigelow Dyk et al. presents additional evidence of transport of a pet flea control products onto human hands and through homes.[3] In the study, researchers monitored transfer of fipronil (from a commercially available spot-on product) onto pet owners' hands and within their homes over a four-week period following spot treatment application. Participants used cotton gloves to pet their dog or cat for 2 minutes at a time at specific intervals after the application (24 hours, 1 week, 2 weeks, 3 weeks, and 4 weeks). Participants also wore cotton socks for 2 hours a night for 7 nights in a row, for four consecutive weeks following application. The gloves, socks, and brushed pet hair were subsequently analyzed for fipronil and its degradates. Bigelow Dyk and colleagues also incorporated a fluorescent dye into the spot treatment to provide photographic evidence of spot-on pesticide transfer. The photographic results shown in the paper illustrate the transfer from the application location to other areas of the pet's fur and onto the pet owners' hands.

  Other studies documenting this pathway for fipronil are Jennings et al 2002 (enclosed) and Cochran et al 2015 (enclosed).

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[2] McTier, T., et al., Comparison of the activity of selamectin, fipronil, and imidacloprid against flea larvae (Ctenocephalides felis felis) in vitro, Veterinary Parasitology, Vol. 116, pp 45-50, 2003.
[3] Bigelow Dyk, M., et al. (2012) Fate and distribution of fipronil on companion animals and in their indoor residences following spot-on flea treatments, Journal of Environmental Science and Health, Part B: Pesticides, Food Contaminants, and Agricultural Wastes, **47**(10): 913-924

- *Spot-on treatment product to glove (hands) pathway*: A 2015 study by Litchfield et al. evaluated the transfer of permethrin and indoxacarb from a topical pet flea control treatment to people's hands.[4] In the study, the topical treatment was applied to dogs that had not received a topical treatment for at least two months. To simulate human exposure to the pesticides, "Glove sampling included the wipe sampling technique, which consisted of petting the dog forward and back along its back and sides, while avoiding the application site, for five minutes while wearing a 100% cotton glove." The cotton glove samples were collected at days 0, 1, 2, 3, 7, 14, 21, 28, and 35. While the results showed that the largest mass of permethrin was transported within the first week, there continued to be measurable transfer to the gloves, even at day 35.

- *Pet collar to glove (hands) pathway*: One such study by Davis et al. quantified glove transfer of tetrachlorvinphos from pet collars.[5] We understand that the U.S. EPA team reviewing tetrachlorvinphos (EPA-HQ-OPP-2008-0316) has examined this paper and is planning to use the glove residue data following feedback from the U.S. EPA's Human Subjects Review Board.[6]

Based on the data from these studies characterizing topical flea control active ingredient transfer to owners' hands[7] and per capita pet population data, owner hand washing as well as washing of clothing and mopping of floors could be a significant source of pesticides to POTWs.[8]

Evidence from Collection Systems

California Department of Pesticide Regulation has completed a collection system ("sewershed") study within the City of Palo Alto's Regional Water Quality Control Plant service area. The study involved twenty-four hour time weighted composite samples (influent, effluent, and ten sites in the collection system). Samples were collected from several discharge-specific sites with potential for relatively large mass flux of pesticides (i.e., discharges from pet grooming operation, pest control operator, and a laundromat). The samples were analyzed for a suite of pesticides, including fipronil. Results from the pet-grooming site provide evidence that pet washing is a pathway for fipronil discharges to sewer systems (See https://www.cdpr.ca.gov/docs/emon/surfwtr/presentations/presentation_155_wastewater_flea_tick_topical_waters.pdf ). We encourage OPP to obtain the final results of this study, which should be published soon.

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[4] Litchfield et al., "Safety Evaluation of Permethrin and Indoxacarb in Dogs Topically Exposed to Activyl® Tick Plus," J Veterinar Sci Technology 2015, 6:2 http://dx.doi.org/10.4172/2157-7579.1000218. (enclosed)

[5] Davis, M., et al. (2008). "Assessing Intermittent Pesticide Exposure From Flea Control Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos," *J. of Exposure Science and Environ. Epidemiology* **18:**564-570.

[6] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0040

[7] Bigelow Dyk, M., et al. (2012) Fate and distribution of fipronil on companion animals and in their indoor residences following spot-on flea treatments, Journal of Environmental Science and Health, Part B: Pesticides, Food Contaminants, and Agricultural Wastes, **47**(10): 913-924

[8] Sadaria, A.M., Sutton, R., Moran, K.D., Teerlink, J., Brown, J.V., Halden, R.U., 2017. Passage of fiproles and imidacloprid from urban pest control uses through wastewater treatment plants in northern California, USA. Environ. Toxicol. Chem. 36:6 1473-1482.

## Appendix 2

## Pet Flea Control Products: Alternatives Analysis

### Alternatives and Mitigation

BACWA requests that U.S. EPA, in coordination with CDPR (which has extensive relevant information and expertise), veterinarians, and registrants, develop mitigation strategies for pet flea control products, including spot-ons and collars. Two specific topics are discussed below, as an effort to provide insight regarding mitigation options for flea control:

- Alternatives: oral medications and integrated pest management appear effective
- Optimization of application rates of pet flea control products

<u>Alternatives: Integrated Pest Management and Oral Medications</u>
Mechanical controls (e.g., vacuuming) appear to be key to avoiding a flea infestation in a home. Further, since the previous registration, there is now an opportunity provided by non-fipronil, non-imidacloprid/non-pyrethroid oral treatments that have come on the market in recent years (available for both dogs and cats) that could avoid the on-pet use of not only fipronil, but also alternatives that are problematic from the water quality perspective (e.g., neonicotinoids, pyrethroids, and indoxacarb).

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.[9] It takes about 18 days for a flea egg to grow into an adult flea, but in cool weather immature fleas can lay dormant in a pupal cocoon for up to 1 year. Adult fleas can live on a pet for 30 to 40 days. Fleas lay 20 to 50 eggs each day; consequently flea problems in residential settings can get out of control quickly.

Therefore, to avoid repeat infestations, one must address all stages of this flea cycle including flea eggs, larvae and pupae.[10] One way to do so is via non-pesticide mechanical controls, including frequent indoor vacuuming, washing of pet bedding, and use of an pet flea comb.[11] 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*

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[9] Halos, L., et al. (2014). Flea Control Failure? Myths and Realities. Trends in Parasitology, 30:5 228-233.
[10] Ibid, 228-233.(enclosed)
[11] American Veterinary Medical Association (2009). External Parasites.

> *vacuum bags are disposed of properly, to prevent recolonization of the home with flea stages previously removed by vacuuming."* [12]

Although spot-on pet flea control products currently dominate the 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.[13]

<u>Optimization of Application Rates of Pet Flea Control Products</u>

Another consideration for pet flea control products is that of application rate. Given that these household and pet flea control products have a transport pathway to the sewer, it would be of great interest to understand whether manufacturers have optimized the amounts applied. While spot-ons and collars do come in different sizes based on pet weight, it is unclear whether that optimization was based solely on pet health or whether that is also the minimum dosage for effective flea control.

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

[13] "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.

**List of Currently Available Oral Pet Treatments for Fleas (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[14] | 2013 |
| **Fluralaner** | Bravecto (Merck) | Dogs only | Both | 2-3 months | X | No | Isoxazoline | 2014 |
| **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) |

[14] 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.