DUE DATE: July 24, 2017

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

Subject: Imidacloprid – Preliminary Aquatic Risk Assessment (EPA-HQ-OPP-2008-0844)

Dear Mr. Jones:

On behalf of the Bay Area Clean Water Agencies (BACWA), we thank you for the opportunity to comment on the Preliminary Aquatic Risk Assessment (PARA) for imidacloprid. 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.

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 imidacloprid 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 and other indoor imidacloprid uses. A recent study involving several of our member agencies suggests that pet flea control products are the primary source of imidacloprid 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 imidacloprid 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 we have no local option to control use of pesticides consumer products, it is essential to us that OPP's Registration Review adequately evaluates potential impacts to wastewater quality, and results in mitigation measures ensuring that impacts to the beneficial uses of the receiving water are *prevented*.

For these reasons, it is of utmost importance to BACWA that pet flea control products and all other imidacloprid-containing products with pathways to the sewer be carefully and thoroughly evaluated.

In addition to commenting on the preliminary aquatic risk assessment, we are also taking this opportunity to provide input on mitigation strategies for U.S. EPA to discuss with imidacloprid registrants. 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 U.S. EPA has prepared its proposed decision.

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

Background – 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 (CWA).

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 (CWA), 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 U.S. 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 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 treatment plants 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 is 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).

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 case, 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. The U.S. EPA (in its CWA 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 U.S. EPA conducts a Registration Review focusing on water quality impacts and for U.S. EPA to take action to ensure that any impacts are prevented or fully mitigated.

Background - Imidacloprid in POTW Influent and Effluent

As summarized below and detailed in attached scientific papers, imidacloprid is frequently detected in POTW influent and effluent. Available data suggest that typical municipal wastewater treatment processes do not reduce imidacloprid concentrations, i.e., that imidacloprid passes through POTWs. Concentrations reported in undiluted POTW effluents exceed the aquatic invertebrates chronic toxicity endpoints used in the PARA, as illustrated in Figure 1.

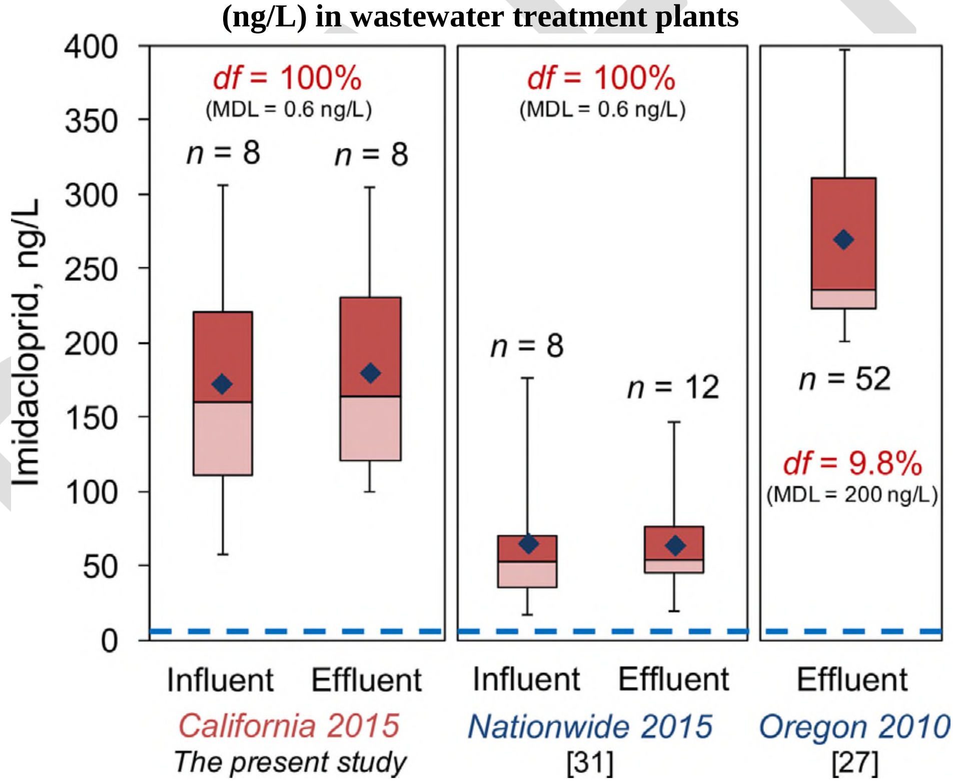
Recent scientific studies have measured imidacloprid in POTW influent and effluent, and have examined sources, per-capita loadings, and the reasons that it appears to pass through POTW treatment processes. We enclose three key papers:

- A recent 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 its degradates, in the influent and effluent of eight urban California POTWs. The results indicated that fipronil, its degradates, and imidacloprid were ubiquitous in the influent sewage and final treated effluent of all eight 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 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.

- Elsewhere in the US, Sadaria et al (2016; enclosed) reported that imidacloprid was detected in 100% of influent and effluent samples from 12 US POTWs. POTWs had similar influent and effluent concentrations (ranging from 18.5 ng/L to 146.4 ng/L). This study included wintertime samples in cold climates, when pet flea pressure is minimal – such samples likely had minimal contributions from pet flea control products (source: personal communication with author).

- In 2010, Hope et al. measured imidacloprid in effluents from 52 Oregon WWTPs. This study (which is enclosed) found a lower detection frequency (9.8%), perhaps due to its relatively high quantification limit (200 ng/L) as compared to the more recent studies above, which had reporting limits <1 ng/L. In this study, effluents with detectable imidacloprid had levels in the range of 202 ng/L to 387 ng/L.

Figure 1. (from Sadaria et. al. 2017) Summary of detected concentrations of imidacloprid (ng/L) in wastewater treatment plants



Note: Dashed blue horizontal line indicates European Union freshwater predicted no-effect concentration value (close to the chronic aquatic invertebrate toxicity endpoint value used in the PARA). df = detection frequency; MDL = method detection limit. "Nationwide 2015" data from Sadaria et al. 2016; "Oregon 2010" data from Hope et al. 2010.

The higher concentrations reported in northern California POTWs 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 imidacloprid 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.

California Department of Pesticide Regulation (CDPR) is in the process of completing a collection system ("sewershed") study with the City of Palo Alto's Regional Water Quality Control Plant. Preliminary results from the pet-grooming site provide evidence that pet washing is a pathway for imidacloprid discharges to sewer systems (See http://www.cdpr.ca.gov/docs/emon/surfwtr/presentations/presentation_130_targeted.pdf). We encourage OPP to obtain the final results of this study, which should be available in 2017.

1) BACWA requests that the PARA be expanded to include an evaluation of sewer discharges from pet flea control treatments and other indoor imidacloprid uses

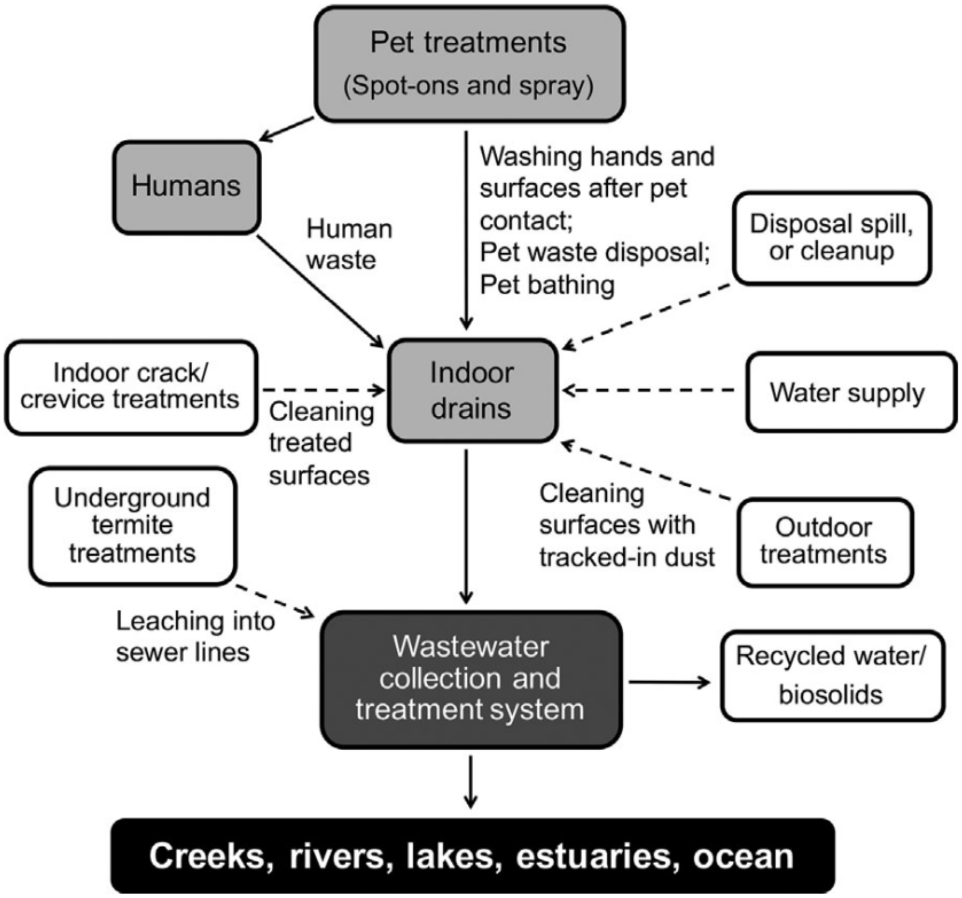
BACWA is concerned that risks associated with indoor imidacloprid use were not examined in the PARA and respectfully asks the U.S. EPA to include this analysis (a "down the drain" risk assessment) in the revised assessment. U.S. EPA has POTW predictive modeling tools to suitable for conducting this assessment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

We request that U.S. EPA specifically analyze sewer discharge sources such as:

- Pet flea control products (including spot-ons and collars)
- Indoor treatments (such as crack/crevice, sprays for ant and roaches, bedbug treatments, houseplant treatments, etc.)
- Direct use of imidacloprid inside sewers and manholes

Based on product labels and information in the literature, Sadaria et al 2017 developed a detailed conceptual model linking imidacloprid use patterns (such as the sources listed above) and the transport pathways by which imidacloprid reaches the wastewater collection system. Due to its myriad of uses, imidacloprid has many pathways by which it can be transported, as shown in Figure 2.

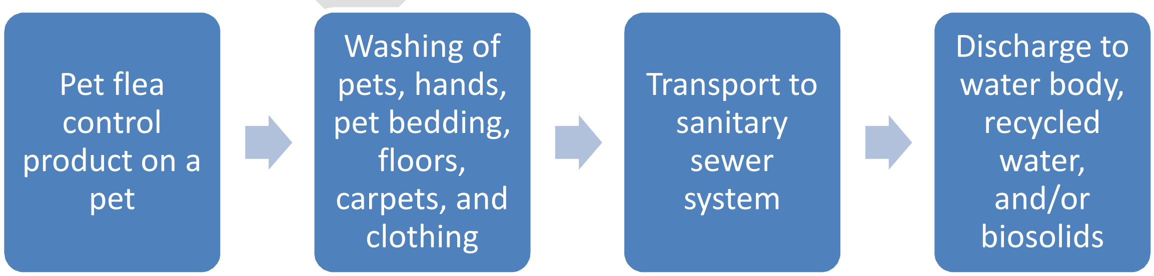
Figure 2. (from Sadaria et. al. 2017)
Conceptual Model of Sources of Imidacloprid in Municipal Wastewater



Note: Dashed lines denote pathways believed to be relatively small in the present 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. Imidacloprid 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 PARA.

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

Because imidacloprid concentrations reported in undiluted POTW effluents exceed the aquatic invertebrates chronic toxicity endpoints used in the PARA, we expect that the "down-the-drain" risk assessment will likely conclude that risk mitigation is warranted to reduce POTW imidacloprid 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 fipronil, 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 imidacloprid. 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 <u>not</u> believe that fipronil or pyrethroids are good alternatives to imidacloprid.

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

- Determine the minimum application rate necessary to achieve pest control. This would eliminate unnecessary overuse and minimize POTW discharge quantities.
- Consider adding wastewater-protective use restrictions to product labels—such as forbidding use of imidacloprid directly in sewers and dissuading pet owners from washing their pets for two weeks after applying treatments. (See Appendix 3 for details)

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

Thank you for your consideration of our comments. If you have any questions, please contact BACWA's Project Managers:

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

Melody LaBella
Central Contra Costa Sanitary District
(925) 229-7370
mlabella@centralsan.org.

Respectfully Submitted,

DRAFT

David R. Williams
Executive Director
Bay Area Clean Water Agencies

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.
2. Sadaria A.M., Supowit SD, Halden RU. 2016. Mass balance assessment for six neonicotinoid insecticides during conventional wastewater and wetland treatment: Nationwide reconnaissance in United States wastewater. Environ Sci Technol 50:6199–6206.
3. Hope BK, Pillsbury L, Boling B. 2012. A statewide survey in Oregon (USA) of trace metals and organic chemicals in municipal effluent. Sci Total Environ 417–418:263–272.
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.
9. Craig, M.S., Gupta, R.C., Candery, T.D., Britton, D.A. Human Exposure to Imidacloprid with Dogs Treated with Advantage ™. 2005. Toxicology Mechanisms and Methods, 15: 287–291.
10. Bay Area Clean Water Agencies (BACWA). July 7, 2017.Comment Letter on U.S. EPA Preliminary Ecological Risk Assessment for the Pyrethroid Insecticides.

cc: Yu-Ting Guilaran, Director, Pesticide Re-Evaluation Division
Rick P. Keigwin, Jr., Acting Director, EPA OPP
Tracy Perry, EPA OPP Pesticide Re-Evaluation Division
Tom Moriarty, EPA OPP Pesticide Re-Evaluation Division
Neil Anderson, Branch Chief, EPA OPP, Pesticide Re-Evaluation Division
Kevin Costello, Branch Chief, EPA OPP, Pesticide Re-Evaluation Division
Marietta Echeverria, Director, Environmental Fate and Effects Division (EFED), EPA OPP
Mah Shamim, Branch Chief, EFED
Keith G. Sappington, M.S., Senior Science Advisor
Mohammed A. Ruhman, Ph. D., Senior Agronomist
Justin Housenger, M.S., Risk Assessment Process Leader
Andrew Sawyers, Director, EPA Office of Water, Office of Wastewater Management
Tomas Torres, Director, Water Division, EPA Region 9
Debra Denton, EPA Region 9
Patti TenBrook, EPA Region 9
Karen Larsen, Deputy Director, California State Water Resources Control Board
Philip Crader, Assistant Deputy Director, California State Water Resources Control Board
Paul Hann, California State Water Resources Control Board
Dawit Tadesse, California State Water Resources Control Board
Matthew Freese, 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
George Farnsworth, Associate Director, California Department of Pesticide Regulation
Nan Singhasemanon, California Department of Pesticide Regulation
Jennifer Teerlink, California Department of Pesticide Regulation
Kelly D. Moran, Urban Pesticides Pollution Prevention Partnership
Chris Hornback, Chief Technical Officer, National Association of Clean Water Agencies
Cynthia Finley, Director, Regulatory Affairs, National Association of Clean Water Agencies
BACWA Pesticides Workgroup
BACWA Executive Board

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 imidacloprid collars and spot-ons is topical in nature, not systemic.[1] 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). Imidacloprid is an adulticide—it targets adult fleas; but it has been shown to have a larvicidial effect.[2] 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 to glove (hands) and dogs' blood pathway:* A 2005 study by Craig et al. demonstrated that a transferable residue of imidacloprid—from application of a spot-on treatment on the dogs' neck and back—can be detected for up to four weeks.[3] Residues were evident in the dogs' blood for up to 72 hours after application, which indicate that imidacloprid can have a systemic mode after topical application, but that is not the primary mode of action. This study reinforces the knowledge that imidacloprid affects fleas by persisting in the environment, rather than being continually emitted by the dogs' bodies. It also documented the levels of imidacloprid that persist on the dog after application: 254.16±25.49 ppm at the 24-hour mark to 0.08±0.02 ppm at the four week mark.

- *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.[4] In the study, researchers monitored transfer of fipronil (from a

[1] 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.
[2] 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)
[3] Craig, M.S., Gupta, R.C., Candery, T.D., Britton, D.A. Human Exposure to Imidacloprid with Dogs Treated with Advantage ™. 2005. Toxicology Mechanisms and Methods, 15: 287–291. (enclosed)
[4] Bigelow Dyk, M., et al. (2012) Fate and distribution of fipronil on companion animals and in their indoor

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.

- *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.[5] 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.[6] 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.[7]

- *Human contact to human urine pathway*: A 2015 study of human urine from 295 human participants in China detected imidacloprid in 100% of rural participants and 95% of urban participants.[8] Urine from rural participants had an average level of 0.18 ng/mL while urine from urban participants had an average of 0.15 ng/mL. Although this study did not look specifically at pet flea control treatments, it did show that imidacloprid is commonly found in human urine, establishing another pathway to the sewer. In non-rural areas, based on the human exposures to pet flea control treatments documented in the papers summarized above, it is likely that one of the key sources of imidacloprid in human urine is from pet flea control products.

---

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] 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)

[6] 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.

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

[8] Wang, L., Liu, T., Liu, F., Zhang, J., Wu, Y., and Sun, H. 2015. Occurrence and Profile Characteristics of the Pesticide Imidacloprid, Preservative Parabens, and Their Metabolites in Human Urine from Rural and Urban China. Environ. Sci. Technol. 2015, 49, 14633−14640.

Based on the data from these studies characterizing topical flea control active ingredient transfer to owners' hands[9] 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.[10]

Evidence from Collection Systems

CDPR is in the process of completing a collection system ("sewershed") study within the City of Palo Alto's Regional Water Quality Control Plant.[11] 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 imidacloprid. Preliminary results from the pet-grooming site provide evidence that pet washing is a pathway for imidacloprid discharges to sewer systems

We encourage OPP to obtain the final results of this study, which should be available within the timeframe of OPP's exploration of mitigation strategies for imidacloprid.

POTW Influent and Effluent

Lastly, further insights regarding transport of indoor flea control products to POTWs comes from a study of fipronil and imidacloprid at eight POTWs that was recently conducted by the San Francisco Bay Regional Monitoring Program in collaboration with BACWA, CDPR and Arizona State University.[12] The study monitored imidacloprid and fipronil, as well as its degradates, in the influent and effluent of eight urban California POTWs. The results indicated that fipronil, its degradates, and imidacloprid were ubiquitous in the influent sewage and final treated effluent of all eight participating POTWs, and – based on a detailed analysis of the sewer discharge sources of these two chemicals, which have relatively little indoor use other than pet flea control – provide compelling evidence that pet flea control products may be the primary source of both chemicals in wastewater. A copy of this paper is enclosed.

[9] 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

[10] 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.

[11] See http://www.cdpr.ca.gov/docs/emon/surfwtr/presentations/presentation_130_targeted.pdf

[12] 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

Alternatives: Integrated Pest Management and Oral Medications
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-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 imidacloprid, but also alternatives that are problematic from the water quality perspective (e.g., fipronil, 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.[13] 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.[14] 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.[15] 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*

---

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

> *stages previously removed by vacuuming."* [16]

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.[17]

[16] "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)

[17] "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[18]	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)

[18] 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.

Optimization of Application Rates of Pet Flea Control Products

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 insecticidal activity.

Appendix 3

Suggested Imidacloprid Product Label Improvements

In this attachment, BACWA respectfully submits suggested concepts and goals for upgrades to the existing imidacloprid labels. Our suggestions come from our expertise as environmental scientists and engineers. As we are not pest control experts, we are not intending to provide specific label language, and recognize that these suggestions should be vetted by pesticide regulators and users.

To clarify some of our suggestions, we have included sections of current labels in boxes below.

1. Pet treatments: (U.S. EPA Registration Numbers 11556-117, -122, -118, -119, -120, -116, 11556-132, -134, -133, -135, etc.)

Examples of Current Label Language (excerpts)

> Advantage is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

> K9 Advantix® is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Suggested change: Remove all label language that encourages washing and water exposure of treated pets. Label statements such as "waterproof" should be removed. All labels should dissuade owners from washing their pets for at least 2 weeks after treatment.

2. Sewer and manhole treatments: (U.S. EPA Registration Numbers 72155-70, 73079-10, 73079-14)

Example of Current Label Language (excerpt)

WHERE TO USE	• Kitchens - Cupboards, Dishwashers*, Garbage Cans, Refrigerators*, Stoves*. • Bathrooms - Bathtubs*, Garbage Cans • Laundry Rooms - Drains, Laundry Tubs*, Washing Machines* • Basements, Garages, Outdoor Areas - Drains, Garbage Cans, Laundry Tubs*, Manholes, Pipe Collars, Sewers, Washing Machines*, Water Pipes* • General - Cabinets, Closets, Counters, Cracks, Crevices, Shelving, Sinks * Do not apply bait inside these items. Locate behind or under item.

Suggested change: disallow all usage inside sewers, storm drains, or inside manholes.

3. Houseplant treatments: (U.S. EPA Registration Number 53883- 217)

Example of Current Label Language (excerpt)

FOR RESIDENTIAL USE ONLY

- Kills birch leaf miner
- Highly effective, Lasting protection
- No spraying…no mess
- Promotes strong roots and beautiful blooms
- For use in potted plants
- Long lasting, effective protection
- Protects plants from damage by Aphids, Scale, Whiteflies and other listed insects
- Even new growth is protected against insects for up to 8 weeks.
- For containerized plants
- Protects plants from damaging insects for up to 2 months

APPLICATION INSTRUCTIONS

For best results, apply IMI 0.22 G Plant Granules evenly, cultivate lightly, and water thoroughly. For containerized plants, apply the appropriate amount of granules evenly to the top of the soil. Mix the granules thoroughly into the top layer of the soil making sure not to damage the upper roots. Water in thoroughly. To help assure that the roots can absorb the insecticide, do not water too heavily for the first 10 days. Work granules into top 1 to 2 inches of soil. For flower beds, sprinkle granules evenly over the bed.

Suggested changes: add statement discouraging over-watering and forbidding discharge of water from treated houseplants in indoor sinks or baths, or anywhere that would allow water to runoff from the houseplant into the drain.