BACWA
BAY AREA
CLEAN WATER
AGENCIES

February 12, 2020

Moana Appleyard
Office of Pesticide Programs (OPP)
c/o Regulatory Public Docket Center (28221T),
U.S. Environmental Protection Agency (EPA)
1200 Pennsylvania Ave. NW.
Washington, DC 20460–0001

Subject: Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals (Docket ID No. EPA–HQ–OPP–2008–0331)

Dear Ms. Appleyard:

On behalf of the Bay Area Clean Water Agencies (BACWA), we thank you for the opportunity to comment on the Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals. BACWA's members include 55 publicly owned wastewater treatment facilities and collection system agencies serving 7.1 million San Francisco Bay Area residents. We take our responsibilities for safeguarding receiving waters seriously.

Every day, BACWA members' Publicly Owned Treatment Works (POTWs) treat millions of gallons of pesticide-containing 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, including several endangered species. 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.

As detailed in our much-appreciated conversations with EPA and our prior correspondence (including our July 2017 letter, enclosed), BACWA is especially interested in pyrethroid insecticides due to their high aquatic toxicity and ability to pass through POTWs and appear in our effluent and biosolids. Even the most sophisticated wastewater treatment plants cannot fully remove pyrethroid insecticides.[1] 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

[1] Markle, J., van Buuren, B., Moran, K., & Barefoot, A. (2014). Pyrethroid Pesticides in Municipal Wastewater: A Baseline Survey of Publicly Owned Treatment Works Facilities in California in 2013. In *Describing the Behavior and Effects of Pesticides in Urban and Agricultural Settings* (Vol. 1168, pp. 177-194): American Chemical Society.

receiving water are prevented. This is not just a California issue – the Clean Water Act toxicity standards that drive our interest in pyrethroids affect POTWs across the entire nation.

BACWA appreciates that EPA's ecological risk mitigation proposal reaffirms EPA's finding that pyrethroids discharges to municipal wastewater systems pose ecological risks that should be mitigated. Because 100% of POTWs must comply with the Federal Clean Water Act 100% of the time, based on both EPA modeling and available monitoring, risk mitigation for pyrethroids is imperative.

While we greatly appreciate that EPA has proposed product label improvements toward preventing incidents like dumping unused products, we are disappointed that EPA did not lay out a specific plan to address the main problem – continuous discharges associated with ordinary use of pyrethroids. We request EPA implement mitigation addressing the primary sources of pyrethroids in municipal wastewater – pet flea treatments. We suggest the following mitigation approaches, which are further detailed later in this letter:

- Pet Shampoos – end use of bifenthrin and permethrin due to their high ecological risk (LOC exceedances) and low benefit (as indicated by limited market presence).
- Pet Spot-Ons and other pet treatments – using the soon to be completed updated efficacy testing guidelines, implement a program to eliminate unnecessary use of pyrethroids and pyrethrins and to minimize POTW discharge quantities.

We have detailed below recommendations to improve and add to EPA's wastewater risk mitigation proposal. Rather than repeat the scientific basis for our input, we have attached our comment letter on the Preliminary Ecological Risk Assessment.

BACWA Requests Correction of EPA's Summary of Potential Impacts to US POTWs

BACWA appreciates that EPA's Ecological Risk Mitigation Proposal acknowledges that pyrethroids have costly impacts on POTWs (Page 34). Because EPA must balance costs and benefits of pesticides use, it is crucial that this information be accurate. We request EPA correct inaccuracies in its summary that understate the nationwide costs to POTWs, specifically:

(1) Clarify that California POTWs do not face unique challenges; POTWs in all states face the same challenges
(2) Clarify that the water quality standard driving the POTW challenges is a national standard that comes directly from the Federal Clean Water Act
(3) Clarify that California has **not** adopted aquatic life criteria for pyrethroids

EPA must recognize that the challenges posed by the presence of pyrethroids in wastewater are not California-specific. Pyrethroids are used nationwide, and their inherent toxicity in wastewater does not change state-to-state. Effluent toxicity is regulated throughout the US. It is Federal law – the US 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.

Neither EPA's responses to public comments nor EPA's discussion of impacts to US POTWs in the Ecological Risk Mitigation Proposal referenced the July 7, 2017 comments from the National Association of Clean Water Agencies (NACWA), which clearly explained that toxicity from pesticides in effluents is a nationwide issue (see Docket ID# EPA-HQ-OPP-2010-0384-0185).

When addressing pyrethroids and other currently used pesticides, California water regulators are implementing the Federal Clean Water Act toxicity standard. As EPA acknowledged in its Ecological Risk Mitigation Proposal, failure to meet this nationwide standard imposes burdensome costs on POTWs.

California has not adopted any water quality criteria for pyrethroids. A few California Regional Water Boards – but not our Regional Water Board – have used calculated criteria values when developing Total Maximum Daily Loads. These values are an addition to (not a replacement for) the nationwide Clean Water Act toxicity standard.

EPA's Sweeping Risk/Benefit Finding Should Be Revised to Differentiate Among the 23 Pyrethroids and Pyrethrins and Among the Various Indoor Uses of the 23 Chemicals

While we agree that there are societal benefits from some pesticide uses like public health pest control, the Ecological Risk Mitigation Proposal treats all indoor uses and all 23 chemicals as having equal costs and benefits. This is untrue. All indoor pyrethroids and pyrethrins uses are not equal in their societal benefits. Because the pyrethroids and pyrethrins do not have equal ecological risks, they do not have equal impacts on POTWs.

A more nuanced approach to completing EPA's statutory obligation to weigh the societal costs and benefits of the 23 pyrethroids and pyrethrins would better serve our nation. Ideally, EPA would evaluate the balance between costs and benefits for each of the 23 chemicals and each use of each chemical, considering the full range of available pest control alternatives for each use. We realize that such a complex evaluation would be impractical. But a focused evaluation of some individual uses – uses that are most closely linked to the external costs of pyrethroids use – are practical, and are necessary to support EPA's decision.

We request an individual evaluation for only one major source of pyrethroids discharges to POTWs, pet shampoos. Our evaluation (below) demonstrates that the benefit of maintaining market availability of just 3 bifenthrin pet shampoo products and only 9 permethrin pet shampoo products is vastly outweighed by the costs to POTWs.

BACWA Requests that EPA End Use of Bifenthrin and Permethrin in Pet Shampoos

Among pet shampoos, the least toxic member of the 23 chemicals – pyrethrins – dominate the market. Pyrethrins are the active ingredient in 51 of the 71 California-registered shampoo products. Only four pyrethroids appear in shampoos – and all have relatively minor market presence based on number of products and observations at retail stores: permethrin (9 products), phenothrin (4 products), bifenthrin (3 products), and etofenprox (2 "master labels" for products, neither of which is a label that currently allows sale of the product California).

There are many other pet flea control alternatives. There are a few registered non-pyrethroids/ pyrethrins shampoos – California has 4 registered pet shampoos that do not contain either pyrethrins or pyrethroids. Additionally, as noted in the Ecological Risk Mitigation Proposal, unregistered FIFRA-exempt shampoos are widely used to address pet flea infestations. Ordinary shampoos may also be used, as recognized by EPA's FIFRA Science Advisory Panel, which noted, "even non-pesticidal soaps may have a mortality factor against fleas and ticks."[2]

As the Ecological Risk Mitigation Proposal states, shampoos are far from the only means to address pet pests; in addition to the spot-ons, sprays, and collars that EPA discussed (page 33), popular alternatives include pet orals and non-pesticide controls (please see the companion animal flea control alternatives discussion, Appendix 1 of the enclosed prior BACWA letter for details).

Pyrethrins pose substantially less aquatic risk – and therefore less cost to POTWs as compared to bifenthrin and (to a lesser extent) permethrin. (The risks from phenothrin and etofenprox are unknown but suspected to be lower based on their shorter environmental half-lives). EPA's summary of risks associated with POTW discharges (Table 3 of the Ecological Risk Mitigation Proposal) shows that pyrethrins consistently had the lowest risk quotients (RQs) among all of the 23 chemicals addressed and only in one case (predicted chronic freshwater concentrations) did the pyrethrins concentration exceed the "level of concern"). To our knowledge, pyrethrins have never been detected in municipal wastewater effluents, though testing is admittedly limited.

In contrast, bifenthrin had the highest RQs (second highest for chronic freshwater invertebrates). Other data sources – particularly environmental monitoring data - lead to the conclusion that bifenthrin is the main contributor to ecological risks from pyrethroids. Acute RQs for permethrin were more than 10 times the acute RQs for pyrethrins. Permethrin occurs at substantially higher concentrations in POTW effluents than any other pyrethroid.[3] These differences between high-risk bifenthrin and permethrin and low-risk pyrethrins translate into real world differences in societal costs.

EPA's benefits assessment for pet shampoos (on page 33 of the Ecological Risk Mitigation Proposal) did not provide any compelling evidence for retaining pet shampoos as a product class. Notably, it did not differentiate between the market-leading, less toxic pyrethrins and the low market share pyrethroids shampoos that pose significantly more risks for POTWs. Given that there are dozens of other shampoo products with the same mode of action, a plethora of non-shampoo options for pet flea control – including the easy and popular orals – and given that the cost of pyrethroids discharges to POTWs, the bifenthrin and permethrin shampoos do not appear to have benefits that outweigh their costs to POTWs – costs that are ultimately borne by the general public (the ratepayers for POTW operations).

---

[2] FIFRA Scientific Advisory Panel Meeting Minutes and Final Report No. 2019-02. https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0161-0037 Page 17.

[3] Markle, J., van Buuren, B., Moran, K., & Barefoot, A. (2014). Pyrethroid Pesticides in Municipal Wastewater: A Baseline Survey of Publicly Owned Treatment Works Facilities in California in 2013. In *Describing the Behavior and Effects of Pesticides in Urban and Agricultural Settings* (Vol. 1168, pp. 177-194): American Chemical Society.; and 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.

BACWA Requests That EPA Provide a Schedule and an Specific Plan to address POTW Discharge Ecological Risks from Pet Spot-Ons and Other Topical Pet Treatments

In the proposed interim decision, EPA states:

> "The Agency is not proposing mitigation at this time in response to comments that pet spot-on applications were left out of the risk assessment and could end up down-the-drain, because there is a larger effort regarding the efficacy of pet products that is being handled by the Agency's Scientific Advisory Panel, with new Proposed Guidelines for Efficacy Testing of Topically Applied Pesticides Used Against Certain Ectoparasitic Pests on Pets, located in docket EPA-HQ-OPP-2019-0161."

In its responses to public comments, EPA further explained:

> "With regard to pet products specifically, the agency is working with the HCPA [Household and Commercial Products Association] Pet Care Products Task Force to quantify household exposures from pet product uses and is also working to develop new Proposed Guidelines for Efficacy Testing of Topically Applied Pesticides Used Against Certain Ectoparasitic Pests on Pets. Additional information and materials from the agency's June 11-14, 2019 Scientific Advisory Panel Meeting on the proposed efficacy guidelines are located in docket EPA-HQ-OPP-2019-0161. Both efforts may inform future work on the fate and transport of pesticides used in pet products."

Neither of these statements, nor any of the documents in docket EPA-HQ-OPP-2019-0161 specify any linkage between the Proposed Guidelines for Efficacy Testing of Topically Applied Pesticides Used Against Certain Ectoparasitic Pests on Pets ("Proposed Guidelines") and ecological risks posed by the post-application transfer of pet flea control chemicals to municipal wastewater treatment plants.

Given the costs to US POTWs, action to minimize pet flea control use of pyrethroids is essential. BACWA requests that that EPA provide a plan and schedule to address POTW discharge ecological risks from pet spot-ons and shampoos. We request that the plan have the specific, stated goals of eliminating unnecessary use of pyrethroids and pyrethrins and to minimize POTW discharge quantities. We request that the plan include the following elements:

(1) A schedule for completion of the Proposed Guidelines
(2) A requirement for testing of all pyrethroid and pyrethrins-containing topically applied pesticides (including pet spot-ons, shampoos, and other products like sprays and dusts) in accordance with the final version of the Proposed Guidelines, conducted with multiple application quantities, to determine the minimum necessary application quantity (by pet size).
(3) A requirement for products to be relabeled or reformulated such that applications do not use excess active ingredient (i.e., more than necessary to control pests).

EPA Proposed Label Clarifications – Pictograms, Stewardship Statement, and Spanish Language – Support with Modifications

BACWA supports the concept of a graphic showing an image of an "X" – or better the "do not" symbol "⃠" – over a drain on product packages. We have extensive experience with regard to graphically communicating "do not discharge" to various audiences and have found this approach to be very effective, if the graphic is properly designed. We appreciate EPA's example (shown to the right), but cannot support the use of the EPA graphic due to lack of clarity, particularly when the image is reduced in size to fit on smaller packaging.

EPA's Example Indoor Drain Pictogram

We request that EPA please select a clear, schematic graphic that is very obvious as to what is prohibited. We would be pleased to work with EPA, our national association NACWA, and registrants toward selecting an appropriate graphic. An example of a preferred schematic graphic is below (courtesy of Dublin San Ramon Sanitary District).

To ensure that these label elements completely and effectively address products that may be discharged "down-the-drain" into municipal wastewater collection systems, we request that EPA modify the "label table" in Appendix B to:

1. Identify a specific graphic and require the same graphic be used on all products.
2. Establish minimum size for the graphic, to ensure that it is legible, i.e., no smaller than 1.5 square centimeters unless this size is greater than 10% of the size of the label.
3. Modify the list of products that must include the graphic, stewardship language, and Spanish translations to specify:
    a. The graphic, stewardship language, and Spanish are required on all types products - <u>except pet shampoos</u> – that are packaged in a form that could be discharged into a drain (i.e., anything other than an impregnated material like a collar or fly strip).
        - The graphic should not be placed on pet shampoo product labels, to avoid inadvertently implying that the wash water should not be discharged to the sewer. The primary discharge alternative – outdoors, would likely direct wash water to storm drains where it could flow untreated to creeks.

    b. The graphic, stewardship language, and Spanish are required on all categories of products, not just those labeled for indoor residential use as indicated in the header on the label table in Appendix B.
        - At a minimum, the label table should be revised to indicate the graphic must be placed on all products labeled for outdoor or indoor use in non-agricultural settings (as indicated in the text on page 39). We would prefer that the graphic be required on all products, as even agricultural and mosquito abatement products are often mixed in facilities with sinks

and floor drains.

c. The graphic, stewardship language, and Spanish are required for all 23 pyrethroids and pyrethrins (not just the subset listed in the left column of the label table in Appendix B), recognizing that all pyrethroids have potential to enter sewer drains.
    - The subset of the 23 chemicals identified for this requirement in Appendix omits pyrethroids (e.g., momfluorothrin) that could also enter sewer drains from indoor residential use.

BACWA also supports EPA's proposal to add drain discharge prohibitions ("stewardship statement") and the Spanish translation of the stewardship statement to product labels. For those products labeled for use directly inside pipes/sinks, instead of EPA's proposal ("Do not allow to enter indoor or outdoor drains unless labeled for drain treatments."), we request that EPA instead require the following language, which is more clear and complete:

> "Do not pour down-the-drain or sewer except when following treatment instructions for [drains] [sewers]". Call your local solid waste agency for local disposal options."

EPA Proposed Label Clarifications – Indoor/Outdoor Use Specification - Support

BACWA supports EPA's proposal to require that product labels specifically state whether particular products are allowed to be used indoors only, outdoors only, or both indoors and outdoors. This will assist with identification of products that may be discharged to the sewer system.

BACWA Requests Additional Label Clarifications for Pet Shampoos

To avoid overuse of pet shampoos, BACWA requests that EPA require the labels for all pyrethroids and pyrethrins pet shampoos provide specific application quantities and allowable frequencies of use. Most current shampoo labels do not specify application quantities, even though overuse could potentially harm a pet. Some product labels already contain this information in a handy table (for example see EPA Reg. No.: 2596-177). We suggest that EPA require all shampoos have a table indicating the correct shampoo volume for the pet body weight.

Labels provide little or no application frequency information – and sometimes that information is inconsistent. For example, one product label indicates "maximum effectiveness" is achieved by washing a dog every 30 days with the product, but across the front of the label it says, "kills ticks and fleas every 7 days" (EPA Reg. No.: 2517-138).

BACWA Requests Modification of Pet Washing Label Language on Spot-On Pet Products

BACWA requests that EPA require removal of all label language on pet spot-on products that encourages washing and water exposure of treated pets. Label statements such as "water proof" should be removed. All labels should dissuade owners from washing their pets for at least 2 weeks after treatment. Please see our prior letter (attached) which provides the scientific basis for this request.

BACWA Requests POTW Notification Requirement for Wastewater Collection System Applications

Wastewater collection systems are commonly managed separately from wastewater treatment plants, and it is not uncommon for multiple municipal and private wastewater collection systems to flow to a single, separately owned and operated wastewater treatment facility. Treatment plant operators may not be aware of chemicals being applied in the upstream collection system. Collection system operators may not be aware of the cost and compliance implications of their selection of insecticides. To bridge this gap, BACWA requests that EPA add label language on the small group of pyrethroids products that may be applied in wastewater collection systems to require downstream POTW notification prior to initiating use of the product. If notification to downstream wastewater treatment facilities is required, wastewater treatment operations staff can work with collection system staff to ensure that applications do not contribute to effluent compliance challenges (e.g., toxicity test failures). Specifically, we request that EPA require the following language be placed on all products labeled for application in wastewater collection systems (including manholes):

> "Applicators must notify downstream wastewater treatment facilities prior to the first application of this product on manholes or in the wastewater collection system."

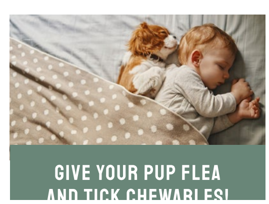
BACWA Requests Correction of Appendix D (List of Chemical Use Sites)

In our review of Appendix D, we found multiple errors and omissions. For example, the Appendix omits Bifenthrin pet flea shampoos (which were EPA registered as of 12/12/19). Multiple indoor uses are listed under "Urban, outdoor, non-agricultural." We request that EPA correct this table so that it accurately reflects the registered uses of pyrethroids. Some of the errors in Appendix D are carried over to Appendix B, which specifies the proposed labeling changes.

BACWA May Submit Additional Comments Because Pyrethroids Ecological Risk Mitigation is Not Complete Without Individual Decisions

BACWA may have additional ecological risk mitigation comments once we are able to review proposed interim decisions for the individual pyrethroids that pose the greatest risks to POTW effluent quality (e.g., bifenthrin and permethrin). These upcoming decisions that are currently unavailable for public review will contain information that is relevant to down-the-drain discharges. For example:

- EPA has indicated that it intends to address Endangered Species Act compliance in its individual decisions.
- EPA recently released information indicating that it intends to revise its assumptions about household exposures, particularly for children, based partly on a new assumption that "exposures to



BACWA Educational Outreach Image (based on stock photo)

children below 6 months of age are expected to be negligible."[4] We anticipate a lively public conversation around this assumption, because we are aware that very young children contact pets that may be treated with pyrethroids. Our own outreach materials include a stock photo of a baby with a pet (see excerpt at right).

Because these updates could provide us relevant information that we lack today and might lead to modifications or additions to EPA's risk mitigation for pet treatments, we reserve the right to provide additional input on ecological risk mitigation during public comment periods on proposed interim decisions for individual pyrethroids.

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

Autumn Cleave
Wastewater Enterprise, San Francisco Utilities Commission
(415) 695-7336
acleave@sfwater.org

Respectfully Submitted,

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

Enclosure: BACWA's July 7, 2017 Letter to US EPA on the Preliminary Ecological Risk Assessment for the Pyrethroid Insecticides (Docket ID No. EPA-HQ-OPP-2010-0384)

cc: Rick P. Keigwin, Jr., Director, EPA OPP
Elissa Reaves, Acting Director, Pesticide Re-evaluation Division
Kevin Costello, Branch Chief, Pesticide Re-evaluation Division
Cathryn Britton, Branch Chief, Pesticide Re-evaluation Division
Melanie Biscoe, Pesticide Re-evaluation Division
Khue Nguyen, Pesticide Re-evaluation Division
Lauren Weissenborn, Pesticide Re-evaluation Division
R. David Jones, Pesticide Re-evaluation Division
Tracy Perry, EPA OPP Pesticide Re-Evaluation Division
Kimberly Nesci, Acting Director, Biological and Economic Analysis Division

[4] US EPA OPP (2019). USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review. Page 6.

Marietta Echeverria, Director, Environmental Fate and Effects Division
Justin Housenger, Branch Chief, Environmental Fate and Effects Division
Amy Blankinship, Branch Chief, Environmental Fate and Effects Division
William Eckel, Environmental Fate and Effects Division
Donna Judkins, Environmental Fate and Effects Division
Zoe Ruge, Environmental Fate and Effects Division
Stephen Wente, Environmental Fate and Effects Division
Katrina White, Environmental Fate and Effects Division
Andrew Sawyers, Director, EPA Office of Water, Office of Wastewater Management
Tomas Torres, Director, Water Division, EPA Region 9
Patti TenBrook, EPA Region 9
Debra Denton, EPA Region 9
Karen Mogus, Deputy Director, California SWRCB
Philip Crader, Assistant Deputy Director, California SWRCB
Tom Mumley, California RWQCB SF Bay Region
Janet O'Hara, California RWQCB, SF Bay Region
Rebecca Nordenholt, California RWQCB, SF Bay Region
James Parrish, California RWQCB, SF Bay Region
Debbie Phan, California RWQCB, SF Bay Region
Val Dolcini, Director, California Department of Pesticide Regulation
Jesse Cuevas, Deputy Director, California Department of Pesticide Regulation
Nan Singhasemanon, California Department of Pesticide Regulation
Jennifer Teerlink, California Department of Pesticide Regulation
Chris Hornback, Chief Technical Officer, National Association of Clean Water Agencies
Cynthia Finley, Director, Reg. Affairs, National Association of Clean Water Agencies
Kelly D. Moran, Urban Pesticides Pollution Prevention Partnership
BACWA Executive Board
BACWA Pesticides Workgroup

BACWA
BAY AREA
CLEAN WATER
AGENCIES

July 7, 2017

Pesticide Re-evaluation Division
Office of Pesticide Programs (OPP)
U.S. Environmental Protection Agency (U.S. EPA)
1200 Pennsylvania Ave., NW.
Washington, DC 20460–0001

Subject: Preliminary Ecological Risk Assessment for the Pyrethroid Insecticides:

Bifenthrin – EPA-HQ-OPP-2010-0384
Cyfluthrins – EPA-HQ-OPP-2010-0684
Cypermethrins – EPA-HQ-OPP-2012-0167
Cyphenothrin – EPA-HQ-OPP-2009-0842
d-Phenothrin – EPA-HQ-OPP-2011-0539
Deltamethrin – EPA-HQ-OPP-2009-0637
Esfenvalerate – EPA-HQ-OPP-2009-0301
Etofenprox – EPA-HQ-OPP-2007-0804
Fenpropathrin – EPA-HQ-OPP-2010-0422
Flumethrin – EPA-HQ-OPP-2016-0031
Gamma-cyhalothrin – EPA-HQ-OPP-2010-0479
Imiprothrin – EPA-HQ-OPP-2011-0692
Lambda-cyhalothrin – EPA-HQ-OPP-2010-0480
Momfluorothrin – EPA-HQ-OPP-2015-0752
Permethrin – EPA-HQ-OPP-2011-0039
Prallethrin – EPA-HQ-OPP-2011-1009
Tau-fluvalinate – EPA-HQ-OPP-2010-0915
Tefluthrin – EPA-HQ-OPP-2012-0501
Tetramethrin – EPA-HQ-OPP-2011-0907

Dear U.S. EPA Chemical Review Managers:

On behalf of the Bay Area Clean Water Agencies (BACWA), we thank you for the opportunity to comment on the Preliminary Risk Assessment for pyrethroids. 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 is especially interested in pyrethroids due to their high aquatic toxicity and ability to pass through POTWs and appear in our effluent and biosolids. Pyrethroids are found in multiple types of consumer products that have transport pathways to the sanitary sewer, such as pet flea control products, lice and scabies treatments, and impregnated clothing. Even the most sophisticated wastewater treatment plants cannot fully remove these complex chemicals. 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 evaluate potential impacts to wastewater quality, and result 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 all pyrethroid-containing products with pathways to the sewer be carefully and thoroughly evaluated. BACWA appreciates that OPP has started to conduct evaluation of risks associated with pesticide discharges to the sewer system. We are grateful that earlier this year EPA OPP staff allocated time to speak with National Association of Clean Water Agencies (NACWA) and BACWA representatives and listen to information we shared about the context for the POTW portion of EPA's Registration Review process.

BACWA appreciates that U.S. EPA has grouped pyrethroids and pyrethrins together in a single ecological risk assessment. Even though it is not a cumulative ecological risk assessment (which we would have preferred, since our effluent toxicity regulations cover pesticides cumulatively), it provides better ability to understand and manage these related chemicals as a group.

The draft pyrethroids ecological risk assessment is comprised of four documents. Our comments focus on the *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins* (PRA), but also include comments addressing the other documents. In addition to commenting on the preliminary ecological risk assessment, we are also taking this opportunity to provide input on mitigation strategies for U.S. EPA to discuss with pyrethroids registrants. It is our intent to provide this in support of the forthcoming discussions between U.S. EPA and the 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 pyrethroids. Follow-up investigations identified that 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.

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.

BACWA Concurs with EPA's Finding of Significant Ecological Risk and Need for Mitigation

EPA's risk assessment, which considers California POTW effluent monitoring data along with data from elsewhere in the US, and uses predictive modeling to estimate POTW effluent concentrations associated with urban pyrethroids use, has concluded that there is measurable ecological risk associated with indoor urban pyrethroids uses, therefore, a need for mitigation. BACWA concurs with these conclusions, as presented in the PRA (page 5):

> "The assessment concludes that the use of bifenthrin, cypermethrin, cyfluthrins, deltamethrin, esfenvalerate, cyhalothrins, permethrin and pyrethrins, when used in accordance with registered labels, can result in acute and/or chronic risk LOC exceedances for freshwater and estuarine/marine invertebrates, from the indoor down-the-drain exposure to POTWs which in turn result in releases to certain bodies of water."

Because 100% of POTWs must comply with the Federal Clean Water Act 100% of the time, based on both EPA modeling and available monitoring, risk mitigation for pyrethroids is imperative.

OPP's POTW Modeling May Underestimate Environmental Exposure

Despite our concurrence with the overall risk assessment conclusion, BACWA continues to have concerns about the accuracy of OPP's POTW modeling methodology. As illustrated by the significant underestimate of permethrin concentrations as compared to monitoring data, it is likely that OPP's POTW modeling current underestimates actual environmental exposures. With regard to modeling, we have two types of concerns: (A) omission of major discharge sources and (B) accuracy of predictive modeling computational assumptions.

<u>A. Omission of Major Pyrethroids Sources</u>
The PRA's assumption that pet spot-ons, collars, and indoor foggers do not contribute to POTW discharges (PRA Attachment V) is inaccurate. A growing body of data summarized below and detailed in Appendix 1 documents that pet spot-on treatments are discharged to sewer systems through direct transfer (pet washing) and indirect transfer (washing hands, fabric, and surfaces contacted by treated pets, and possibly through human waste). A less focused larger set of scientific evidence connects pet collars and indoor foggers to POTW discharges. These pyrethroids sources – particularly pet spot-ons – appear to be among the largest sources of insecticide discharges to the sewer system.

Another source that is mentioned in the PRA – but not modeled – is permethrin-containing head lice and scabies treatments. These treatments are washed directly into the sewer after use. Even though EPA and FDA have agreed that FDA will be the primary regulator for these treatments, they are part of the context in which risk management decisions must be made, so understanding their contribution to aquatic risks is important.

Given their significance, the contributions from these pyrethroids sources must be considered in development of mitigation strategies.

<u>B. Accuracy of Wastewater Discharge ("Down-the-Drain") Modeling Computational Assumptions</u>
We have previously informally shared a list of recommended improvements for EPA's predictive modeling methodology, which we believe could be implemented within the existing E-FAST model. For the record, we have provided an updated version of this list in Appendix 2 of this letter. We were pleased to see that the POTW modeling discussion in the PRA acknowledged these recommendations and that some (e.g., effluent dilution) were implemented in the current version of the E-FAST model. We urge EPA to make the recommended modeling refinements

and to use the refined model to explore the potential benefits of mitigation options.

Unknown Risk for "Non-PWG" Pyrethroids – Risk Mitigation Opportunity?

The PRA only analyzed a set of pyrethroids that are manufactured by an industry organization called the Pyrethroid Working Group (PWG). Other pyrethroids were not explicitly evaluated in the PRA. The rationale for this approach, presented in the "Ecological Risk Management Rationale for Pyrethroids in Registration Review" (page 1), was:

> "The aquatic risks in the current assessment for these chemicals are representative of the risks for the non-PWG pyrethroids, also now undergoing registration review. These chemicals include cyphenothrin, d-phenothrin, etofenprox, flowmetric, imiprothrin, momfluorothrin, allethrin, tau-fluvalinate, tefluthrin, and tetramethrin. All of the pyrethroids have been assessed in the last ten years. Quantitatively assessing the non-PWG chemicals again in the registration review process would give similar results as previous assessments. Risks to mammals and birds have been found for certain pyrethroids in the past. Efforts to mitigate aquatic risks may benefit all taxa."

If we understand this correctly, U.S. EPA is stating that the ten pyrethroids not manufactured by PWG members (the "non-PWG pyrethroids" that are listed in the Federal Register as being part of this registration review) do not need to be part of the ecological risk assessment because (1) the "PWG-pyrethroids" are representative of the "non-PWG-pyrethroids" and (2) to review the "non-PWG pyrethroids" at this time would provide the same results as prior reviews of these chemicals.

Eight of the ten "non-PWG pyrethroids" (all except tau-fluvalinate and tefluthrin) were identified in the PRA as having indoor/wastewater discharge-related uses, including pet spot-ons, pet collars, dog sprays, sewer pipes treatments, food-contact surfaces sprays, and various indoor domestic dwelling treatments, such as for furniture, rugs, and carpets.

We reviewed available information about the "non-PWG pyrethroids," finding that:

(1) Most of the uses associated with wastewater discharges (e.g., pet flea control) were not addressed in prior EPA risk assessments that were made available in the Registration Review online dockets nor in the "Ecological Risk Management Rationale for Pyrethroids in Registration Review." We searched EPA records for all eight pyrethroids and found no evidence that POTW risks had been assessed for any of these chemicals based on modern knowledge of POTW pesticide sources.

(2) In Registration Review, OPP required environmental fate and ecological toxicity data for all ten chemicals that was unavailable when the chemicals were first registered and therefore could not have been considered in prior risk assessments. These data, which we understand are in reports in EPA's files, have not been made available to the public, so we are unable to use them to inform our review of the risk assessment nor our input to OPP on these chemicals. These data are crucial to evaluation of POTW discharges. To be scientifically sound, any prior risk assessment would need to be updated based on these data.

We therefore respectfully disagree with the assertion that an evaluation of the risks today for the "non-PWG pyrethroids" would yield the same conclusion as prior risk assessments. We find the available information insufficient to assess the PRA's conclusion that the range of risk presented by the PWG pyrethroids and pyrethrins is representative of the "non-PWG pyrethroids."

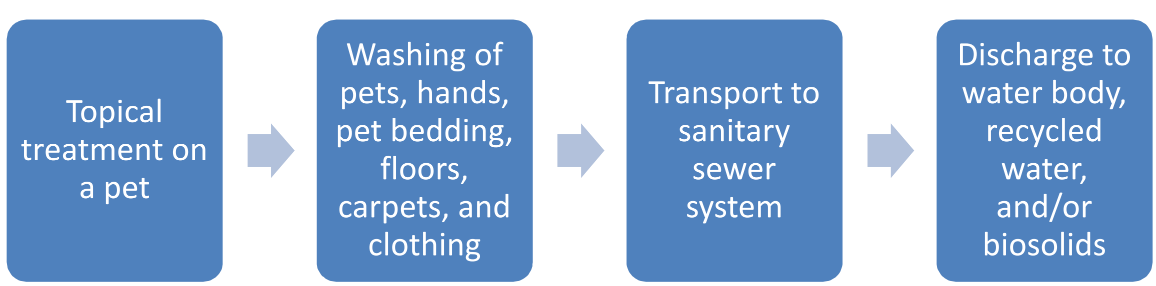
The limited available environmental fate and toxicity data characterizing the un-assessed pyrethroids suggests that they tend to be less persistent than the PWG pyrethroids and that some of them might be less toxic to sensitive organisms than the PWG pyrethroids. These differences could provide an important risk mitigation opportunity. We request that OPP examine the potential for replacing higher risk (e.g., PWG pyrethroids) with one or more non-PWG pyrethroids with environmental fate and aquatic toxicity profiles more conducive to decomposition by POTW treatment processes and with overall low potential to pass through POTWs at concentrations that are toxic to sensitive organisms.

BACWA Requests On-Pet Treatments Be Included in the Risk Assessment and Risk Mitigation

In the PRA, POTW modeling excluded pet spot-on treatments and pet collars (together referred to as "topicals") based on the following rationale:

> "Considerable attention has placed on the use of 'spot on' treatments for pets (*e.g.,* flea and tick control) as well as insecticide-impregnated collars. With spot on treatments, it is expected (and advised on some pesticide labels) that shampooing soon after application of spot on treatments would reduce the efficacy of such treatments, and those would not be cost effective and are discouraged. Regarding pet collars, the potential substantive releases to POTWs are considered low based on their expected slow release rate of pesticides from the collars." (Section 5.1 of PRA)

As explained in Appendix 1, this assumption that topical pet treatments do not contribute to POTW influent pesticides loads is incorrect. Topical pet applications are transported within a home to an indoor drain that flows to a POTW via the pathways illustrated in the graphic below. Scientific studies detailed in Appendix 1 examined the pathways that transport active ingredients from pet topicals to the sewer system, both directly (through dog washing) and indirectly (such as 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 topicals are significant sources of pesticides to POTWs.



BACWA asks that U.S. EPA revise its risk assessment to include pet topical treatments. Revisions only need to be made to the extent necessary to inform risk mitigation discussion.

BACWA requests that OPP conduct its risk-benefit evaluation for pet flea control products as a group and in the context of available non-pesticide alternatives, including FDA-approved oral medications and mechanical controls (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 1 identified plentiful alternatives that are far less environmentally problematic than pyrethroids. 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. As detailed in other BACWA communications to OPP, we do not believe that fipronil or imidacloprid are good alternatives.

BACWA suggests that EPA consider the following risk mitigation strategies for pet flea/tick control products:

- **Examine the environmental fate properties and toxicity of all pyrethroids and pyrethrins (including those for which data are not provided in the risk assessment) and allow continued use of only the lowest risk pet flea control alternatives**. Pyrethroids and pyrethrins individually have quite different fate & toxicity profiles; some are much more likely than others to pass through POTWs at concentrations sufficient to cause or contribute to Clean Water Act permit violations. Critical data for OPP to consider when completing the requested examination have all been required by EPA, i.e., anaerobic aquatic half-life, octanol-water partition coefficient, and acute and chronic toxicity to *H. azteca* and *A. bahia*. We understand that human health risk (which is not our area of expertise) would be an important part of the requested evaluation.
- **Determine the minimum application rate necessary to achieve pest control**. This would eliminate unnecessary overuse and minimize POTW discharge quantities.
- **Remove all label language that encourages washing and water exposure of treated pets.** Label statements such as "water proof" should be removed. All labels should dissuade owners from washing their pets for at least 2 weeks after treatment.

Risk Mitigation – Pyrethroid Impregnated Fabrics

BACWA agrees with the PRA conclusion that washing pyrethroid-treated fabric is a significant source of pyrethroids (particularly permethrin) to POTWs. As U.S. EPA explores POTW risk mitigation alternatives with registrants, we encourage review of published scientific studies that evaluated mosquito control effectiveness and wash-off rates of permethrin-treated clothing in both laboratory and field conditions.[1] These studies suggest that typical treatment levels may far exceed concentrations necessary for pest control. Two very different studies, one with in-lab weathering and another in-field, both concluded that the initial permethrin concentration in the fabric decreases with each wash, yet the clothing provides effective mosquito control even when < 20% of the original permethrin remains on the fabric.[2,3] These data suggest that the initial

---

[1] S. D. Banks, N. Murray, A. Wilder-Smith, and J. Logan, "Review Article: Insecticide-treated clothes for the control of vector-borne diseases: a review on effectiveness and safety" *Medical and Veterinary Entomology* (2014) 28 (Suppl. 1), 14–25.

[2] R. K. Gupta, L. C. Rutledge, W. Reifenrath, G. A. Gutierrez and D. W. Korte, Jr., "Effects of Weathering on Fabrics Treated with Permethrin for Protection Against Mosquitos," Journal of the American Mosquito Control Association, (1989) Vol. 5, No. 2.

[3] Bruno Most, Vincent Pommier de Santi, Frédéric Pagès, Marie Mura, Waltraud M. Uedelhoven, and Michael K.

fabric impregnation concentration may be higher than necessary.

Based on these data, we suggest that OPP work with registrants to eliminate unnecessary pyrethroids use by optimizing fabric treatment concentrations. Consideration should also be given to requiring pre-washing of treated fabric at manufacturing facilities, where on-site wastewater treatment can be optimized for pyrethroids removal. After the first wash – which generates the greatest pyrethroid discharge – remaining residual concentrations could be designed to be sufficient to control mosquitoes. Pre-washed fabric would generate much smaller discharges in subsequent residential washes, where pyrethroids-specific wastewater treatment is unavailable.

Risk Mitigation Decisions for Permethrin Should Account for Head Lice and Scabies Treatment Discharges

While the U.S. EPA included pet shampoos and dips in the analysis, it disregarded lice shampoos for people. Such shampoos are typically used following outbreaks, and therefore could be used in concentrations that could result in observable toxicity to the POTW. The PRA notes that lice treatments:

> "…are considered drug uses, and are not considered in this assessment. These products are regulated by FDA, but if the active ingredient in these products is also a pesticidal active ingredient, the risk assessor should consider the pesticidal uses in the ecological risk assessment."

Not including lice treatments in the analysis limits U.S. EPA's opportunity to develop effective mitigation measures. To inform mitigation strategy development, BACWA encourages OPP to examine the additional loading to a POTW following an outbreak of lice at a single school in a POTW service area. This high-end scenario could occur at any POTW in the nation; it is not specific to POTWs in California as OPP has suggested in the PRA (PRA page 31).

Risk Mitigation – Please Evaluate Bifenthrin-Specific Mitigation for All Indoor Uses

Bifenthrin's aquatic persistence is striking – it is among the most persistent pesticides on the market today. Unlike any other urban pyrethroid for which U.S. EPA has provided environmental fate data,[4] bifenthrin's aerobic and anaerobic aquatic half-lives both exceed one year (see table). It is the only pyrethroid where both aerobic and anaerobic aquatic half-life data exceed U.S. EPA's standard for highly persistent chemicals (180 days). Bifenthrin's aerobic aquatic half-life is five times as high as the next urban pyrethroid (deltamethrin). Omitting lambda-cyhalothrin (where we question the data in the PRA),[5] bifenthrin's anaerobic aquatic half-life is more than three times as high as the next urban pyrethroid (permethrin). Based on published (Budd et al., 2011) and anecdotal reports of attempts to measure bifenthrin's sediment aquatic half-life that did not find any degradation

---

Faulde, "Long-lasting permethrin-impregnated clothing: protective efficacy against malaria in hyperendemic foci, and laundering, wearing, and weathering effects on residual bioactivity after worst-case use in the rain forests of French Guiana," Parasitol Research (2017) 116:677–684.

[4] We exclude fenpropathrin, which has no indoor uses. There are eight additional pyrethroids – most of which have discharge pathways to POTWs – for which EPA has not yet made public environmental fate data.

[5] This value appears to be based on one of three tests, where the result was orders of magnitude higher than the other tests. The value is inconsistent with data for structurally similar chemicals.

at all, we do not question the relatively high bifenthrin anaerobic aquatic half-life and suspect that that the true value could even be greater than reported in the PRA (which was based on "supplemental" data indicating questions about data quality, PRA Att. 3, p. 9).

Aquatic Half-lives (Days) for Urban Pyrethroids [Source: PRA, Part II, page 32]

Pyrethroid	Anaerobic Half-Life	Aerobic Half-Life
L- Cyhalothrin	6080*	48
Bifenthrin	***650***	***466***
Permethrin	193	57
Deltamethrin	139	86
Esfenvalerate	138	80
Cyfluthrin	26	45
Cypermethrin	53	26

*We have questions about this value (see text).

Bifenthrin is classified as "very highly toxic" to aquatic invertebrates (PRA, Part II) and is at least as toxic – and in some cases (e.g., permethrin) substantially more toxic – to sensitive organisms (e.g., freshwater and estuarine/marine invertebrates) as most other pyrethroids. Bifenthrin is known to be particularly toxic to *Hyalella azteca* and *Americamysis bahia;* these species are of particular concern to BACWA because they are cited in EPA toxicity testing guidance, included in monitoring requirements in NPDES permits, used as the basis for TMDL targets.

For these reasons, BACWA requests that U.S. EPA consider bifenthrin-containing products separately from other pyrethroids, looking toward stronger mitigation measures including potentially eliminating all indoor uses that have a direct pathway to the sewer. Given the plethora of alternative indoor pest control options, it does not seem necessary to use a chemical as persistent as bifenthrin for indoor pest control. For example, there is a bifenthrin pet flea shampoo; a single washing of one pet with this shampoo could potentially cause a typical sewage treatment plant's effluent to exceed toxicity thresholds for sensitive organisms (see Appendix 4). U.S. EPA, DPR, and bifenthrin registrants have previously recognized the need for bifenthrin-specific mitigation – for example, they jointly implemented bifenthrin-specific mitigation for outdoor bifenthrin uses in 2011.

While the discussion above focuses on bifenthrin, BACWA requests that U.S. EPA provide similar controls to ensure that there is adequate mitigation for any other pyrethroid that has similar or greater persistence in aquatic environments.

Thank you for the opportunity to provide this feedback regarding both the risk assessment and subsequent mitigation strategies. We ask that OPP continue to refine this analysis so that pyrethroid discharges to POTWs are able to be thoroughly evaluated and mitigation options fully explored, particularly for pet flea treatments, impregnated clothing, lice and scabies treatments, and all indoor bifenthrin uses. BACWA requests that U.S. EPA, in coordination with CDPR (which has extensive relevant information and expertise), veterinarians, treated clothing manufacturers, and registrants, bring in the latest scientific information – including CDPR scientific studies and modeling that are currently underway – and develop mitigation strategies for pyrethroids.

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,

David R. Williams

David R. Williams
Executive Director
Bay Area Clean Water Agencies

Enclosures:

1. Sadaria, A.M. et al. (2016). 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. 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
3. Halos, L. et al. (2014). Flea Control Failure? Myths and Realities. *Trends in Parasitology*, 30:5 228-233.
4. Blagburn, B., and Dryden, M., Biology, Treatment, and Control of Flea and Tick Infestations, *Vet Clin Small Anim,* 2009, Vol 39, pp 1173-1200.
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.
6. 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.
7. S. D. Banks, N. Murray, A. Wilder-Smith, and J. Logan, "Review Article: Insecticide-treated clothes for the control of vector-borne diseases: a review on effectiveness and safety" *Medical and Veterinary Entomology* (2014) 28 (Suppl. 1), 14–25.
8. Bruno Most, Vincent Pommier de Santi, Frédéric Pagès, Marie Mura, Waltraud M. Uedelhoven, and Michael K. Faulde, "Long-lasting permethrin-impregnated clothing: protective efficacy against malaria in hyperendemic foci, and laundering, wearing, and weathering effects on residual bioactivity after worst-case use in the rain forests of French Guiana," Parasitol Research (2017) 116:677–684.
9. R. K. Gupta, L. C. Rutledge, W. Reifenrath, G. A. Gutierrez and D. W. Korte, Jr., "Effects of Weathering on Fabrics Treated with Permethrin for Protection Against Mosquitos," Journal of the American Mosquito Control Association, (1989) Vol. 5, No. 2.
10. 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.
11. 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.
12. McKelvey, Wendy, J. Bryan Jacobson, Daniel Kass, Dana Boyd Barr, Mark Davis, Antonia M. Calafat, and Kenneth M. Aldous, "Population-Based Biomonitoring of Exposure to Organophosphate and Pyrethroid Pesticides in New York City," Environmental Health Perspectives, Volume 121, Number 11-12, November-December 2013,

cc: Yu-Ting Guilaran, Director, Pesticide Re-Evaluation Division
Rick P. Keigwin, Jr., Deputy Office Director for Programs, Acting Director, EPA OPP
Tracy Perry, 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, Environmental Fate and Effects Division (EFED)
Thomas Steeger, Ph.D., Senior Science Advisor, EFED
Jean Holmes, D.V.M., Branch Chief, EFED
José Meléndez, EPA OPP Pyrethroid Review Team
Keith Sappington, EPA OPP Pyrethroid Review Team
Donna Judkins, EPA OPP Pyrethroid Review Team
Stephen Wente, EPA OPP Pyrethroid Review Team
William Eckel, EPA OPP Pyrethroid Review Team
Frank Farrugia, EPA OPP Pyrethroid Review Team
Katrina White, EPA OPP Pyrethroid Review Team
Cathryn Britton, Pesticide Re-Evaluation Division, EPA OPP
Bilin Basu, Pesticide Re-Evaluation Division, EPA OPP
Brian Kettl, Pesticide Re-Evaluation Division, EPA OPP
Brittany Pruitt, Pesticide Re-Evaluation Division, EPA OPP
Garland Waleko, Pesticide Re-Evaluation Division, EPA OPP
James Parker, Pesticide Re-Evaluation Division, EPA OPP
Margaret Hathaway, Pesticide Re-Evaluation Division, EPA OPP
Maria Piansay, Pesticide Re-Evaluation Division, EPA OPP
Marianne Mannix, Pesticide Re-Evaluation Division, EPA OPP
Marquea King, Pesticide Re-Evaluation Division, EPA OPP
Miguel Zavala, Pesticide Re-Evaluation Division, EPA OPP
Nathan Sell, Pesticide Re-Evaluation Division, EPA OPP
Rachel Ricciardi, Pesticide Re-Evaluation Division, EPA OPP
Susan Bartow, Pesticide Re-Evaluation Division, EPA OPP
Wilhelmena Livingston, Pesticide Re-Evaluation Division, EPA OPP
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
Dawit Tadesse, California State Water Resources Control Board
Matthew Freese, California State Water Resources Control Board

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
Tom Mumley, California Regional Water Quality Control Board, SF Bay Region
Janet O'Hara, California Regional Water Quality Control Board, SF 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 Executive Board

Appendix 1

On-Pet Flea Treatments:
(1) Evidence for the Pathway to the Sewer and
(2) Alternatives Analysis

Part I – Evidence for the Pathway to the Sewer

There is mounting evidence that pesticides from on-pet flea treatments (spot-ons and collars – together "topicals") 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 Topicals - Background
The pesticidal mode of action for all pyrethroid-based collars and spot-ons is topical in nature, not systemic. 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.[6]

Pet Topicals – Sewer Discharge Pathways
Pet washing is likely to be a significant pathway by which pet topical applications enter the sewer system. In a study recently conducted by the California Department of Pesticide Regulation (CDPR), dogs were washed at 2, 7, or 28 days after application of a fipronil-based topical flea treatment.[7] 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 rinsate 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. While water solubilities differ between pesticides and even amongst the pyrethroids, shampoos almost always include surfactants that enhance the mobility of less soluble chemicals like pyrethroids.

Several scientific studies have examined the transport of active ingredients from pet topicals onto surfaces, such as human hands, that are subsequently washed, completing a transfer pathway to the sewer system.

- One such study quantified glove transfer of tetrachlorvinphos from pet collars.[8] 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

[6] An exception to this mode of action is a non-pyrethroid, selamectin, which is in topically applied spot treatments, but is systemic in action.
[7] 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.
[8] 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.

feedback from the U.S. EPA's Human Subjects Review Board.[9]

- A 2012 study by Bigelow Dyk et al. presents additional evidence of transport of a topical pet treatment onto human hands and through homes.[10] 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.

- A 2015 study evaluated the transfer of permethrin and indoxacarb from a topical pet treatment to people's hands.[11] In the study, the topical 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.

Based on the data from these studies characterizing topical flea control active ingredient transfer to owners' hands[12] 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.[13]

<u>Evidence from Collection Systems</u>
CDPR is in the process of completing a collection system ("sewershed") study within the City of Palo Alto's Regional Water Quality Control Plant.[14] 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

---

[9] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0316-0040
[10] 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
[11] 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.
[12] 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
[13] 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.
[14] See http://www.cdpr.ca.gov/docs/emon/surfwtr/presentations/presentation_130_targeted.pdf

laundromat). The samples were analyzed for a suite of pesticides, including pyrethroids. Based on preliminary results that DPR has shared with BACWA, pyrethroids were among the most frequently detected pesticide chemicals – but some pyrethroids were not detected . These preliminary results could be indicative of the active ingredients used – or, intriguingly, could indicate that, pyrethroids have differing environmental fates. Preliminary results from the pet-grooming site provide evidence that pet washing is a pathway for pyrethroids 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 pyrethroids.

<u>POTW Influent and Effluent</u>
Lastly, further insights regarding transport of indoor flea control products to POTWs comes from a collaborative 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.[15] 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 topicals – provide compelling evidence that topical pet products may be the primary source of both chemicals in wastewater.

Part II – 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 shampoos, dips, and topicals (including both spot-ons and collars). Three 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
- Alternatives: indoor foggers and sprays raise concerns
- Optimization of application rates of on-pet treatments

<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-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 pyrethroids, but also alternatives that are problematic from the water quality perspective (e.g., fipronil, imidacloprid, 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

[15] 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.

environment.[16] 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.[17] One way to do so is via non-pesticide mechanical controls, including frequent indoor vacuuming, washing of pet bedding, and use of an on-pet flea comb.[18] 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."* [19]

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.[20]

---

[16] Halos, L., et al. (2014). Flea Control Failure? Myths and Realities. *Trends in Parasitology*, 30:5 228-233.
[17] "Flea Control Failure? Myths and Realities," Halos, L., et al., Trends in Parasitology, May 2014, Vol. 30, No. 5.
[18] American Veterinary Medical Association (2009). External Parasites.
[19] "Biology, Treatment, and Control of Flea and Tick Infestations," Blagburn, B., and Dryden, M., Vet Clin Small Anim, 2009, Vol 39, pp 1173-1200.
[20] "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[21]	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)

[21] 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.

Alternatives: In-House Foggers and Sprays Raise Concerns
While BACWA is interested in minimizing on-pet treatments of pyrethroids that persist through POTWs, we are concerned about the potential for consumers to replace them with indoor foggers and sprays, both from the POTW discharge perspective and out of concern for human health hazards that have been raised by other experts, including our partners in regional pesticides outreach and educational programs (e.g., the California "Our Water Our World" educational program) Below we summarize three studies that support the avoidance of such in-house treatments.

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.[22] 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.[23] 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.

A 2004 human-health study incorporated four boroughs of New York City (NYC), including high-density housing units in which individuals would have little voice in the use of sprays and

---

[22] 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.
[23] 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.

foggers throughout the building.[24] The study was modeled after the National Health and Nutrition Examination Survey (NHANES), which is an "ongoing, population-based, cross-sectional survey of the health and nutrition status of residents of the United States." The researchers found higher urinary pyrethroid metabolites in the NYC residents than found in other parts of the United States, leading them to conclude:

> "The use of sprays and foggers spreads chemicals indiscriminately around the living area and potentially into neighboring spaces. At the high end of the distribution, our data suggest that exposure to pyrethroid and some organophosphate pesticides may be higher in NYC than in the United States overall, underscoring the importance of considering pest and pesticide burdens in cities when formulating pesticide use regulations."

Given that a fogger or spray is designed to deposit active ingredient throughout the room, and is subsequently transferred to people and their clothing, this indicates a direct pathway to the sewer. Further, the NYC results may indicate that these concentrations may be higher in high-density urban areas. BACWA asks that U.S. EPA seek to avoid the use of indoor foggers as a mitigation strategy for on-pet pyrethroids treatments.

<u>Optimization of Application Rates of On-Pet Treatments</u>
Another consideration for on-pet treatments is that of application rate. Given that these household and on-pet treatments have a transport pathway to the sewer, it would be of great interest to understand whether manufacturers have optimized the amounts applied. In the table below, we have sought to compare the mass of active ingredient in various pet treatments. This is clearly not an exhaustive list, given the wide variety of products on the market. While topicals 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. As for shampoos and dips, it is often unclear from the label instructions what dosage is appropriate for effective flea control and size of pet.

Example On-Pet Treatment	**Pyrethroid**	**Mass per Dose**	**Days of Control (per label)**
Dip, dogs only (Sentry)	Permethrin (5.7% in 8 oz. bottle)	3.4 grams for each 2 oz. of dip diluted into 1 gallon of water	35 days
Shampoo (Hartz Ultra Guard)	Phenothrin ***(non-PWG)***	0.04-0.12 grams (Estimated. No suggested dosage on bottle. Assuming 1-3 tablespoons at 0.27%)	28 days
Topical (Activyl for dogs)	Permethrin	0.24-2.4 grams (dependent on animal size)	1 month
Collar (multiple brands)	Deltamethrin	0.7-1.1 grams (dependent on length)	6 months

---

[24] McKelvey, Wendy, J. Bryan Jacobson, Daniel Kass, Dana Boyd Barr, Mark Davis, Antonia M. Calafat, and Kenneth M. Aldous, "Population-Based Biomonitoring of Exposure to Organophosphate and Pyrethroid Pesticides in New York City," Environmental Health Perspectives, Volume 121, Number 11-12, November-December 2013, http://dx.doi.org/10.1289/ehp.1206015.

Appendix 2

These 2016 recommendations are included here for the record. We were pleased to see that the POTW modeling discussion in the PRA acknowledged these recommendations and that some (e.g., effluent dilution) have been implemented in the current version of the E-FAST model.

Wastewater Discharge ("Down-the-Drain") Modeling Refinements

BACWA recommends the following refinement for the modeling of indoor pesticide discharges and transport through a sanitary sewer to a water body:

1) Adjust consumer product discharge estimates to reflect geographic and seasonal use
2) Update per capita water use to reflect today's conditions and account for conservation
3) Assume zero dilution
4) Improve POTW removal estimates
5) For pesticides likely to partition to sediment, include a biosolids analysis

1) Adjust Consumer Product Discharge Estimates to Reflect Geographic and Seasonal Use

For the discharge of consumer products to a sewer, the default approach for the E-FAST down-the-drain (DTD) model involves assuming 100% discharge of the annual manufacturing production volume of the chemical and equal discharge throughout all US households. While this approach could be useful for screening purposes, it is unreasonable for many categories of products.

In the case of flea control products, usage is not consistent throughout the year or across the nation, as flea pressure differs based on geography and by season. For example, flea pressure is low during freezing winters and highest in late summer. Geographic areas with climates most conducive to flea reproduction (e.g., mild weather coastal areas) experience the highest flea pressure. And, while veterinarians typically recommend regular use of topical treatments, consumers often seek treatments upon identifying a flea outbreak.

2) Update Per Capita Water Use to Account for Conservation

The overall daily water use in a household dilutes the concentration of chemicals entering the sanitary sewer. The water use default in the E-FAST DTD model appears to be significantly greater than currently observed per capita water use in many of the nation's urban areas. Particularly in regions of the US that are impacted by drought, the influent flow volume to POTWs has reduced significantly since the 1990s, due to conservation, national and state code requirements for installation of low-flow toilets and showerheads, and new high-efficiency washing machines (see table below). BACWA recommends that U.S. EPA consider using 5th or 10th percentile per capita flows to be sufficiently conservative in the model analysis.

Daily Per-Capita Water Use Comparison

Location	Per Capita Daily Water Use (Liters)	Source
E-FAST DTD Model	364 (original) 388 (current)	1990 and 1996 U.S. EPA POTW surveys[25]
California, January 2016 (includes outdoor uses)	230 (statewide) <190 (many cities)	California State Water Board[26]
Texas, 2012	230	Texas Water Development Board[27]

3) <u>Assume Zero Dilution</u>

The 2007 E-FAST model manual notes that a range of dilution factors may be employed when analyzing POTW impacts to receiving waters: "Measured dilution factors are typically between 1 (representing no dilution) and 200 and are based on NPDES permits or regulatory policy."[28] BACWA recommends that the spot-on modeling analysis assume no dilution.

In California, approximately 20 percent of NPDES permits provide for no dilution. Throughout the US, about 23 percent of POTWs have a permitted dilution factor less than 10. Further, treated wastewater effluent makes up more than 90 percent of stream flow for 49 percent of a representative sample of major POTWs in Texas, Oklahoma, New Mexico, Arkansas, and Louisiana.[29] In the case of multiple sanitary sewer systems and/or urban and agricultural runoff discharging into the same water body, the "diluting" waters may also contain the pollutant.

4) <u>Improve POTW Removal Estimates</u>

Because there is variety in POTW treatment trains, with different types and levels of treatment, and different detention times, pesticide removal rates are expected to vary from facility to facility. Rather than use an average removal rate, consider using a range of removal rates to determine whether certain treatment trains might be more at risk of permit violation.

It is important to avoid estimating POTW removal rates from grab sample data. This is why the data from Markle et al study of pyrethroids at California POTWs (which we participated in)[30] are inappropriate to use as the basis for development of POTW removal estimates.

---

[25] Versar (1999). Exposure and Fate Assessment Screening Tool (E-FAST) Beta Version Documentation Manual prepared for U.S EPA OPPTS; Versar (2007). Exposure and Fate Assessment Screening Tool (E-FAST) Version 2.0 Documentation Manual. Prepared for U.S. EPA OPPTS.

[26] California water usage data are available online: http://www.waterboards.ca.gov/water_issues/programs/conservation_portal/conservation_reporting.shtml January data, which are during the rainy season in California's Mediterranean climate and thus reflect minimal outdoor water use, are typically used to estimate indoor water use and wastewater discharges.

[27] Hermitte, S.M. and Mace, R.E. (2012). *The Grass Is Always Greener…Outdoor Residential Water Use in Texas*. Texas Water Development Board, Technical Note 12-01.

[28] Versar (2007). Exposure and Fate Assessment Screening Tool (E-FAST) Version 2.0 Documentation Manual. Prepared for U.S. EPA OPPTS. Page 3-33.

[29] Brooks et al. (2006). Water quality of effluent-dominated ecosystems: ecotoxicological, hydrological, and management considerations. *Hydrobiologia* **556:**365–379

[30] Markle, J.C., van Buuren, B.H., Moran, K.D., Barefoot, A.C. 2014. Pyrethroid pesticides in municipal wastewater: A baseline survey of publicly owned treatment works facilities in California in 2013. Technical Report sponsored by the Pyrethroid Working Group. January 22, 2014.

5) For Pesticides Likely to Partition to Sediment, Include a Biosolids Analysis

Given the low volatility and the octanol-water coefficient for pyrethroids, they are likely to partition into biosolids. Therefore, BACWA requests that U.S. EPA include an evaluation of the adsorption and partitioning to the POTW biosolids. The E-FAST DTD model assumes that the biosolids (referred to as "sludge") are landfilled. This assumption does not reflect the routine use of biosolids as a soil amendment in agriculture, gardens, parks and reclamation sites. POTWs have come to consider biosolids to be valuable resource. It is important to understand how the partitioning of industrial insecticides into biosolids could impact the value and end uses of this resource.

Appendix 3

Minor Comments

1. POTW Modeling Permethrin Concentration Underestimate – Probably Due to Shortcomings of EPA DtD Modeling, not to Permethrin-Based Lice Shampoos

The PRA notes that the California POTW monitoring data for permethrin was far higher than estimated concentrations from OPP's DtD model. The PRA concluded – without any evidence – that this was due to lice outbreaks, and that California differs from the rest of the country with regard to lice outbreaks, stating (PRA page 30):

> "For permethrin, the predicted concentration was around an order of magnitude below the maximum concentration detected in California POTWs, which may be due to the additional permethrin uses for lice control…"

In a related footnote, it is stated (emphasis added):

> "Uses for lice control, which are considered pharmaceutical uses, and *possible higher usage of this chemical in California* than elsewhere in the nation, may be the reasons why the maximum monitored concentration is above the predicted EEC for permethrin."

However, according to the Centers for Disease Control (CDC):

> "Head lice are found worldwide. In the United States, infestation with head lice is most common among pre-school children attending childcare, elementary schoolchildren, and the household members of infested children. Although reliable data on how many people in the United States get head lice each year are not available, an estimated 6 million to 12 million infestations occur each year in the United States among children 3 to 11 years of age."[31]

The California POTW pyrethroids monitoring data cited in the PRA were generated by a study in which BACWA was an active participant.[32] These data came from diverse POTWs. The estimated modeled permethrin concentration (12 ng/L) is similar to the median value in the California POTW pyrethroids survey (9 ng/L) and less than the average concentration in that survey (20 ng/L). It is highly unlikely that some special lice outbreak was occurring in multiple locations in California exactly at the time of the study and that such an outbreak would only occur in California.

It is more likely that shortcomings in the modeling approach, i.e., omitted sources noted in the body of the letter and non-conservative modeling parameters (such as overestimated per capita flow rates - see Appendix 2) explain the underestimated permethrin concentrations.

---

[31] https://www.cdc.gov/parasites/lice/head/gen_info/faqs.html

[32] Markle, J.C., van Buuren, B.H., Moran, K.D., Barefoot, A.C. 2014. Pyrethroid pesticides in municipal wastewater: A baseline survey of publicly owned treatment works facilities in California in 2013. Technical Report sponsored by the Pyrethroid Working Group. January 22, 2014.

2. Potential Underestimate of Pet-Related Indoor Use Estimates

BACWA noticed what appears to be a minor calculation error with regard to estimating pet product indoor use volumes. In PRA Attachment V, BEAD provides estimated total pet product sales volumes for pyrethrins. According to BEAD, an estimated 78% of pet-related *pesticide* use is shampoos/ dips/ spots while 5% is collars and 15% is tablets (orals). These market share estimates appear to be generic, covering all pesticide active ingredients. The market share data to not apply to any individual insecticide. For example, there are no pyrethroids or pyrethrins-containing tablets. BEAD appears to have multiplied the total amount of pyrethrins reportedly used in pet products by 78%, apparently to attempt to remove collars and tablets. This is an unwarranted adjustment. While this adjustment does not modify the significant risk conclusion, we call it to OPP's attention in an effort to improve the accuracy of future risk assessments.

REVISED Appendix 4
Rough Bifenthrin Shampoo Effluent Concentration Calculations

1. Single Discharge Event

Information from product label [1]:

- Concentration = 0.05%
- Application quantity (from label instructions – depends on dog size) = 0.5 to 10 fluid ounces = 15 to 296 ml

Assume density = 1 g/ml

Therefore, quantity applied = 0.0074 to 0.15 g

Assume discharge from one pet washing is a "slug" flowing from pet wash water to POTW. Collection system and publically owned treatment works (POTW) removal efficiencies vary, so estimate 3 reduction levels to bracket the real reduction between point of discharge to the sewer and wastewater effluent:

Reduction	Quantity in effluent
50%	0.0037 to 0.075 g
90%	0.00074 to 0.015 g
95%	0.00037 to 0.0075 g

From EPA risk assessment:

Lowest acute aquatic LC50 (fresh water invertebrate) = 0.493 ng/L (*H. azteca*)

Reduction of bioavailability due to organic material in effluent is unknown and therefore is not accounted for in these rough calculations.

Estimate amount of diluting (bifenthrin-free) water necessary to reduce the bifenthrin concentration from a single pet shampoo discharge to the H. azteca LC50, using the quantities in table above.

Quantity in Effluent from single dog shampoo event	Amount of diluting water necessary to achieve concentration = 0.5 ng/L
0.00037 g	0.74 million liters (0.2 MG)
0.00074 g	1.5 million liters (0.4 MG)
0.0037 g	7.4 million liters (2 MG)
0.0075 g	15 million liters (4 MG)
0.015 g	30 million liters (8 MG)
0.075 g	150 million liters (40 MG)

MG = million gallons

In half of the combinations of pet size and bifenthrin reductions above, >2 million gallons of dilution are required for one pet-washing event to reach effluent concentrations below the *H. azteca* LC50. According to EPA's 2008 Clean Water Act Needs Survey (see table below) [2], more than half of California POTWs have flows of 1 million gallons per day or less. While the above effluent concentration estimates do not account for bioavailability, even if bioavailability reduction due to organics were as high as 50%, they suggest that acute toxicity threshold exceedances from a single pet shampoo event could easily occur at more than half of California POTWs.

California POTWs by Size

Flow, 2008 (MGD)	# POTWs
<1	337
1-9.9	174
10-19.9	30
20-100	22
>100	6
Total	**569**

Source: EPA 2008 Clean Water Act Needs Survey data [2].

2. Ongoing Discharges

The above examines only a single event of pet flea control shampoo use. This is unrealistic, as pet flea control shampoos are used daily, likely on more than one dog a day in any given urban or suburban sewershed. The following equation describes an approach to estimate these discharges:

$$\text{Effluent concentration} = \frac{(\text{f dogs treated/person} * \text{quantity a.i./treatment})}{(\text{treatment frequency in days} * \text{flow/person})} * \text{reduction in system}$$

$$\text{F dogs treated/person} = \frac{\text{dogs}}{\text{person}} * (\text{f dogs receiving flea treatments}) * \text{f flea treatments that are bifenthrin shampoo}$$

Estimates based on this equation are described below. These estimates build on methodologies used in two recent papers exploring wastewater pesticides discharges from pet flea control treatments [3,4].

Fraction dogs treated per person (f dogs treated/person)

Dogs/person
Per capita dog ownership was estimated to be 0.24 dog / person on the basis of the July 1, 2015 US population of 321 million [5] and total US dog ownership of 77.8 million [6].

Fraction (f) dogs receiving flea treatments
An estimated 75% of pet owners use flea/tick treatment products [7].

Together, the above values suggest that it is reasonable to estimate that in the US there are about 0.18 dogs receiving flea/tick treatment products / person.

Fraction (f) flea treatments that are bifenthrin shampoo
The fraction of these dogs receiving bifenthrin shampoos is unknown, so a range of estimated use fractions (from 0.5% to 5%) is explored to explore the overall potential contribution of this product to bifenthrin levels in POTW effluent. This relatively low range of use fractions was selected in recognition of data suggesting that there are many other products on the market [4].

Treatment frequency in days

Based on product label directions, the treatment frequency is assumed to be 30 days, as label instructions direct users to reapply once every 30 days. In other words, it is assumed that each day, 1 dog out of every 30 dogs in the bifenthrin-shampoo treated dog population receives its bifenthrin shampoo treatment.

Quantity of active ingredient (a.i.) per treatment
For simplicity, washing a mid-sized dog (e.g., Labrador retriever) was assumed. The quantity applied for this washing was estimated based on label instructions (5 oz. product used) and the assumptions above (see page 1) to be 0.075 grams/wash.

Wastewater flow per person

Both California and Texas estimate average daily water use at 230 L per capita [8]. This value is used, even though it may overestimate dilution somewhat because it includes outdoor water use (though this is minimal in the January California rainy winter season data that are the basis of the California usage estimate.) To be conservative, we assume no further dilution, as would be the case in dry weather (limited infiltration/inflow) and assume the POTW receives only residential flow, i.e., that the additional potential dilution from non-residential activities is unavailable.

Reduction in system

Pyrethroids reductions in collection systems and POTWs vary, so 3 estimated reduction levels (50%, 90%, 95%) were used to bracket the real reduction between point of discharge to the sewer and wastewater effluent.

Estimates and Evaluation

Rather than calculate a single estimate of effluent bifenthrin concentrations associated with bifenthrin pet flea shampoo use, this approach provides a range of values to characterize the range of potential effluent concentrations. The lines in the figure below show estimated bifenthrin effluent concentrations at the three reduction fractions 50%, 90%, and 95%. The estimated fraction of applied dog flea treatments that are bifenthrin shampoo (i.e., market fraction) is on the X axis.

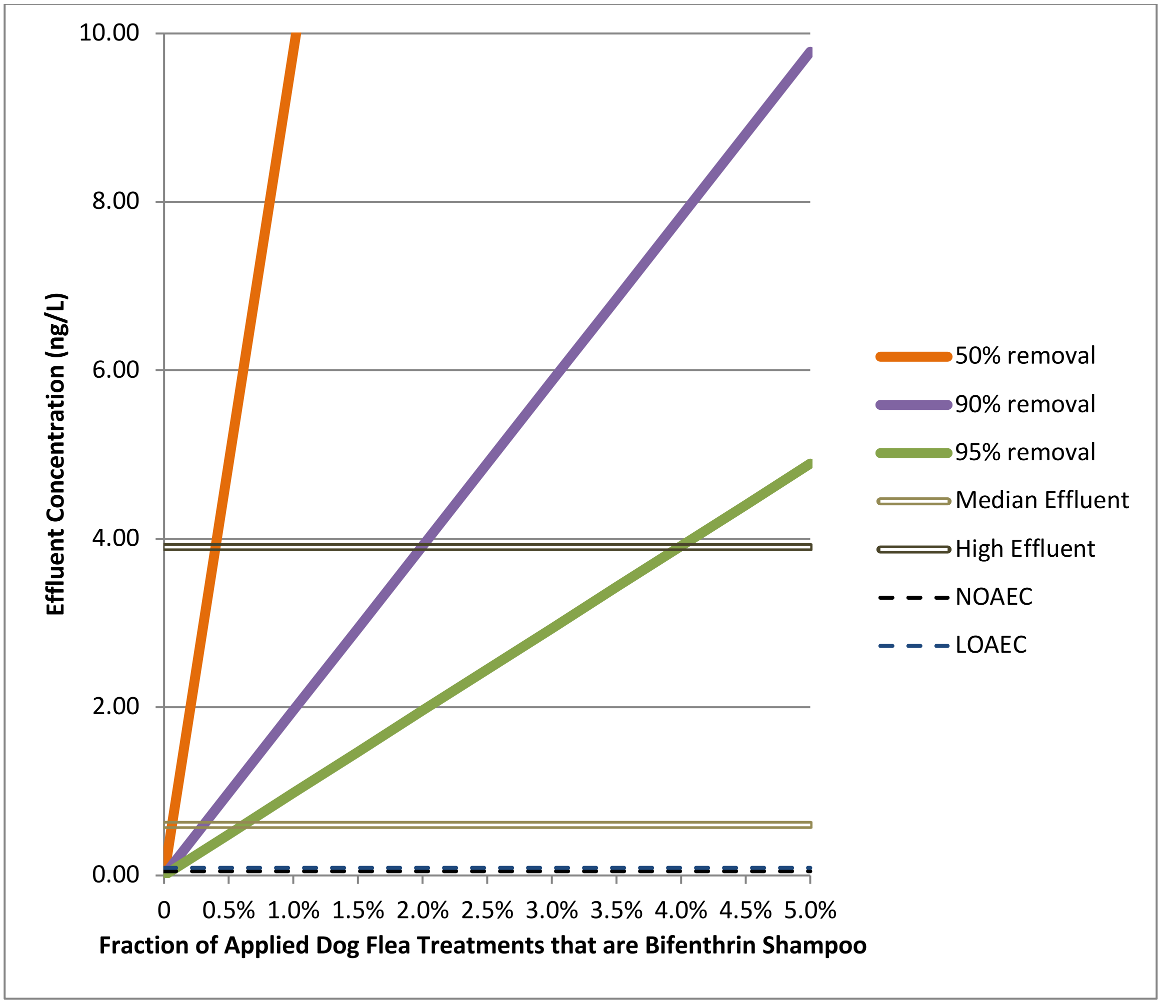


Figure 1. Comparison among effluent concentrations estimated as a function of removal fraction and bifenthrin pet flea shampoo market fraction. For reference, the graph shows wastewater monitoring (parallel lines) from Markle et al. 2014 [9] and chronic reference values from the PRA (LOAEC and NOAEC for freshwater invertebrates).

At the lower end of the range finding estimates (market fraction <1%), the estimated effluent concentrations are in the range of concentrations reported in the literature. For example, Markle et al. (2014) [9] reported bifenthrin detections in 51/62 effluent grab samples, with a highest concentration of 3.9 ng/L, average of 0.89 ng/L, and a median concentration of 0.6 ng/L. Bifenthrin has relatively few indoor uses. None of bifenthrin's indoor uses except the pet flea shampoo product entail direct discharge of the product to the sewer system. As such, it would be unsurprising if this single product were the primary bifenthrin discharge source.

As noted in BACWA's comments, a significant fraction of POTW discharges receive zero or near zero dilution for at least part of the year, such as those occurring in effluent dominated streams and estuaries. Recognizing this and the fact that these are continuous discharges (shampoos happen daily and POTW discharges are continuous), the effluent concentration are compared directly to the most sensitive chronic endpoint values in the PRA: 0.05 ng/L (NOAEC) / 0.09 ng/L (LOAEC) (both values for freshwater invertebrates).

Most of the range-finding estimates are significantly higher than the chronic toxicity endpoints, suggesting that continuous effluent discharges from POTWs are likely to contain bifenthrin from pet flea shampoo at concentrations above these chronic toxicity levels. While this comparison does not account for bioavailability, even if bioavailability reduction due to organics were as high as 50%, the comparison suggests that chronic toxicity threshold exceedances are likely in effluents and in effluent dominated surface waters.

References

[1] Sergeant's Master Label, Dog Shampoo, EPA Registration # 2517-138, dated Jan. 16, 2014; EPA approved April 8, 2015.
[2] US EPA. 2008 Clean Water Act Needs Survey.
[3] Sadaria, A.M. et al. (2016). 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.
[4] Teerlink, J. et al. (2017). "Fipronil washoff to municipal wastewater from dogs treated with spot-on products." *Sci. Tot. Environ*. **599-600**: 960-966.
[5] US Census Bureau. 2016. American Fact Finder. Monthly Population Estimates for the United States: April 1, 2010 to December 1, 2016. July 1 2015 Population Estimate, US resident population.
[6] American Pet Products Association (APPA). 2015. 2015-2016 APPA National Pet Owners Survey. 660 p.
[7] Puro G. 2015 Packaged Facts: Pet Medications in the US, 4th Edition. 159 p.
[8] California State Water Board, 2016. California water usage data portal: http://www.waterboards.ca.gov/water_issues/programs/conservation_portal/conservation_reporting.shtml; values are January data, which are during the rainy season in California's Mediterranean climate; Hermitte, S.M. and Mace, R.E. (2012). *The Grass Is Always Greener…Outdoor Residential Water Use in Texas*. Texas Water Development Board, Technical Note 12-01.
[9] Markle, J.C., van Buuren, B.H., Moran, K.D., Barefoot, A.C., 2014. Pyrethroid pesticides in municipal wastewater: A baseline survey of publicly owned treatment works facilities in California in 2013. Pyrethroid Working Group.