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.

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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."

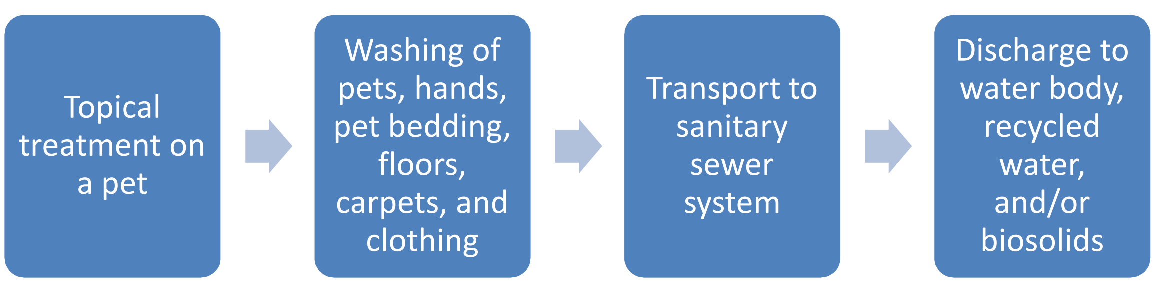
The limited available environmental fate and toxicity data characterizing the un-assessed pyrethroids suggests that they tend to be less persistent than the PWG pyrethroids and that some of them might be less toxic to sensitive organisms than the PWG pyrethroids. These differences could provide an important 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

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[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

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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:

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Respectfully Submitted,

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Enclosures:

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3. Halos, L. et al. (2014). Flea Control Failure? Myths and Realities. *Trends in Parasitology*, 30:5 228-233.
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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.
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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.
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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

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[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

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[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]

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[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

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[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) Assume Zero Dilution

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) Improve POTW Removal Estimates

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.

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[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.

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[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.

Appendix 4
Rough Bifenthrin Shampoo Influent Load Calculation

Information from product label:

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

Assume density = 1 g/ml

Therefore, Quantity applied = 0.75 to 15 g

Assume discharge is a "slug" flowing from pet wash water to POTW. Collection system + POTW removal efficiencies vary, so estimate 3 reduction levels to bracket real value:

Reduction	**Quantity in effluent**
50%	0.375 to 7.5 g
90%	0.075 to 1.5 g
95%	0.0375 to 0.75 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.

POTW flows depend on POTW size and service area characteristics, so there is no way to estimate dilution generically.

Instead, 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**
0.0375 g	75 million liters (20 MG)
0.075 g	150 million liters (40 MG)
0.375 g	750 million liters (200 MG)
0.75 g	1,500 million liters (400 MG)
1.5 g	3,000 million liters (800 MG)
7.5 g	15,000 million liters (4,000 MG)

MG = million gallons

Only a small portion of the nation's POTWs exceed 20 MG flow in an entire day. While these estimates do not account for bioavailability, even if bioavailability reduction due to organics were as high as 50%, they suggest that LC50 exceedances are likely.