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U.S. Environmental Protection Agency (U.S. EPA)
1200 Pennsylvania Ave., NW.
Washington, DC 20460–0001

Subject: Spinetoram Draft Risk Assessment, Case # 7448 (Docket ID Number EPA–HQ–OPP–2011–0666)

Dear Mr. Johnson:

On behalf of the Bay Area Clean Water Agencies (BACWA), we thank you for the opportunity to comment on the draft risk assessment for spinetoram, a pet flea control pesticide.

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. We are concerned about discharges of pesticides into wastewater systems that may compromise compliance with NPDES permit requirements, effluent and recycled water quality, and biosolids reuse.

BACWA is especially interested in pesticides, like pet flea control products, that are used in manners that have transport pathways to the sanitary sewer. OPP has historically omitted evaluation of risks associated with pesticide discharges to the sewer system. Omitting evaluation of the sewer discharge environmental exposure pathway 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 water, recycled water and/or biosolids reuse, in addition to exposing POTWs to the potential for third party lawsuits under the Clean Water Act.

Spinetoram appears to be the first of many spot-on topical pesticides for companion animals that U.S. EPA is considering in its Registration Review process. The primary purpose of this letter is to request evaluation of sewer discharges from cat spot-on treatments in the spinetoram ecological risk assessment and in all future ecological risk assessments for pet spot-on treatments. We also summarize information about the transport of pet spot-on pesticides to the sanitary sewer and provide our recommendations for POTW "down-the-drain" modeling refinements for pet spot-on discharges.

BACWA's Interest in Spinetoram and Other Pet Spot-On Treatments

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Spinetoram is used as a topical spot-on treatment for flea control on cats. Spot-on treatment has become a common method of flea control.[1] According to the U.S. Census Bureau, there are 0.27 cats per capita in the US.[2] Industry market data indicate that 75 percent of pet owners use a pet flea control treatment.[3] BACWA member agencies recently participated in a scientific study conducted by the San Francisco Bay Regional Monitoring Program that identified two pet flea control pesticides with otherwise limited indoor use (fipronil and imidacloprid) in wastewater influent, effluent, and biosolids, and suggested that spot-on products may be their primary source.[4]

Spinetoram is persistent in aquatic ecosystems and highly toxic to aquatic invertebrates. According to U.S. EPA's ecological risk assessment of outdoor uses,[5] due to spinetoram's persistence, U.S. EPA anticipates spinetoram concentrations to increase continually in aquatic ecosystems (Executive Summary), with the greatest risk to sediment-dwelling organisms (aquatic toxicity data summary table, page 27).

Pet Spot-On Transport to Sanitary Sewer

In 2012, Bigelow Dyk et al. published a study that presents evidence of transport of a pet spot-on treatment through homes.[6] 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 degradates. The measured transfer of the spot-on pesticide from the pet and subsequent washing of hands, socks, and other indoor surfaces, readily explains the entire influent fipronil load at San Francisco Bay Area POTWs.[7] 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.

Given that the spinetoram and fipronil products are applied in the identical manner and are

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[1] A BACWA market review identified the following active ingredients in pet spot-on flea and tick control products: cyphenothrin, etofenprox, fipronil, imidacloprid, indoxacarb, S-methoprene, pyriproxyfen, permethrin, selamectin, and spinetoram.

[2] 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.

[3] Puro G. (2015) Packaged Facts: Pet Medications in the US, 4th Edition.

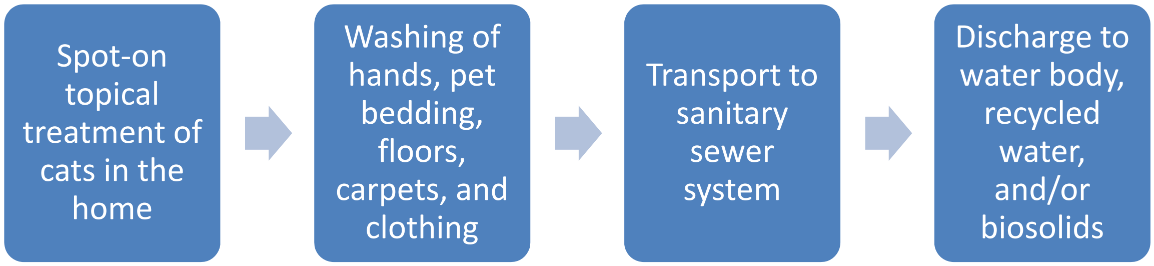
[4] Sadaria, A.M. (2016). Passage of Fiproles and Imidacloprid from Urban Pest Control Uses Through Wastewater Treatment Plants in Northern California. *Environmental Toxicology and Chemistry*. (In press).

[5] US EPA (2016). Preliminary Environmental Fate and Ecological Risk Assessment for the Registration Review of Spinetoram.

[6] 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

[7] 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*. (In press).

comprised of comparable mass of active ingredient, this implies that the spinetoram spot applications also have transport routes in the home that provide a direct route to the POTW (see graphic).



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 California Department of Pesticide Regulation and Arizona State University.[8] The study, which is enclosed, monitored imidacloprid and fipronil as well as its degradates at the influent and effluent of eight urban California POTWs. The results indicated that fipronil, its degradates, and imidacloprid were ubiquitous in both the influent sewage and final treated effluent, and suggested that spot-on products may be the primary source of both chemicals in wastewater.

BACWA Requests Evaluation of Cat Spot-On Treatments in Ecological Risk Assessment

While not specific to spinetoram, the San Francisco Bay Regional Monitoring Program study provides proof that pathways to the sanitary sewer exist for pet spot-on products, and therefore require analysis in EPA's risk assessments. U.S. EPA's spinetoram ecological risk assessment did not address indoor spinetoram use. Pet spot-on treatments are apparently the sole indoor use. According to the ecological risk assessment:

> "*The spot treatment on cats is considered de minimis exposure to the environment and will not be considered further in this assessment*" (Use Characterization, page 8).

While this assumption is standard practice for OPP,[9] now that scientific data have demonstrated that aquatic exposures from pet spot-on treatments are not de minimis, BACWA requests that EPA revise its ecological risk assessment to include evaluation of sewer discharge-related risks from such pet treatments. If significant risks are identified, we request that U.S. EPA OPP consider risk mitigation options.

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

Because 100% of POTWs must comply with the Federal Clean Water Act 100% of the time, it is imperative to avoid underestimating pesticide discharge risks. To do so includes addressing both fresh and salt water discharges and modeling of a reasonable worst case – not average

[8] Sadaria, A.M. (2016). Passage of Fiproles and Imidacloprid from Urban Pest Control Uses Through Wastewater Treatment Plants in Northern California. *Environmental Toxicology and Chemistry*. (In press).
[9] BACWA teleconference meeting with Pesticide Reevaluation Division, Environmental Fate and Effects Division, and Biological and Economic Analysis Division staff, January 20, 2016.

conditions. As this is the first risk assessment of a spot treatment, the discussion below is relevant to spinetoram as well as future pet spot-on flea treatment products.

U.S. EPA OPP uses the “down-the-drain” module from the E-FAST model to estimate surface water concentrations associated with wastewater pesticide discharges. BACWA recommends the following refinement for the modeling of indoor use of spot-on treatments 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 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) <u>Adjust Consumer Product Discharge Estimates to Reflect Geographic and Seasonal Use</u>

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 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 even throughout the year and across the nation – there are specific geographic areas and seasons for which there is more use of the product.

For instance, while veterinarians typically recommend regular monthly dosing of spot-on treatments, consumers often seek spot-on treatments upon identifying a flea outbreak. 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.

2) <u>Update Per Capita Water Use to Account for Conservation</u>

The overall daily water use in a household dilutes the concentration entering the sanitary sewer. The water use default in the E-FAST DTD model appears to be significantly greater than currently observed flows 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). BACWA recommends that U.S. EPA consider using 5th or 10th percentile per capita flows to be sufficiently conservative in the model analysis.

Location	Per Capita Daily Water Use (Liters)	Source
E-FAST DTD Model	364 (original) 388 (current)	1990 and 1996 U.S. EPA POTW surveys[10]
California, January 2016 (includes outdoor uses)	230 (statewide) <190 (many cities)	California State Water Board[11]
Texas, 2012	230	Texas Water Development Board[12]

3) Assume Zero Dilution

The 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."[13] 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.[14] 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, pesticide removal rate is 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. Because it is unlikely that POTWs currently have data influent and effluent data for spinetoram, one approach would be to use the EPI Suite model, as a predictive tool of percent removal, developed by the Office of Pollution Prevention and Toxic Risk Assessment Division and Syracuse Research Corporation.

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

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[10] 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.

[11] 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.

[12] 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.

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

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

Given the findings in the Draft Risk Assessment that spinetoram is persistent and likely to partition into sediment, 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 product.

BACWA Requests Benefits Assessment Consider Alternatives to Spot-On Insecticides for Pet Flea Control

Since FIFRA is a risk-benefit statute, OPP is required to consider risk mitigation options in the context of the benefits of pesticide use. BACWA requests that for pet flea control products, OPP conduct this examination in the context of available non-pesticide alternatives. Although pet spot-on products currently dominate the flea control market, new pill form products have recently become available. The new pills, which are registered by FDA rather than EPA, appear to eliminate aquatic (and human) exposure pathways and should be equally or more convenient for pet owners. Non-pesticide mechanical controls, such as frequent indoor vacuuming and washing of pet bedding are another alternative (and may be key to effectively overcoming any flea infestation,[15] because the fleas found on one's pet are estimated to represent only 1-5% of the flea cycle in a home; the other 95% are found as eggs, larvae, pupae, and adult fleas throughout the home and surrounding environment.[16].

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:
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*. (In press).

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

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.

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