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August 5, 2020

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Pesticide Reevaluation Division (7508P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW
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OPP Docket
Environmental Protection Agency
Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Attention: EPA-HQ-OPP-2011-0448: Fipronil (Case 7423)

RE: Pesticide Registration Review:
Draft Human Health and/or Ecological Risk Assessments for Several Pesticides (Fipronil)

Dear Mr. Stanton:

On May 4, 2020, the U.S. Environmental Protection Agency (EPA) published a notice of availability of draft risk assessments for fipronil.[1] The Attorney General of California has reviewed the draft risk assessments and submits these comments to the regulatory docket.[2]

EPA's draft ecological and human health risk assessments for fipronil contained several problematic data gaps and inconsistencies. First, the draft assessments recognize that fipronil is polluting California's urban waterways, but they fail to analyze why the pollution is occurring or how fipronil pollution in urban waterbodies affects the broader environment. Second, the assessments fail to acknowledge scientific evidence provided to them by California state agencies indicating that fipronil is contaminating wastewater and sewage treatment plants in the state. Finally, the assessments make inconsistent statements about the human health risks associated with fipronil, appearing to conclude that fipronil products pose immitigable risks to

[1] EPA-HQ-OPP-2011-0448-0070

[2] The Attorney General submits these comments pursuant to his independent power and duty to protect the environment and natural resources of the State of California. (See Cal. Const., art. V, § 13; Cal. Govt. Code, §§ 12511, 12600-12; *D'Amico v. Board of Medical Examiners* (1974) 11 Cal.3d 1, 14-15.)

infants, while also dismissing 15 years' worth of troubling incidents involving severe human reactions to the same products. Per the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is required to conduct additional investigation and analyses to resolve these data gaps and inconsistencies before proceeding further with fipronil registration review.

I. Pesticide Registration Under FIFRA

All pesticides must receive regulatory approval before their use.[3] EPA registers pesticides pursuant to FIFRA, which includes several registration requirements. Most relevant here, EPA cannot register a pesticide unless it determines that the pesticide "will perform its intended function without unreasonable adverse effects on the environment."[4] This requirement is crucial to ensure that pesticides do not cause unreasonable harm to public health or the environment when used as directed and in accordance with label instructions.

EPA must reevaluate pesticide registrations every 15 years.[5] As part of registration review, EPA releases updated risk assessments evaluating the pesticide's impacts on public health and the environment.[6] These documents form the basis for EPA's analysis of whether the pesticide will cause unreasonable adverse effects on the environment.

II. Impacts of Fipronil in California

A. Fipronil Usage in California

Fipronil is an insecticide that is designed to control a broad variety of insect pests such as cockroaches, fleas, mites, and termites. Although it was developed for both agricultural and non-agricultural uses, fipronil is not registered for crop use in California.[7] The California Department of Pesticide Regulations (CDPR) describes fipronil usage in California as comprised primarily of structural treatments for termites, roaches, and ants, and of pet treatments for fleas and ticks.[8]

According to CDPR, fipronil products come in three main types of products in California: structural pest control products, dog and cat pest control products, and turf products.[9] Liquid concentrate structural applications accounted for the vast majority of fipronil use in California

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[3] 7 U.S.C. § 136a(a).

[4] 7 U.S.C. § 136a(c)(5)(C)-(D).

[5] 40 C.F.R. § 155.40(a).

[6] 40 C.F.R. § 155.53.

[7] CDPR, "Problem Formulation Document – Fipronil," February 9, 2017, p. 10, *available at* https://www.cdpr.ca.gov/docs/risk/rcd/fipronil.pdf ("CDPR 2017 Problem Formulation").

[8] *Id.* at p. 2.

[9] *Id.* at pp. 4-6.

with over 95% of fipronil use in the state being accounted for in these products, which are commonly used to control termites, ants, and spiders.[10]

Pet pest control products are used by professional pet groomers, veterinarians, and private pet owners. The products come in two types of applications: spot-on and spray. Spot-on products require the applicator to squeeze a tube of liquid onto the back skin of the pet, while spray products require applicators to spray the product using hand-triggered containers while simultaneously ruffling the pet's fur.[11]

B. Water Quality Impacts of Fipronil

Fipronil's impact on water quality has given California state agencies cause for concern. The California State and Regional Water Quality Control Boards (California Water Boards) have identified water quality impacts from fipronil in both urban surface waters and in wastewater and sewage treatment streams.

The California Water Boards provided extensive comments on EPA's May 2011 Preliminary Problem Formulation regarding fipronil's impacts to surface water quality in urban watersheds. Specifically, the California Water Boards explain that although fipronil was a relatively new pesticide in 2011, it was frequently detected in urban surface water samples at levels above aquatic life toxicity benchmarks and may be harmful to sediment-dwelling organisms.[12] The California Water Boards encouraged EPA to use more accurate impervious area runoff models, contending that the model used by EPA "most certainly underestimates the mass of pesticide runoff in urban areas."[13] The California Water Boards emphasized that adverse impacts to water quality from fipronil exposure were overwhelming state and local water quality agencies, and urged EPA to evaluate fipronil more thoroughly in order to prevent fipronil from precipitating "another major pesticide water quality problem."[14]

A July 2013 report confirms that fipronil contamination is a water quality problem in California.[15] The report, prepared for the California Stormwater Quality Association (CASQA),

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[10] *Id.* at p. 4.

[11] *Id.* at p. 5.

[12] California Regional Water Quality Control Board, San Francisco Bay Region, Comments on Fipronil Registration Review, August 26, 2011, p. 2, Docket ID No. EPA-HQ-OPP-2011-0448-0020.

[13] *Id.* at p. 3.

[14] California Regional Water Quality Control Board, Central Valley Region, Comments on Fipronil Registration Review, August 26, 2011, pp. 1-2, Docket ID No. EPA-HQ-OPP-2011-0448-0031, at p. 1.

[15] Armand Ruby Consulting, "Review of Pyrethroid, Fipronil and Toxicity Monitoring Data from California Urban Watersheds," prepared for CASQA, July 10, 2013.

summarized water quality data from monitoring performed in California urban water bodies for the years 2003 to 2012. Fipronil was detected in 39% of the water quality samples and in 19% of the sediment samples, while fipronil degradates were detected in 24% of the water quality samples and in 35% of the sediment samples. In total, fipronil or fipronil degradates were detected in over 3,200 samples reviewed by the report, including 871 water samples, and the average concentrations of fipronil in these samples were over eight times higher than EPA's aquatic life benchmarks for the pesticide.[16] The report further indicated that fipronil and its associated toxic impacts are present within urban watersheds throughout the state. [17]

The California Water Boards also note that fipronil is also presenting a problem for wastewater treatment plants (WWTPs) in California, which manage wastewater and sewage treatment. A 2017 study examined the presence of fipronil in eight San Francisco-area WWTPs during drought conditions and fipronil was detected in all eight WWTPs, both within wastewater and within sludge.[18] For indoor uses of fipronil, the study explained that post-application activities associated with fipronil pet products, such as bathing the treated pets, washing hands, and wet-mopping indoor areas, provided indirect transport pathways for fipronil to enter the waste treatment system. For outdoor uses of fipronil, the study noted that fipronil could enter waste treatment systems when traces of fipronil products are brought indoors by animals and human applicators and are then washed away into the system.[19]

The study's review suggests that pet flea treatments could be the chief contributor of fipronil to WWTPs. Indeed, the study cites to earlier reports finding that while fipronil was practically ubiquitous in indoor residential dust, it was found in concentrations over 20 times higher in homes with fipronil-treated pets than in those without fipronil-treated pets.[20] Finally, while the data shows that fipronil is being discharged through wastewater streams and WWTPs, the study observes that existing WWTP technology is unable to significantly treat or remove fipronil in wastewater or sludge.[21] Indeed, if the fipronil in waste treatment facilities is occurring at the same average concentrations as it was in the water quality samples analyzed in the CASQA report discussed above, this fipronil contamination is likely violating water quality objectives associated with wastewater discharges. This is a concern not only for the public and private WWTPs all over California who are required to eliminate discharges that are toxic to aquatic life pursuant to state and federal laws, but also for jurisdictions in the state who are exploring

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[16] *Id.* at pp. 11-12.

[17] *Id.* at p. 13.

[18] Sadaria, A.M. et al. 2017. Passage of Fiproles and Imidacloprid from Urban Pest Control Uses Through Wastewater Treatment Plants in Northern California, USA. *Environmental Toxicology and Chemistry* 36 (6), pp. 4-5.

[19] *Id.* at p. 7.

[20] *Id.* at pp. 7-8.

[21] *Id.* at p. 8, 9.

projects to recycle their wastewater into drinking water.[22]

CDPR has also observed the prevalence of fipronil in wastewater treatment streams. A 2017 study found that fipronil residues from routine bathing of treated pets could be detected in wastewater systems up to 28 days after application.[23] Moreover, a 2018 study confirmed that pet spot-on treatments are a source of fipronil in wastewater, and that fipronil and its degradates are frequently detected in treated wastewater at concentrations of toxicological concern to non-target aquatic organisms.[24]

In sum, fipronil poses concerns to California's urban watersheds, its municipal storm water systems, and its wastewater treatment facilities. Moreover, the issues being encountered in California are indicative of larger concerns nationwide regarding fipronil's effects on the environment and waste treatment infrastructure. These concerns not only present threats to aquatic organisms and receiving waters, but they also burden waste treatment facilities in the state, many of which are publicly operated, with significant liabilities and costs. It is therefore essential that the water quality problems caused by fipronil, and the risks they pose, be adequately analyzed as part of EPA's registration review for the pesticide. As discussed below, EPA did not conduct a sufficient analysis of these issues in their March 2020 draft Ecological Risk Assessment.

C. Health Concerns Relating to Fipronil Exposure

EPA's March 2011 Review of Human Incidents described a troubling 15-year history of severe human health incidents associated with fipronil exposure, including reports of convulsions, seizures, comas, renal failure, blindness, and, in one case, death.[25] The vast majority of the incidents involved pet pest control products.[26] EPA observed that the incidents appeared to be declining over time, and although it did not explain this trend, it conceded that the health

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[22] The study notes "although most of the source waters…related to the present study are essentially free of…treated wastewater influences…the same cannot be said for the water supplies of many other regions." *Id.* at p. 9. See also, e.g., https://www.sandiego.gov/public-utilities/sustainability/pure-water-sd

[23] Teerlink, J., J. Hernandez and R. Budd. 2017. Fipronil Washoff to Municipal Wastewater from Dogs Treated with Spot-On Products. Sci. Total Environ. 599: 960-966.

[24] Sutton, R., Y. Xie, K.D. Moran and J. Teerlink. 2018. Occurrence and Sources of Pesticides to Urban Wastewater and the Environment. Pesticides in Surface Water: Monitoring, Modeling, Risk Assessment, and Management. ACS Symposium Series, American Chemical Society: Washington, DC, Vol. 1308. Chapter 5.

[25] Fipronil: Review of Human Incidents, EPA-HQ-OPP-2011-0448-0005, at p. 3, Appendix 1 ("EPA Review of Human Incidents").

[26] *Id.*

effects of fipronil warranted further investigation.[27] After reviewing the same incident history, CDPR also concluded that further investigation of fipronil was warranted.[28]

As discussed below, EPA's draft human health risk assessment dismisses fipronil's troubling incident history, concluding after performing additional epidemiology studies that there is insufficient evidence of a causal or associative connection between fipronil and the health effects observed in the incidents. EPA's analysis in the draft human health risk assessment, however, is inconsistent and contradictory about the human health risks presented by fipronil, and it fails to resolve these inconsistencies sufficiently.

III. EPA's Draft Risk Assessments

EPA's draft risk assessments of fipronil contain problematic data gaps, insufficient analyses, and inconsistent conclusions. The risk assessments fail to establish that fipronil will not have an unreasonable adverse effect on the environment, as required by FIFRA. We urge EPA to undertake additional investigations to address fipronil's potential effect on water quality and human health prior to registering the pesticide.

A. EPA's Draft Ecological Risk Assessment Fails to Adequately Analyze Fipronil's Impacts on Urban Watersheds and Waste Treatment Facilities.

EPA's March 2020 Ecological Risk Assessment (Ecological Assessment) suffers from insufficient analysis regarding fipronil pollution of urban water bodies and contamination of water treatment facilities. The Ecological Assessment acknowledges the water quality concerns raised by the California Water Boards, and discusses monitoring evidence from CDPR demonstrating widespread fipronil pollution of urban water bodies across California.[29] However, the Ecological Assessment does not analyze these findings further. For instance, no analysis is provided as to how this data affected EPA's risk conclusions, how indoor fipronil pet products might be polluting urban waterbodies, and what effects on the environment might be expected from persistent fipronil pollution of urban water bodies. Moreover, the Ecological Assessment fails to analyze whether there are any measures that would resolve these problems.

Additionally, although the California Water Boards notified EPA that fipronil is being transported into and contaminating wastewater facilities, and have provided scientific evidence to EPA documenting this problem, the Ecological Assessment fails to even mention, discuss, or

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[27] *Id.* at p. 1.

[28] CDPR 2017 Problem Formulation, at pp. 1-2.

[29] Fipronil: Draft Ecological Risk Assessment for Registration Review, EPA-HQ-OPP-2011-0448-0071, at pp. 45-46. The Ecological Assessment observed that CDPR collected over 500 water quality samples across California from 2008 to 2013. The data showed fipronil in 49% of the samples, while fipronil degradates were present in 33%-43% of the samples. Moreover, 15% of the samples contained levels of fipronil that exceeded EPA's acute aquatic life toxicity benchmarks, and 48% of the samples exceeded EPA's chronic aquatic life toxicity benchmarks.

analyze fipronil's exposure to and impacts on these facilities.[30] Fipronil contamination of the waste treatment stream exacerbates risks to aquatic organisms and imposes significant regulatory costs on California public agencies.[31] This risk could be compounded further if the jurisdictions in California considering projects to convert wastewater into drinking water proceed with their plans – in such a scenario, the risks of adverse human health effects from fipronil exposure could be significant. Given the prevalence of fipronil observed in California's waste treatment systems, and the probable association of that contamination with fipronil-based pet products, this exposure pathway presents too many potential risks to human health and the environment to ignore.[32]

EPA's Ecological Assessment has failed to analyze the risks posed to urban waterbodies by fipronil pollution, and it has failed to gather evidence and analyze fipronil's transport into and contamination of waste treatment facilities. Therefore, it has failed to meaningfully review the potential environmental risks posed by fipronil pursuant to FIFRA. Accordingly, EPA should not proceed with registration of fipronil until it adequately investigates and resolves these data gaps and analytical omissions.

We understand that the California Water Boards and CDPR are submitting their own comments on the Ecological Assessment. The California Water Boards request in their comments that EPA devise a plan that addresses pet product fipronil in wastewater, that EPA conduct assessments for fipronil discharges to the sewer system from pet flea control products and other indoor-use treatments, and that EPA evaluate alternatives to fipronil pet flea control products. CDPR likewise requests that EPA include pet products in down-the-drain modeling scenarios and future risk characterizations for fipronil, that EPA add an analysis of rainy season applications to their risk evaluations, and that EPA clarify its impervious surface models and use updated urban waterway monitoring data. We echo those comments and requests.

B. <u>EPA's Draft Human Health Risk Assessment Makes Contradictory Conclusions regarding the Human Health Risks Associated with Fipronil.</u>

EPA's draft human health risk assessment (Health Assessment), in turn, is inconsistent in its analysis of the human health risks posed by fipronil pet products. Notwithstanding the 15-year history of severe health incidents implicating fipronil pet products, EPA's Health Assessment dismisses the health risks associated with these products. The Health Assessment's discussion of fipronil's incident history is relegated to two pages at the end of the document, where EPA

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[30] California Regional Water Quality Control Board, San Francisco Bay Region, Comments on Imidacloprid Registration Review, July 24, 2017, pp. 3-5 (discussing Sadaria, et al, *supra*), Docket ID No. EPA-HQ-OPP-2008-0844-1223.

[31] California Regional Water Quality Control Board, Central Valley Region, Comments on Fipronil Registration Review, August 26, 2011, pp. 1-2, Docket ID No. EPA-HQ-OPP-2011-0448-0031, at p. 1.

[32] Sadaria, et al., *supra*.

explains that the incident history prompted it to perform additional epidemiology evaluations in 2019.[33] EPA's epidemiology study found that the most-often reported exposure was from in-home pet treatment use, and the most common health effects involved neurological, dermal, ocular, and respiratory symptoms. However, EPA concludes, "there was insufficient evidence to suggest a clear associative or causal relationship exists" between fipronil exposure and the health outcomes observed in the incidents.[34]

EPA's conclusion is inconsistent with its other conclusions in the same Health Assessment document. Specifically, the Health Assessment finds that fipronil poses risks of concern for chronic residential post-application exposure.[35] EPA determined that the risk to infants and toddlers from chronic post-application exposure to pets treated with fipronil products was so great that it remained a concern even after expanding that exposure across a 28-day time span.[36] Accordingly, EPA concedes, "a safety finding could not be made for purposes of the chronic aggregate risk assessment at this time given the risks of concern identified in the individual chronic dietary and long-term residential scenarios."[37] It is unclear how EPA can find no causal or associative relationship between fipronil exposure and adverse health effects, but simultaneously conclude that fipronil poses severe and immitigable health risks to infants and toddlers. Either EPA believes that the risks to children from fipronil pet products are minor and unsubstantiated, or it believes that the risks to children are significant. EPA, however, seems to conclude that both are simultaneously true.

EPA's Health Assessment has inconsistently analyzed the risks posed to humans from fipronil-based pet products, and the Health Assessment provides contradictory conclusions on the issue. EPA fails to explain how it reconciles its conclusion that there is no causal or associative connection between fipronil pet products and adverse health impacts with its conclusion that fipronil pet products pose serious risks to infants and toddlers. As such, the public is left to speculate as to EPA's reasoning, and EPA has failed to demonstrate that it has meaningfully reviewed the potential human health risks posed by fipronil pursuant to FIFRA. Therefore, EPA should not proceed with registration of fipronil until it adequately resolves these analytical inconsistencies and contradictions.

IV. Conclusion

The federal courts have ruled that EPA may not register pesticides using flawed or incomplete data, or while underestimating the risks posed by the pesticide to the environment

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[33] Fipronil: Draft Human Health Risk Assessment for Registration Review, EPA-HQ-OPP-2011-0448-0076 ("Health Assessment"), at pp. 81-82.

[34] *Id.* at p. 82.

[35] *Id.* at pp. 9, 52-55.

[36] *Id.* at pp. 9, 55.

[37] *Id.* at p. 9.

when used as directed.[38] EPA's draft risk assessments suggest, however, that EPA is proceeding down this path with fipronil.

As demonstrated above, EPA's draft risk assessments are incomplete and lack meaningful discussion of several important fipronil exposure risks. If EPA proposes re-registration of fipronil based on the incomplete and inconsistent draft risk assessments, it may violate FIFRA, which bars registrations that would "cause unreasonable adverse effects on the environment."[39] We therefore urge EPA to resolve these data gaps and inconsistencies before proceeding further with fipronil registration, and to recirculate revised risk assessments that address these issues for public review and comment. We also echo the comments submitted by the California Water Boards and CDPR, and reiterate the specific requests for additional investigation described in their comment letters.

Sincerely,

/s/ Davin A. Widgerow

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[38] See *Pollinator Stewardship Council v. U.S. E.P.A.* (9th Cir. 2015) 806 F.3d 520; *Nat'l Family Farm Council v. U.S. E.P.A.* (9th Cir. 2020) 2020 WL 2901136.

[39] 7 U.S.C. § 136a(c)(5)(D).