



October 11, 2018

Office of Pesticide Programs
Docket number EPA-HQ-OPP-2013-0226
Environmental Protection Agency Docket Center (EPA/DC)
(28221T)
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001

Re: Comments on EPA's Receipt of Applications for New Uses – Flupyradifurone
Docket #: EPA-HQ-OPP-2013-0226

Please accept the following comments on behalf of the Center for Biological Diversity (“Center”) in response to the Environmental Protection Agency’s (“EPA”) Receipt of Application for New Uses under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) regarding the active ingredient flupyradifurone, proposed for new use on tobacco. As a threshold matter, we believe that this new use should not be allowed as it is likely to cause unreasonable adverse effects on the environment, specifically to pollinators and endangered species. We urge the EPA to carry out required analysis of the effects of flupyradifurone before proceeding with a decision on this application.

As a separate, discretionary action that may affect endangered and threatened species, the EPA cannot approve this new use prior to the completion of consultation, pursuant to Section 7 of the Endangered Species Act (ESA), with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (“the Services”). Without such consultation, on the cumulative and synergistic uses of flupyradifurone, the EPA cannot satisfy its legal duty to insure that its action does not jeopardize the continued existence of imperiled species across the country or adversely modify or destroy their critical habitat. Moreover, unless and until the EPA completes ESA consultation, any taking of protected species from the use of this pesticide is unlawful under Section 9 of the ESA.

Section 7(a)(2) of the ESA requires that “each federal agency *shall*, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary . . . to be critical.”

Under the Services’ joint regulations implementing the ESA, the EPA is required to review its actions “at the earliest possible time” to determine whether the action may affect listed species or critical habitat.¹ Indeed, the EPA’s policy *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes* envisions informal consultations with the Services beginning at the preliminary risk assessment stage.² The EPA must initiate consultation under Section 7 whenever its

¹ 50 C.F.R. § 402.14(a).

² U.S. Environmental Protection Agency 2013, Office of Chemical Safety and Pollution Prevention- Office of Pesticide Programs, *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation*

action “may affect” a listed species or critical habitat.³ The phrase “may affect” has been interpreted broadly to mean that “any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement.”⁴ The EPA must satisfy its ESA Section 7 duties *before* it allows the expanded use of flupyradifurone.

As noted in the attached comments, the Center has repeatedly emphasized these legal obligations to the EPA.⁵ Indeed, the Center is currently involved in litigation challenging the EPA’s failure to engage in ESA consultation prior to registering flupyradifurone. *Center for Biological Diversity et al. v. U.S. Environmental Protection Agency*, D.C. Cir Case No. 15-1054 (filed May 13, 2015). The deficiencies outlined in those comments and litigation remains today and equally apply with EPA’s approval of this new use for flupyradifurone on tobacco. The Center has also provided the attached guidance, *Endangered Species Act Consultation Obligations for Pesticide Approvals by the Environmental Protection Agency*.

The EPA must consult on the adverse effects of the use of flupyradifurone.

Flupyradifurone is a systemic insecticide belonging to the butenolide class of insecticides. Flupyradifurone works by binding with nicotinic acetylcholine receptors, which leads to impaired nerve function and subsequent death.⁶

EPA’s own ecological risk assessment demonstrates that flupyradifurone will cause both acute and chronic adverse effects on listed species:

Acute risk to federally threatened and endangered (listed) species and chronic risk Levels of Concern (LOCs) for freshwater and estuarine/marine invertebrates were exceeded for the majority of proposed uses in this assessment . . . risk estimates exceeded the acute risk to listed birds LOC for all proposed foliar and soil drench uses, as does the proposed seed treatment use⁷

Additionally, the EPA risk assessment found that flupyradifurone is highly toxic to honeybees on an acute oral exposure basis, but did not evaluate the risk to any endangered terrestrial invertebrates.⁸ The EPA risk assessment concludes that acute and chronic harm (which includes potential harm to designated critical habitat) and indirect effects will occur for numerous taxonomic groups that are represented on the list of threatened and endangered species including plants, birds, amphibians,

Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives, Docket ID #: EPA-HQ-OPP-2012-0442-0038 (March 19, 2013) at p. 8

³ 50 C.F.R. § 402.14(a).

⁴ *Western Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2011) (brackets omitted) (quoting 51 Fed. Reg. at 19,949). The threshold for triggering ESA consultation “is relatively low.” *Lockyer v. U.S. Dep’t of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009).

⁵ Center for Biological Diversity 2014, Comments on EPA Proposed Registration of Flupyradifurone as a New Active Ingredient (Docket #: EPA-HQ-OPP-2013-0226) (October 24, 2014); Center for Biological Diversity 2015, Notice of Violations of the Endangered Species Act Regarding Registration of Flupyradifurone (March 16, 2015).

⁶ U.S. Environmental Protection Agency 2014. Environmental fate and ecological risk assessment for foliar, soil drench, and seed treatment uses of the new insecticide flupyradifurone (byi 02960) (hereafter “flupyradifurone risk assessment”). Office of Pesticide Programs Environmental Fate and Effects Division. Docket #: EPA-HQ-OPP-2013-0226-0015.

⁷ Flupyradifurone risk assessment at 6-7.

⁸ *Id.*

reptiles, mammals, fish, and invertebrates, including mollusks.⁹

Because EPA's own analysis for flupyradifurone makes clear that the use of this pesticide "may affect" listed species and "may affect" the critical habitat of listed species, the EPA must consult with the Services prior to approving any additional uses.

Tobacco was harvested from 303,680 acres in 2018 and 321,470 acres in 2017.¹⁰ Tobacco is grown primarily in central and western Kentucky and north-central Tennessee¹¹ as well as south-central Virginia, north and east North Carolina, the northeastern corner of South Carolina, and south-central Georgia.¹² The number of listed species in counties that grow tobacco is numerous, below are the species listed as endangered and threatened (T) in each areas tobacco is grown and that could require consultation.¹³

In Kentucky and Tennessee: Gray bat, Indiana bat, Northern Long-eared bat (T), Cumberland bean pearlymussel, Rayed bean mussel, Clubshell mussel, Fanshell mussel, Pink mucket pearlymussel, Sheepnose mussel, Snuffbox mussel, Rough pigtoe, Orangefoot pimpleback, Rabbitsfoot mussel (T), Ring pink mussel, Kentucky cave shrimp, Spectaclecase mussel, Short's bladderpod plant, Running Buffalo Clover, Short's goldenrod, Braun's rock-creep; In North Carolina, South Carolina, and Virginia: Red knot (T), Yellow Lance mussel, Roanoke logperch, Piping plover, James spiny mussel, Tar River spiny mussel, Wood stork (T), Shortnose sturgeon, Dwarf wedgemussel, Red-cockaded woodpecker, American chaffseed plant, Smooth coneflower, Sensitive joint-vetch (T), Pondberry, Michaux's sumac; and In Georgia: Frosted flatwoods salamander (T), Eastern indigo snake (T), Altamaha spiny mussel.

As listed above, there are several endangered species in areas that tobacco is grown that are likely to be impacted by any new use approval of flupyradifurone on tobacco, particularly the many imperiled freshwater mussels. Like other neonicotinoid-type pesticides, flupyradifurone is highly water-soluble and found in detectable levels in aquatic ecosystems.¹⁴ Independent peer-reviewed articles have found flupyradifurone harms non-target organisms, including aquatic invertebrates and honey bees.

Among pesticides tested, flupyradifurone had the strongest negative impact to aquatic mayfly larvae survival at 1000 µg/L, along with imidacloprid and acetamiprid.¹⁵ Similar to the neonicotinoids clothianidin and dinotefuran, flupyradifurone caused negative alterations in mayfly larvae behavior (namely, caused larvae to leave the protection of their burrows) at 100 µg/L.¹⁶ Thus, sublethal effects occur at much lower doses than lethal effects, showing that testing and reporting on mortality only greatly underestimates the negative impact of flupyradifurone on non-target organisms.

Flupyradifurone also decreased the viability of freshwater mussel larvae at 600 µg/L¹⁷ and caused

⁹ Flupyradifurone risk assessment at 120.

¹⁰ <http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-29-2018.pdf>

¹¹ https://www.nass.usda.gov/Charts_and_Maps/Crops_County/tbu-ha.php

¹² https://www.nass.usda.gov/Charts_and_Maps/Crops_County/tfc-ha.php

¹³ <https://www.fws.gov/endangered/species/index.html>

¹⁴ Prosser, R. S., et al. "Sensitivity of the early-life stages of freshwater mollusks to neonicotinoid and butenolide insecticides." *Environmental pollution* 218 (2016): 428-435 pgs. 428-429.

¹⁵ Bartlett, Adrienne J., et al. "Lethal and sublethal toxicity of neonicotinoid and butenolide insecticides to the mayfly, *Hexagenia* spp." *Environmental Pollution* 238 (2018): 63-75 pg. 66.

¹⁶ *Id.* pg. 68.

¹⁷ Prosser, R. S., et al. "Sensitivity of the early-life stages of freshwater mollusks to neonicotinoid and butenolide insecticides." *Environmental pollution* 218 (2016): 428-435 pgs. 428-429 pg. 432.

dose-responsive sublethal effects at the cellular level,¹⁸ indicating potential cumulative effects with neonicotinoids that have the same mode of action (see below). Considering the numerous rare freshwater species in the area, approval of flupyradifurone in these fragile aquatic ecosystems is risky and the EPA must consult to determine the impact on threatened and endangered species.

Flupyradifurone also impacts honey bees, as it was found to significantly reduce their affinity for sugar reward as well as significantly lower their gustatory response in a dose-dependent manner.¹⁹ Most concerning, honey bees treated with flupyradifurone were unable to learn the association of a stimulus and sucrose reward at the same rate as control bees and also had impaired memory performance.²⁰ As listed above, there are several threatened and endangered plants in the counties in which tobacco is grown. If use of flupyradifurone on tobacco is approved, bees will be exposed to the pesticide and their pollination abilities (stemming from reduction in learning, memory, and sucrose affinity) will be reduced. Reduction in pollination by bees will greatly negatively impact the reproduction of the listed flowering plants. Further, as flupyradifurone is easily taken up through roots and transported throughout a plant,²¹ threatened and endangered plants could take up the pesticide via groundwater or drift, exposing and threatening any specialist pollinators of those plants.

The EPA must analyze the unreasonable adverse effects of the new uses of flupyradifurone.

The EPA must require that the registrant provide and the EPA must analyze all necessary data and studies, including, but not limited to any previously identified data or study gaps, additional studies to evaluate effects on pollinators in accordance with the *Guidance for Assessing Pesticide Risks to Bees*,²² information concerning estrogen or other endocrine disruption effects,²³ and any information regarding potential synergistic effects. Flupyradifurone is acutely toxic to bees. The Government Accountability Office has advised the EPA to better evaluate the effects of pesticides on bees.²⁴ However, the approval of this new use provides no analysis whatsoever on the effects of the new use on the environment, endangered species, or bees. The EPA must consider all risks to humans, wildlife and the environment prior to any further approval of flupyradifurone.

As noted above, flupyradifurone impairs honey bee learning and memory and, in fact, acts similarly to neonicotinoids.²⁵ Thus, if flupyradifurone is approved for use on tobacco in areas where neonicotinoids are present, bees will be exposed to high rates of acetylcholine receptor inhibitors, which is concerning considering sublethal dose-dependent effects on learning and memory. If bees have a reduced ability to learn then they are unable to make an association with floral resources and their nectar/pollen reward. In addition, bees will be unable to locate or recall floral resources. The net result is that foraging bees exposed to flupyradifurone will collect less nectar and pollen needed to provision their offspring, further resulting in lower reproduction and smaller or less populations.

¹⁸ *Id.* pg. 433.

¹⁹ Hesselbach, Hannah, and Ricarda Scheiner. "Effects of the novel pesticide flupyradifurone (Sivanto) on honeybee taste and cognition." *Scientific reports* 8.1 (2018): 4954 pg. 4956.

²⁰ *Id.* pgs. 4956-4957.

²¹ Nauen, Ralf, et al. "Flupyradifurone: a brief profile of a new butenolide insecticide." *Pest management science* 71.6 (2015): 850-862 pg. 860.

²² EPA 2014. *Guidance for Assessing Pesticide Risks to Bees*. Available at https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

²³ See 21 U.S.C. §§ 346a(d)(2)(A)(x) and 346a(p).

²⁴ GAO 2016. *Bee Health, USDA and EPA Should Take Additional Actions to Address Threats to Bee Populations*. GAO-16-220

²⁵ Hesselbach, Hannah, and Ricarda Scheiner. "Effects of the novel pesticide flupyradifurone (Sivanto) on honeybee taste and cognition." *Scientific reports* 8.1 (2018): 4958.

The EPA must consult on all synergistic and cumulative uses of flupyradifurone.

The EPA must insure that all uses of flupyradifurone do not jeopardize species protected by the ESA or adversely modify or destroy their critical habitat through consultation with the Services. Expanding the range of crops that flupyradifurone is approved for use upon likely expands the total amount of pesticide used in a given period of time and the total acreage on which the pesticide is used, combinations of different tank mixtures, environmental combinations, and cumulative impacts. In order to meet the standard of no unreasonable adverse effects on the environment, the EPA must analyze potential synergistic effects of pesticides in the environment, all product formulations, and in tank mixtures. The EPA cannot come to the conclusion that no unreasonable adverse effects on the environment will result from the new use of this pesticide until an analysis of synergistic and/or additive effects is performed.

Specifically, neonicotinoids have the same mode of action as flupyradifurone but different bioactive scaffold.²⁶ In some bioassays, flupyradifurone was found to have stronger binding affinity²⁷ and LC₅₀²⁸ than imidacloprid. As such, overlapping use of flupyradifurone, neonicotinoids, and sulfoxaflor will expose non-target organisms to additional and potentially harmful levels of nicotinic acetylcholine receptors inhibitors. These cumulative effects could be additive and cause exposure beyond toxic levels. Indeed, in the areas that tobacco is grown, neonicotinoids are used on thousands of acres of crops. Tobacco overlaps with corn²⁹ and soy³⁰, particularly in the Carolinas and Georgia. Imidacloprid is commonly used in areas tobacco is grown, and often as seed treatment on soybeans.³¹ Clothianidin is also used commonly as a corn seed treatment in the same counties as tobacco is grown.³² Thiamethoxam is used commonly as a seed treatment on corn and soy in counties where tobacco is grown, especially in North Carolina.³³ Sulfoxaflor is commonly used on cotton in North Carolina and in Georgia in counties where tobacco is grown.³⁴ As such, the EPA must consult on all synergistic and cumulative uses of flupyradifurone.

The Center urges the EPA to meet its threshold legal obligations under the ESA to protect imperiled species and to assure that any new pesticide approval or new use does not result in unreasonable adverse effects in contravention of the Federal Insecticide Fungicide and Rodenticide Act.



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²⁶ Nauen, Ralf, et al. "Flupyradifurone: a brief profile of a new butenolide insecticide." *Pest management science* 71.6 (2015): 850-862 pg. 851.

²⁷ *Id* pg. 856.

²⁸ *Id* pg. 858.

²⁹ https://www.nass.usda.gov/Charts_and_Maps/Crops_County/cr-pl.php

³⁰ https://www.nass.usda.gov/Charts_and_Maps/Crops_County/sb-pl.php

³¹ https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2016&map=IMIDACLOPRID&hilo=L&disp=Imidacloprid

³² https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2016&map=CLOTHIANIDIN&hilo=L&disp=Clothianidin

³³ https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2016&map=THIAMETHOXAM&hilo=L&disp=Thiamethoxam

³⁴ https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2015&map=SULFOXAFLOR&hilo=L