May 25, 2022

Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001.
Federal Register Number 2022-08792 EPA-HQ-OPP-2022-0348-0001
EPA File Symbol: 7969-UIO. Docket ID number: EPA-HQ-OPP-2022-0348.

Re: Comments on Broflanilide proposed for use as corn seed treatment.

To Whom It May Concern,

Recently, EPA published a notice in the Federal Register for the receipt of an application to register broflanilide on corn seed. Despite the extensive comments that the Pollinator Stewardship Council and the Center for Biological Diversity made concerning the registration of this new insecticide, EPA approved the use of broflanilide. Below are some of the previous comments as well as new comments that can be made concerning the approval of broflanilide.

Broflanilide was registered by the U.S. Environmental Protection Agency on January 13, 2021 during the last days of the Trump Administration. Broflanilide is a persistent, bioaccumulative, and toxic (PBT) chemical, similar to the organochlorines, many of which were banned in the 1970's based on their high risk to aquatic and terrestrial ecosystems. Organochlorines include DDT, dieldrin, aldrin, and heptachlor. Although EPA and the manufacturer claim that broflanilide has a different mode of action (MOA) than the organochlorines, both broflanilide and organochlorines bind to the GABA (gamma-aminobutyric acid) receptor site and inhibit neurotransmission, resulting in convulsions and the death of the target pest. Broflanilide is registered for use in agricultural, residential, and commercial settings and can be applied as a seed treatment, soil treatment, granules, in-furrow, spray treatment, spot treatment, crack and crevice, and bait.

According to industry-submitted studies, broflanilide is highly persistent in the environment, with half-lives ranging from 2-4 years in water bodies and half-lives ranging from

3 – 16 years in soils. The physical and chemical characteristics of this insecticide indicate that it is likely to accumulate in water, soil, and fish with successive applications. EPA's risk assessment did not consider accumulation in these media. Given the high bioconcentration factor of broflanilide in fish tissues (266-364x), EPA should ask the manufacturer to submit data that measure the residue data for broflanilide and its metabolites in fish over time.

Broflanilide is highly toxic to freshwater and estuarine/marine fish and to aquatic invertebrates (fish food) on an acute basis. Based on industry-submitted studies, chronic toxicity of broflanilide in fish is uncertain. Fish can also be exposed indirectly to broflanilide from their food source – aquatic invertebrates (mayflies, caddisflies, stoneflies, beetles, etc.), which can further increase the risk of this insecticide . aquatic organisms. EPA has proposed to mitigate risk to aquatic organisms by requiring a 15-foot vegetative buffer strip. On the product label for the broflanilide product Cimegra, the manufacturer suggests that a vegetative buffer strip can be used and indicates that broflanilide has a "high potential for reaching aquatic sediment via runoff for several months or more after application. A level, well-maintained vegetative buffer strip… will reduce the potential loading of this active ingredient or its degradates from runoff water and sediment. Since buffer strips are not a requirement, there is no guarantee that users will construct or maintain vegetative filter strips to reduce the risks of broflanilide to aquatic organisms. Furthermore, in its risk assessment and decision document, EPA does not provide data to support its assumption that a 15-foot buffer strip would effectively prevent run-off of broflanilide into water bodies. Researchers at the University of Manitoba examined the effectiveness of buffer strips at multiple sites and found that buffer strips were highly inefficient in filtering runoff of nutrients from agricultural lands and more likely to increase water pollution. https://www.grainews.ca/features/buffer-strips-are-not-that-effecient/.

Broflanilide is extremely toxic to adult honey bees, bumble bees, and larval bees on an acute and chronic basis. A 10-day chronic study indicated that a dose of only 1 nanogram active ingredient/bee/day of broflanilide would kill 30% of adult bees, while a dose of 2.4 nanograms active ingredient(a.i.)/bee/day of broflanilide would kill 93% of adult bees. A 22-day chronic test indicated that 18% of larval bees would be killed with a dose of only 0.27 nanograms a.i./larva/day. EPA concluded that with in-furrow soil and seed treatment (agricultural uses), the risks to honey bees would be low. However, spray and spot treatments could increase the risks to honey bees as well as to other pollinators; the impact of these types of applications should be included in EPA's bee assessments. In addition, EPA's risk assessments should include an assessment of risks to bee larvae, the most sensitive lifestage of honey bees.

With the proposed seed treatment use of broflanilide, dust-off from planting seeds is a likely route of exposure for bees. Instead of continuing to claim that the agency is working with the pesticide companies to develop a technological fix for this problem, EPA should assign a default value for dust-off until the agency has determined what the actual values are. European risk assessments include dust-off and water as major routes of exposure for bees and could provide advice to EPA on how to calculate these values.

With the proposed soil and seed treatment uses of this pesticide, ground-dwelling bees, which are the majority of the bees, will be hit the hardest. EPA's risk assessment, however, only

considers honey bees and not the thousands of solitary native bees that live in or near the ground where they are exposed to contaminated soil and seed treated chemicals. Solitary bees also do not have the repair mechanisms afforded to bees living in colonies. Because the lifestyles of native bees are very different from honey bees, the European Academies Science Advisory Council has concluded that "owing to their life history, honey bees appear to be an inappropriate model system to evaluate the role of environmental stressors for populations of pollinating bees." (https://easac.eu/fileadmin/Reports/Easac_15_ES_web_complete_01.pdf). EPA contends that it cannot assess the risks to soil-dwelling organisms and bees because it does not have a "vetted method for quantifying the risks to ground dwelling bees." Instead of finding excuses for not moving beyond its 1980's scenarios, EPA should ask the manufacturer, USDA and/or academia to conduct studies on the impact of pesticide-contaminated soil on ground dwelling bees.

EPA's data requirements and guidelines for pollinators are over 35 years old and are not suitable for assessing the risks of pollinators to the predominant systemic pesticides that are currently used in the United States. Although EPA has developed a guidance document that lists certain additional bee studies that can be submitted to EPA, manufacturers are only required to submit to EPA one study for pollinators: an acute contact toxicity study for honey bees. Oral toxicity studies with adult honey bees and larvae and studies with other bees and pollinators are optional and are not required for approval of a new pesticide or the reregistration of an older pesticide.

The new proposed use of seed treatment for broflanilide will also increase the risk to birds and mammals that eat seeds. Although EPA claims that birds do not eat large corn seeds, a University of Minnesota multi-year field study showed that birds can crack open large seeds with their beaks. https://pubmed.ncbi.nlm.nih.gov/31121352/ This study also showed that seeds are commonly spilled on fields during planting. Placing statements on labels that encourage farmers to cover all spilled seeds is unrealistic and will not stop birds from digging up seeds. EPA needs to regulate pesticides based on what actually happens in the real world and not on what they hope will happen at some unknown date.

In its risk assessment, EPA compared the toxicity and fate/chemical properties of broflanilide to other diamides, but did not include tetraniliprole, a newly registered diamide which controls many of the same pests as broflanilide and other diamides. Compared to other diamides, "broflanilide is of similar toxicity to birds, mammals, and plants" and significantly (orders of magnitude) more toxic to honey bees, fish, and aquatic invertebrates.

EPA classified broflanilide as "Likely to be Carcinogenic to Humans" based on Leydig cell adenomas and combined ovarian tumors (granulosa cell, benign and malignant; luteomas; thecomas; and sex cord stromal tumors). The agency quantified the carcinogenic potential using a low-dose linear extrapolation approach (i.e., Q1*) for cancer risk. EPA's aggregate cancer risk of broflanilide for adults is 1×10^{-6}, which is considered the safe level for cancer risk. The aggregate cancer risk for children is not mentioned.

With respect to benefits, EPA "concluded that broflanilide is likely to provide pest control that is comparable to the currently registered insecticides for soil-dwelling pests in each

agricultural use site (e.g., corn, cereals, and tuberous and corm vegetables)." In addition, EPA's benefit assessment mentions that broflanilide's new mode of action would be beneficial in resistance management; however, given the similarity of broflanilide to organochlorines, this may be more of a problem (increased resistance) than an advantage. In relationship to target pests, the one possible advantage that the manufacturer mentions is that broflanilide may be more toxic than the neonicotinoids to wire worms. Grower group comments only mentioned that broflanilide would be useful in controlling wire worms, and their comments were verbatim the same.

The EPA also concluded that "broflanilide would only provide benefits to integrated pest management in scenarios where the use of soil-applied or seed-applied broflanilide is warranted by pest population sampling data that necessitates chemical control, when broflanilide is not used in conjunction with other chemical controls (e.g., neonicotinoid seed treatments, plant-incorporated protectants), and when other appropriate non-chemical control or non-conventional insecticide options (e.g., tillage; planting date, depth, or rate; crop variety; biopesticides) are also used and/or rotated with broflanilide for pest management purposes." With the original IPM practices, the target pest is identified before a pesticide is applied. With respect to pesticide-seed treatments, though, the target pests are not always identified, and pesticides are applied prophylactically to the environment whether they are needed or not.

When EPA makes a decision concerning the approval of a new pesticide, the agency usually weighs the risks of a pesticide against its benefits. In the case of broflanilide, the risks to pollinators, fish, aquatic invertebrates, birds, and other animals from the use of this insecticide far outweigh the one possible minor benefit.

Sincerely,

Steve Ellis, President
Pollinator Stewardship Council
1617 White Water Ct. Berthoud, CO 80513
www.pollinatorstewardship.org 970-213-3099

Gregory C. Loarie
Earthjustice (Counsel for Pollinator Stewardship Council)

May 26, 2022

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Although broflanilide is less soluble in water than some other pesticides and its residues measured in nectar and pollen appear low, the hazards it poses to ground nesting bees and other ground nesting pollinators are significant. The EPA Risk Assessment states, “acute and chronic risks to individual bees were identified following potential spray drift to flowering vegetation for ground furrow proposed uses. Additionally, any non-target terrestrial invertebrates, including bees that come into contact with or consume terrestrial sediments (*e.g*., ground dwelling/nesting bees), are at risk from the proposed uses. Because of the persistence of broflanilide in sediments, the risks to sediment dwelling/interacting invertebrates would increase with every subsequent use of broflanilide.” It is therefore surprising that studies on the effects of brofilanide on ground nesting bees, which are important pollinators for native plants and crops, have not been conducted. Given this gap of data and the known toxicity of broflanilide to bees (see Table 1 and 3 in https://www.regulations.gov/document/EPA-HQ-OPP-2018-0053-0009), we request that the EPA not register broflanilide for use as a corn seed treatment until the necessary field-realistic safety studies have been conducted with ground nesting bees.

Table 1. Comparison of the Toxicity of Broflanilide to Alternative Insecticides

Pesticide:		Broflanilide	Imidacloprid	Thiamethoxam	Clothianidin	F
PC Code:		283200	129099	060109	044309	1
Class:		Diamide	Neonicotinoid	Neonicotinoid	Neonicotinoid	P
Crops		wheat, corn, potato	potato	wheat, corn, potato	wheat, corn	p
Taxa						
Birds	Acute Oral LD_{50} (mg/kg-bw)	> 2000	17	576	423	1
	Dietary LC_{50} (mg/kg-diet)	> 5000	1536	>5200	>5,040	4
	Repro. NOAEC (mg/kg-diet)	29.7	125	300	205	1
Mammals	Acute Oral LD_{50} (mg/kg-bw)	> 5000	424	1563	389	9
	Repro. NOAEC (mg/kg-diet)	26	250	1000	150	3
Honey Bees	Acute Contact LD_{50} (ug/bee)	0.0088	0.043	0.021	0.0275	0
	Acute Oral LD_{50} (ug/bee)	0.0149	0.0039	0.0038	0.0037	0
	Chronic Adult NOAEC (ug/bee)	0.00062	0.00016	No Data	0.00036	N
	Acute Larval LD_{50} (ug/bee)	> 0.029	No Data	No Data	>15	0
	Chronic Larval NOAEC (ug/bee)	0.00008	0.0018	No Data	0.680	N

Table 3. Comparison of the Environmental Fate Properties of Broflanilide and Alternative Insecticides

Pesticide:	PC Code:	Class:	Half-lives (days)						Mobility
			Hydrolysis @ PH 7.0	Aquatic Photolysis	Aerobic Soil Metabolism	Anaerobic Soil Metabolism	Aerobic Aquatic Metabolism	Anaerobic Aquatic Metabolism	K_F (K_D) or K_{FOC} or K_{OC} (L/kg)
Broflanilide	283200	Diamide	Stable	80	829-5742	157-2354	945-1430	871-1411	*113-248*[A] 3596-20204
Flubendiamide	027602	Diamide	Stable		Stable	Stable	Stable	289	1076-3318
Cyantraniliprole	090098	Diamide	31	0.33	16.2-89.4	4.3	3.9-25.1	2.4-12	157-376
Chlorantraniliprole	090100	Diamide	Stable	33	228-924	Not Measured	125-231	208	152-535
Imidacloprid	129099	Neonicotinoid	Stable	0.2	139-608	Not Measured	30-159	33	98-487
Thiamethoxam	060109	Neonicotinoid	Stable	3.6-3.9	34.3-464	45.6-118.0	16.3-35.1	20.7-28.6	33.1-176.7
Clothianidin	044309	Neonicotinoid	Stable	0.6	148-1155	Not Measured	177.7-182.4	27	84-345

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