CENTER FOR FOOD SAFETY

May 26, 2022

U.S. Environmental Protection Agency
Office of Pesticide Programs
1200 Pennsylvania Ave., NW
Washington, DC 20460–0001

RE: Docket No.: EPA-HQ-OPP-2022-0348; EPA File Symbol 7959-UIO
Receipt of Application for New Use of Broflanilide as a Corn Seed Treatment

Center for Food Safety appreciates the opportunity to comment on the application of BASF to have EPA register a new use of the insecticide broflanilide for seed treatment of corn, on behalf of itself and its 970,000 members and supporters. Center for Food Safety (CFS) is a public interest, nonprofit membership organization with offices in Washington, D.C., San Francisco, California, and Portland, Oregon. CFS's mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. Through groundbreaking legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and the environment. CFS has consistently supported comprehensive EPA review of registered pesticides and individual inert ingredients.

INTRODUCTION

Broflanilide is a diamide insecticide that targets the larvae of many chewing insects, and is thought to act by binding to the gamma-aminobutyric acid (GABA) receptor, inhibiting neurotransmission, a disruption that leads to impaired muscle contractions, paralysis, and death. Broflanilide was first registered as a new active ingredient in January of 2021 for use as a seed treatment on small grains, as a soil-applied insecticide for corn, tuberous and corm vegetables (subgroup 1C), and for a variety of non-agricultural uses (EPA Registration 1/31/21). BASF has applied for registration of a new use as a seed treatment on corn. CFS urges EPA to reject this application.

Seed treatment use on corn seed planted on 90 million acres a year or more would mean a dramatic expansion relative to existing uses, potentially extending this insecticide's adverse impacts to tens of millions of more acres.

RELEVANT LEGAL STANDARDS

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

FIFRA authorizes EPA to regulate the registration, use, sale, and distribution of pesticides in the United States. Pursuant to FIFIRA, EPA oversees both initial registration of an active ingredient as well as any new uses of the registered active ingredient.

Section 3(c) of FIFRA states that a manufacturer must submit an application to register the use of a pesticide.[1] Under Section 3(c)(5) of FIFRA, EPA shall register a pesticide only if the agency determines that the pesticide "will perform its intended function without unreasonable adverse effects on the environment" and that "when used in accordance with widespread and commonly recognized practice[,] it will not generally cause unreasonable adverse effects on the environment."[2] FIFRA defines "unreasonable adverse effects on the environment" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[3] Alternatively, where there are data gaps and missing information, EPA can register a pesticide with conditions (conditional registration) under Section 3(c)(7) of FIFRA "for a period reasonably sufficient for the generation and submission of required data," but only if EPA also determines that the conditional registration of the pesticide during that time period "will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest."[4]

The culmination of the registration process is EPA's approval of a label for the pesticide, including use directions and appropriate warnings on safety and environmental risks. It is a violation of the FIFRA for any person to sell or distribute a "misbranded" pesticide.[5] A pesticide is misbranded if the "labeling accompanying it does not contain directions for use which...if complied with …are adequate to protect health and the environment."[6]

Endangered Species Act

As recognized by the Supreme Court, the Endangered Species Act (ESA) is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation."[7] The ESA's statutory scheme "reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies."[8] Federal agencies are obliged "to afford first priority to the declared national policy of saving endangered species."[9]

Section 7(a)(2) of the ESA requires every federal agency to consult the appropriate federal fish and wildlife agency—the U.S. Fish and Wildlife Service (FWS), in the case of land and freshwater species and the National Marine Fisheries Service (NMFS) in the case of marine

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[1] 7 U.S.C. § 136a(c)(1); 40 C.F.R. § 152.42.
[2] 7 U.S.C. § 136a(c)(5).
[3] 7 U.S.C. §136(bb).
[4] 7 U.S.C. §136a(c)(7)(C).
[5] 7 U.S.C. § 136j(a)(1)(E).
[6] 7 U.S.C. § 136(q)(1)(F).
[7] *Tenn. Valley Authority v. Hill*, 437 U.S. 153, 180 (1978).
[8] *Id*. at 185.
[9] *Id.*

species—to “insure” that the agency’s actions are not likely “to jeopardize the continued existence” of any listed species or “result in the destruction or adverse modification” of critical habitat.[10] The ESA’s implementing regulations broadly define agency action to include “all activities or programs of any kind authorized, funded or carried out … by federal agencies,” including the granting of permits and “actions directly or indirectly causing modifications to the land, water or air.”[11] A species’ “critical habitat” includes those areas identified as “essential to the conservation of the species” and “which may require special management considerations or protection.”[12]

EPA is required to review its actions “at the earliest possible time” to determine whether the action may affect listed species or critical habitat.[13] To facilitate compliance with Section 7(a)(2)’s prohibitions on jeopardy and adverse modification, the ESA requires each federal agency that plans to undertake an action to request information from the expert agency “whether any species which is listed or proposed to be listed [as an endangered species or a threatened species] may be present in the area of such proposed action.”[14] If FWS/NMFS advises the agency that listed species or species proposed to be listed may be present, the agency must then prepare a biological assessment for the purpose of identifying any such species that are likely to be affected by the proposed agency action.[15]

If, based on a biological assessment, an agency determines that its proposed action may affect any listed species and/or their critical habitat, the agency generally must engage in formal consultation with FWS/NMFS.[16] At the end of the formal consultation, FWS/NMFS must provide the agency with a “biological opinion” detailing how the proposed action will affect the threatened and endangered species and/or critical habitats.[17] If FWS/NMFS concludes that the proposed action will jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat, the biological opinion must outline “reasonable and prudent alternatives” to the proposed action that would avoid violating ESA section 7(a)(2).[18]

Pending the completion of formal consultation with the expert agency, an agency is prohibited from making any “irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures.”[19]

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[10] 16 U.S.C. § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b).
[11] 50 C.F.R. § 402.02 (emphasis added).
[12] 16 U.S.C. § 1532(5)(A).
[13] 50 C.F.R. § 402.14(a).
[14] 16 U.S.C. § 1536(c)(1); *see also* 50 C.F.R. § 402.12(c).
[15] *Id.*
[16] 50 C.F.R. § 402.14.
[17] 16 U.S.C. § 1536(b); 50 C.F.R. § 402.14.
[18] 16 U.S.C. § 1536(b)(3)(A).
[19] 16 U.S.C. § 1536(d).

ECOLOGICAL IMPACTS

Terrestrial Invertebrates

All of broflanilide's currently registered uses, and the proposed use, involve application to soil – either in-furrow application or as a seed treatment. Broflanilide is highly persistent in the soil, with aerobic soil metabolism half-lives of 829 to 2,220 days, or 2.3 to six years, in different soil types (EPA 10/27/20, Table 5-3, p. 19). Therefore, it is particularly important to assess potential hazards posed by broflanilide to organisms whose life histories involve soil contact, including bees.

There are roughly 20,000 species of bees worldwide. Of bee species found in temperate ecosystems, 70% are solitary bees, of which about two-thirds are ground nesters that have more or less continual exposure to soil and any contaminants it harbors, both as adults and especially in the larval stage (Sgolastra et al. 2019). Many bumble bees also nest in the ground and have similar exposure to soil. Yet despite these facts, EPA collects data on just one terrestrial vertebrate, the honey bee, that has virtually no contact with soil, as a faulty surrogate species for the plethora of bees and other invertebrates that do. In EPA's words, it "does not routinely quantify [pesticidal] risks to terrestrial invertebrates using empirical data for non-Apis [non-honey bee] terrestrial invertebrates" (EPA Response 1/13/21, p. 8).

This assessment failure is particularly concerning with regard to broflanilide. As EPA also admits:

> "All non-target invertebrates, including bees (ground dwelling/nesting bees) that interact with soils for foraging diet, nesting, reproduction, etc., are at risk. These risks follow a single application and because of the persistence of broflanilide in soils, will likely increase with each annual application" (EPA Registration 1/13/21, p. 20)

Besides being persistent, broflanilide is the most potently toxic insecticide for acute contact (adults) and chronic larval exposure, based on honey bee data provided by EPA (see EPA Registration 1/13/21, Table 3, pp. 22-23 for the following discussion). Contact with just 8.8 billionths of a gram of broflanilide (= 0.0088 ug/bee) is enough to kill half the adult honeybees that come into contact with this amount (lethal dose 50 or LD_{50}), making broflanilide the most toxic of 13 insecticides for this route of exposure.

The insecticide is a still more potent killer of honeybee larvae. Incredibly, daily exposure over 22 days to just 0.27 billionths of a gram broflanilide per larva (LOAEC) is enough to kill 18% of larvae so exposed, with a presumably safe exposure level (NOAEC) of 0.08 billionths of gram (one-twelfth of one billionth of gram) (EPA 10/27/20, p. 29). This makes broflanilide 12 times more potent to honeybee larvae than the infamous chlorpyrifos, which EPA has banned, and 22 times more potent than the neonicotinoid imidacloprid (EPA Registration 1/13/21, Table 3, p. 22).

Sgolastra et al. (2019) find that various solitary bee species are more highly exposed to pesticides in soil and on plant surfaces (adult and larvae), and from pollen contact (adults), relative to honeybees. While soil concentrations of broflanilide from corn seed treatment use are unknown, since the amount intended for coating on seed has not been divulged, one can estimate soil concentration from the already registered in-furrow corn use. With 0.0445 lbs applied per acre, the top 3" to 6" of soil would contain on average 20-40 nanograms broflanilide per gram soil, or 20-40 ppb. Ground-nesting bee larvae are protected in cells, but would need to be exposed to only very little soilborne broflanilide to be harmed. Broflanilide in water at EPA's peak EEC of 0.4 to 0.5 ug/liter (ppb) could also conceivably infiltrate larval cells (Sgolastra et al. 2019).

EPA simply cannot continue to find risks to soil-dwelling or -contacting invertebrates and then do nothing to mitigate them. One full decade ago, a FIFRA Scientific Advisory Panel detailed the many reasons the honey bee was not an acceptable surrogate for the vast majority of solitary and bumble bees that either dwell in or have extensive contact with the soil in the course of their lives, advising EPA to "require testing on at least one additional species to address the stated goal of protecting diversity" (SAP 2012, p. 15). That same year, the European Food Safety Authority came out with the scientific foundations for risk assessments of exposure of bumble and solitary bee as well as honeybees to pesticides, followed the next year by a guidance document to the same end (EFSA 2012, 2013). The guidance noted that potential protocols for testing the latter two groups were "available in the published literature," and included first proposals for such testing protocols in the guidance document (EFSA 2013, p. 2).

Indeed, Chan et al. (2019) have developed a hazard quotient scheme for assessing the exposure of hoary squash bees to pesticides in the soil. There are certainly other models from the published literature. Where precisely delineated test protocols are not yet available, EPA must develop conservative assessment schemes based on existing data, erring on the side of caution as better testing methods are developed.

Aquatic Invertebrates

Broflanilide is also incredibly toxic to aquatic invertebrates, though lack of a proper study prevents EPA from quantifying this risk even for the single surrogate species for which it has data, and which represents all invertebrates in estuarine and marine environments: the mysid (*Americamysis bahia*), a tiny shrimp-like crustacean that inhabits the estuaries of Texas and Florida. Chronic (28-day) exposure to just 0.0018 ug/liter (equivalent to 1.8 billionths of a gram per liter of water) is enough to reduce the number of mysid offspring per female by 22%, and reduce survival of the remaining offspring (F1 generation) by 17% (EPA 10/27/20, p. 23). Because this was the lowest concentration of broflanilide tested in this registrant study, EPA cannot say what concentration of broflanilide is safe for this creature. However, EPA estimates that surface waters will contain up to 0.41 ug/liter (concentration over 21-days, with furrow application in corn) (EPA 10/27/20, Table 8-2, p. 36). When one divides this estimated environmental concentration (EEC) by the lowest dose tested – 0.41 ug/liter divided by 0.0018 ug/liter – the result is a risk quotient of 228. In other words, EPA estimates that the amount of broflanilide in the water is up to 228 times greater than the amount known to substantially reduce reproduction and offspring survival of the mysid shrimp. As EPA says, given "the magnitude of the exceedance of the lowest test concentration in the mysid study by the EECs, there is little doubt about the potential risks to aquatic invertebrates from the proposed uses" (EPA 10/27/20, p. 9, see also p. 11).

Many other aquatic invertebrates will likely be threatened by the proposed action. Common mayflies, for instance, have declined across the upper Mississippi watershed and in the Lake Erie region over the last decade, and sublethal impacts of pesticide exposure in water and sediment have been identified as contributing factors (Stepanian et al. 2020).

Aquatic Vertebrates

Broflanilide is also highly toxic to fish. However, there is uncertainty as to its chronic toxicity to freshwater fish, because the available study did not employ the species that was most sensitive in acute toxicity testing – the bluegill or rainbow trout.

Broflanilide was far more acutely toxic to bluegill (96-h LC50 = 251 ppb) than to sheepshead minnow, only 10% of which died over 96 hours of exposure to 1300 ppb, with an indeterminate LC50 higher and perhaps far higher than 1300 ppb (EPA 10/27/20, Table 6-1, pp. 24-25).

In terms of chronic toxicity, sheepshead minnow experienced reduced growth and time to hatch at just 25.2 ppb, with an NOAEC of 11 ppb (Ibid., pp. 22-23). Based on an acute to chronic toxicity ratio, bluegill would be roughly 10-fold more sensitive to broflanilide than sheepshead minnow, and the imputed chronic toxicity to bluegills would be 2.5/1.1 ppb (LOAEC/NOAEC).

EPA's estimated environmental concentrations for surface waters 0.46 ppb (1-day) and 0.41 (21- and 60-day) (Ibid., Table 8-2, p. 36) – are fully one-third to one-half the imputed chronic threshold for bluegill. This imputed value is close enough to the EEC to suggest that a chronic test conducted with either bluegill or rainbow trout could result in an LOC exceedance. EPA must demand such a test – which it acknowledges as a data gap – before considering the proposed new use application.

In addition, broflanilide's affinity for lipids means it bioconcentrates in fish. In a registrant study reviewed by EPA, rainbow trout bioconcentrated broflanilide in their tissues at levels 266 to 364 times the concentration in the surrounding water (Ibid., pp. 16-17). However, in this study the trout were exposed for only 28 days, which for many chemicals is too short a period of time to achieve a steady state concentration (Gobas 2001, pp. 150-151). In fact, for large organisms like fish, equilibrium may not be reached even over their lifetime (Wang 2016). This suggests fish exposed in real-world conditions exceeding 28 days may well bioconcentrate more than 266-364 times the broflanilide level in surrounding water. In addition, when the exposed trout were placed in uncontaminated water, depuration was gradual. Finally, EPA makes no attempt to assess bioaccumulation of broflanilide in fish, which is the sum of bioconcentration from surrounding water and biomagnification from ingestion of contaminated prey items (Gobas 2001, EPA Response 1/13/21, p. 10).

Thus, EPA failed to fully assess the risks posed by broflanilide to aquatic invertebrates upon its initial registration, and should do so before taking action on this new use application.

Birds and Mammals

Chronic exposure of birds to broflanilide results in fewer eggs laid and a reduction in number of hatchlings that survive, based on a mallard duck study, while chronic exposure of mammals reduces the weight of pups in a two-generation reproduction study in rats (EPA 10/27/20, Table 6-2, pp. 29-30). The threshold for such effects can be reached in several ways, particularly through consumption of treated seeds by birds and mammals. A small bird would be at risk from eating just 28 treated barley or 34 treated wheat or sorghum seeds, while a small mammal would need to eat several hundred of these very small treated seeds (EPA 10/27/20, Table 9.2, p. 46).

Risks and Costs vs. Putative Benefits

In its original registration action, EPA conducted a FIFRA-violative "Benefits Assessment" rather than assessing putative benefits against costs and risks as the law demands (EPA Registration 1/13/21, pp. 23-24). We urge EPA to change course for this proposed action. The risks and costs of broflanilide recounted above clearly outweigh any minor benefits, particularly given the superabundance of insecticides with efficacy against broflanilide's targets that are already available to corn growers, some of which are foisted upon them whether wanted or not.

With respect to soil application to field corn, EPA notes that broflanilide provides little or no benefit, both because corn rootworm is by far the most damaging pest targeted by this insecticide, and because nearly all field corn seeds are already protected against corn rootworm (CRW) in two ways: they contain one or more plant-incorporated protectants (PIPs),20 and are coated with neonicotinoid seed treatments, both of which target CRW; while one and/or the other also protect against the secondary corn pests targeted by broflanilide, like seedcorn maggot, that are in any case rarely a problem for the great majority of corn growers most of the time. It is for these reasons that EPA itself finds broflanilide's benefits limited primarily to popcorn and sweet corn, which for the most part do not contain the Bt PIP toxin, though they may well be treated with neonicotinoids:

> "However, the benefit of soil-applied broflanilide to IPM and IRM programs for the control of CRW and other soil-insects in field corn will be limited to scenarios when broflanilide is used without plant-incorporated protectants (PIPs) or neonicotinoid seed treatments, of which field corn growers have limited access. Therefore, broflanilide is likely to provide a greater benefit to growers of popcorn and sweet corn as they are not reliant on Bacillus thuringiensis (Bt)

[20] PIPs are the generic name for toxins derived from soil bacteria known as *Bacillus thuringiensis* (Bt) and introduced into corn and cotton via genetic engineering.

traited varieties for production relative to field corn growers." (EPA Registration 1/13/21, p. 24).

This analysis of soil-applied use of broflanilide in corn (which is already registered) applies with still greater force to the proposed seed treatment use, in part because soil-applied use already represents a third mode of action against CRW and other pests, and additional registration as a seed treatment opens up the possibility of dual use of broflanilide on field corn seeds, together with Bt toxins and neonicotinoid seed treatments. Dual use would accelerate evolution of resistance to this new insecticide, undermining whatever value it possesses.

Therefore, while CFS opposes registration of broflanilide for treatment of any corn seed, it is particularly objectionable for field corn due to lack of benefit in light of existing options.[21] On the risk side of the equation, too, treatment of field corn seed has the potential to introduce this highly toxic insecticide to as much as 90 million acres of the country that is planted to corn; and as noted, some of these acres would be treated twice with the insecticide – applied to both seed and soil. The risks described above to terrestrial and aquatic invertebrates, birds, mammals and also to aquatic vertebrates from existing uses would all be intensified and extended to more areas of the country with registration as a treatment of field seed corn.

In short, contrary to EPA's conclusory statements, the risks and costs far outweigh the putatative benefits of this use, particulary with respect to field corn seed.

Mitigations

The mitigations enacted by EPA for the initial registration are of little help in reducing the adverse effects of this pesticide, and will be equally ineffective for the use as a corn seed treatment.

First of all, EPA provides no mitigation for the exposure of ground-nesting bees to broflanilide in soil, because for EPA such bees do not merit quantitative consideration in the Agency's assessment scheme.

Second, the 15' foot-wide buffer strips between fields of use and water bodies are insufficient to ameliorate risks to aquatic invertebrates, particularly given the huge risk quotients of up to and beyond 200 (mysid shrimp). This mitigation first appears under the name "buffer strip," but then its name magically changes to "vegetative filter strip" by virtue of nothing more than EPA's restriction against cultivation of it (EPA Registration 1/13/21, p. 26). However, it is difficult to predict the effectiveness of such strips (Congrong et al. 2019), and in some cases they have been show not to have any filtering effect with respect to surface water runoff concentrations (of neonicotinoids) (Hladik et al. 2017). While maintenance is critical to whatever effectiveness such strips might have, EPA makes no provision for upkeep. Finally, EPA's ecological scientists admit they have essentially no confidence these strips will serve their purpose:

[21] Unfortunately, "options" is something of a misnomer, since corn farmers find it difficult to access high-quality corn seed that does NOT contain both PIPs and neonicotinoid seed treatments (Hitaj et al. 2020).

> "Currently, the Agency does not quantitatively assess the effectiveness of these practices in reducing pesticide concentrations in runoff. In addition, the current surface water model used by the Agency does not have the capability to account for prescribed setbacks or vegetative buffer distances. While a well-maintained vegetative buffer could potentially intercept broflanilide-laden runoff (both soluble and sediment bound) prior to reaching surface waters, there is still a great deal of uncertainty regarding the performance of buffers, which includes but is not limited to proper design and placement and the duration of their efficacy." (EPA 10/27/20, p. 35).

Finally, EPA provides no evidence that or to what degree a label exhortation to incorporate treated small grain seed in the soil will be followed, and if so how effective it is at preventing birds and mammals from finding and consuming the seeds (EPA Registration 1/13/21, p. 27). There is little reason to think such a label admonition to do the same with treated corn seed will be followed or effective.

Synergy

EPA permitted BASF to do its own patent search for potential synergies, or more than additive effects, of broflanilide and other pesticides or chemicals. Though BASF apparently identified 40 such patents, excessively stringent "criteria for relevancy" resulted in all 40 being rejected for EPA's ecological risk assessment (Ibid., p. 25). EPA should conduct these searches itself, and not exclude them based on excessively stringent criteria (EPA Registration 1/13/21, p. 24)

Risks to Threatened and Endangered Species

EPA has not completed an assessment of broflanilide for its impact on threatened and endangered species. EPA must comply with its duties under Section 7 of the ESA prior to registering these new uses, as this action may affect species listed as threatened or endangered under the ESA. Because imperiled species listed under the ESA are highly susceptive to additional threats, it is clear that listed species would be at increased risk from an approval.

The following listed species are among those likely to be adversely impacted by the proposed registration.

Aquatic Invertebrates

Alabama moccasinshell
Coosa moccasinshell
Fat pocketbook
Fat threeridge
Finelined pocketbook
Georgia pigtoe
Gulf moccasinshell
Iowa pleistocene snail

Littlewing pearlymussel
Orangenacre mucket
Oval pigtoe
Oyster mussel
Plicate rocksnail
Purple bankclimber
Riverside fairy shrimp
Round ebonyshell
Sheepnose mussel
Snuffbox mussel
Southern clubshell
Stock Island Tree snail
White catspaw pearly mussel

Insects
American burying beetle
Dakota skipper
Delta Green Ground Beetle
Hines Emerald Dragonfly
Poweskiek's skipperling
Rusty patched bumble bee
Valley Elderberry Longhorn Beetle

Fish
Chinook salmon
Delta smelt
Steelhead

Birds
Bachman's warbler
Least tern
Masked bobwhite
Piping plover
Red-cockaded woodpecker
Roseate tern
Streaked horned lark

Sincerely,

Bill Freese, Scientific Director
Center for Food Safety

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