



Pollinator Stewardship Council

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Draft Comments on Broflanilide Proposed Decision Document

Please accept these comments on behalf of Pollinator Stewardship Council, American Beekeeping Federation and American Honey Producers Association, in response to EPA's ecological risk assessment and decision document for the proposed registration of broflanilide.

The Pollinator Stewardship Council has reviewed EPA's ecological risk assessment and decision document for the proposed registration of broflanilide and would like to offer the following comments. The physicochemical properties and toxicity of this insecticide to non-target organisms is of great concern to the Pollinator Stewardship Council. Based on industry-submitted studies, broflanilide is highly persistent in the environment, with an average half-life of > 5 years in water and an average half-life > 6 years in soil.

(<https://www.regulations.gov/document?D=EPA-HQ-OPP-2018-0053-0011>). Broflanilide is highly lipophilic with a high bioaccumulation potential in honey bee fat bodies and wax. It is also highly toxic to terrestrial and aquatic invertebrates, fish, and birds (seed treatment). Given these characteristics, broflanilide can be considered a persistent, bioaccumulative, and toxic (PBT) chemical, similar to the organochlorines, which were banned in the 1970's and 1980's based on their high risk to aquatic and terrestrial ecosystems.

With respect to pollinators, EPA determined that 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. Because the proposed application methods for broflanilide are in-furrow soil and seed treatment (agricultural uses) and spot, crack and crevice, and bait (non-agricultural uses), EPA determined that the risk to adult honey bees would be low. However, EPA's risk assessments did not assess risk to bee larvae, the most sensitive endpoint for honey bees.

Given the lipophilic nature of broflanilide, its persistence and its bioaccumulation, dangerous buildup in the fat bodies (a bees' immune system) of bees and, for honey bees and bumble bees, the wax they use to build their nests, is likely. Contaminated beeswax is already an unaddressed pesticide exposure avenue for honey bees (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6359572/>). Neither long-lived exposure (in bees' bodies or in wax) was addressed in the EPA's registration review for broflanilide. Commercial applications for the beeswax will also be impacted and were also not considered.

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In addition, EPA did not assess the risk to the thousands of pollinating ground-dwelling/nesting bees that would be at significant risk from the proposed uses of broflanilide. Since EPA's guidance for conducting risk assessments for bees is based solely on one bee species (*Apis mellifera*, Western Honey Bee), the risks to ground-dwelling bees and other terrestrial invertebrates are usually not determined. (https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf). EPA needs to revisit its policy of only assessing the risk to one species of bee.

Unlike honey bees, which live in colonies above the ground, solitary native bees often live in or near the ground and thus are at greater risk than honey bees of being killed by pesticides that are commonly applied to the soil or coated on seeds.

(<https://entomology.cals.cornell.edu/extension/wild-pollinators/native-bees-your-backyard>).

They also do not have the repair mechanisms afforded to bees living in colonies. Because the life styles 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).

The bee risk assessment for broflanilide is also based on one application. Given the persistence of broflanilide in soil, the risks to ground-dwelling bees and other sediment dwelling/interacting invertebrates would increase substantially with repeated applications.

Although native bees do not receive the same attention that managed honey bees receive, a number of studies have shown that native bees are better pollinators than honey bees for certain crops, including tomatoes, pumpkins, cherries, blueberries, and cranberries,

(<http://news.cornell.edu/stories/2011/10/native-bees-are-better-pollinators-honeybees>;

<https://besjournals.onlinelibrary.wiley.com/doi/10.1111/j.1365-2664.2007.01418.x>;

<https://www.fs.fed.us/wildflowers/pollinators/documents/BeeBasics.pdf>). In an online pamphlet, USDA describes the benefits of native bees and how growers can increase native bee populations for various fruits and vegetables

(https://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/stelprdb1143636.pdf. A number of

studies have shown that the combination of native bees and honey bees can increase the yields for crops requiring pollination. (<https://www.sciencealert.com/wild-bees-contribute-over-1-5-billion-each-year-by-pollinating-just-a-handful-of-crops>;

<https://www.scientificamerican.com/article/return-of-the-natives-how-wild-bees-will-save-our-agricultural-system/>). Given the important contributions of native solitary bees to pollination

services, EPA and USDA need to develop actions for protecting native bees as well as commercial honey bees rather than approving more pesticides that kill bees.

In February 2016, the Government Accounting Office (GAO) issued a report on additional actions that USDA and EPA should take to address threats to bee populations

(<https://www.gao.gov/assets/680/675109.pdf>). The report noted that the White House Pollinator Health Task Force's strategy directed USDA together with other federal agencies to develop a monitoring plan for wild, native bees. Although the GAO report contained a number of useful

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recommendations for improving the health of bee populations, it does not appear that USDA or EPA are implementing the recommendations of the GAO or the White House Pollinator Health Task Force.

EPA's exposure and risk assessments for broflanilide were only based on exposure to nectar and pollen and not on other exposure routes such as water, guttation fluid, contaminated soil, and contaminated dust from seed planting. In addition, the risk assessment only examined the risk to adult bees to broflanilide and not the combination of pesticides and chemicals on the treated seeds. Thus, it is likely that EPA has underestimated the risk to bees from exposure to broflanilide products, especially from repeated exposures.

We are concerned that broflanilide may have systemic properties; other diamides are systemic, and the stated use of broflanilide as a seed treatment indicates systemic nature, the impact of which is unaddressed in the registration.

In EPA's proposed registration decision and risk assessment, the agency determined that broflanilide is highly toxic to freshwater and estuarine/marine fish and to aquatic invertebrates. Because the proposed application of broflanilide is an in-furrow soil application and seed application (agricultural uses), EPA assumed that the exposure and risk to fish will be low (<https://beta.regulations.gov/document/EPA-HQ-OPP-2018-0053-0027>). However, with repeated applications, the risks to fish could be higher as broflanilide can accumulate in sediments and bioaccumulate in fish (266 -364X). Fish can also be exposed indirectly to broflanilide from their food source – aquatic invertebrates (mayflies, caddisflies, stoneflies, beetles, etc.), which can further increase risk.

In its risk assessment, EPA determined that broflanilide posed a high risk to aquatic invertebrates, especially benthic and estuarine/marine invertebrates, for all uses. The agency's solution for mitigating the risk to aquatic invertebrates is a 15-foot vegetative buffer strip. However, it is highly unlikely that this size buffer strip could effectively mitigate the risk to aquatic organisms from exposure to broflanilide. Independent studies have found that vegetative buffer strips are not efficacious and are difficult to maintain. 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 were more likely to increase water pollution (<https://www.grainews.ca/features/buffer-strips-are-not-that-efficient/>). Of course, buffer strips would be useless in protecting solitary ground-dwelling/nesting bees exposed to soil applications of broflanilide. Given the states' past record in enforcing pesticide label requirements for protecting aquatic and terrestrial organisms, it is unlikely that many state resources will be devoted to enforcing this new requirement.

EPA also determined that risks to birds and mammals are low for in-furrow treatment. However, small and medium size birds could be at risk from consuming corn seeds (chronic risk). Small birds would only need to eat more than 28 corn seeds and medium birds would only need to eat more than 170 corn seeds to exceed the risk level of concern.

The human health risk assessment indicates that broflanilide is of low aggregate risk to mammals (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2018-0053-0012>). Even though EPA classified this pesticide as “likely to be carcinogenic to humans” based on ovarian tumors and Leydig cell adenomas, EPA’s exposure estimates were low enough that the agency could characterize broflanilide as a low risk to mammals and humans. The registrant is proposing use of broflanilide in food handling establishments and in residential areas. With repeated applications, the exposure and risks could increase in these areas. In the future, the registrant may be applying for use of broflanilide as a public health pesticide for use on mosquitoes. (<https://malariajournal.biomedcentral.com/articles/10.1186/s12936-020-03466-4>).

The benefit assessment indicates that most of the target pests for broflanilide can be killed using other insecticides. There are three other diamides that can be used as alternatives for this chemical. Organic practices are also effective alternative to chemical registration. Organic practices eliminate the need for toxic chemicals and mitigate the adverse health impacts of toxic chemical exposure. Because broflanilide has limited benefits compared to other insecticides on the market and results in high risks to non-target organisms, EPA’s risk-benefit analysis should indicate that the risks of this pesticide to non-target organisms far outweigh the benefits.

The Pollinator Stewardship Council urges EPA to reconsider its proposed decision and to not register another persistent, bioaccumulative, and toxic chemical.

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