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Registration Division (7505P)
Robert McNally
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

OPP Docket
Environmental Protection Agency
Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Attention: EPA-HQ-OPP-2016-0013

RE: Pesticide Product Registration: Receipt of Applications for New Uses (November 2019) (Flonicamid)

Dear Messrs. Goodis and McNally:

On January 21, 2020, EPA published a notice that it had received an application for new uses of flonicamid.[1] The Attorney General of California has reviewed the notice of receipt and submits these comments to the regulatory docket.

Flonicamid is currently undergoing registration review, and EPA recently released draft risk assessments as part of that review.[2] As the Attorney General of California noted in comments submitted on that docket,[3] flonicamid's draft ecological risk assessment fails to adequately characterize flonicamid's environmental impacts as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Specifically, despite new studies showing that flonicamid presents significant risks to pollinators, EPA failed to collect data from required follow-up studies. As a result, EPA found that a "full assessment of pollinator risk cannot be conducted until data are available." Our prior comments urged EPA to revise the draft ecological risk assessment to remedy the data gap and recirculate the risk assessment for further public comment.

[1] EPA-HQ-OPP-2016-0013-0018.
[2] EPA-HQ-OPP-2014-0777-0019, -0020, -0021.
[3] EPA-HQ-OPP-2014-0777-0023.

The new flonicamid application seeks registration for residential outdoor use on roses, flowers, shrubs, and small (non-fruit bearing) trees. If EPA finds that these uses would expose pollinators to flonicamid, EPA must collect data from the required studies of flonicamid's effects on pollinators and adequately mitigate any adverse effects before registering these new uses.

I. Pesticide Registration under FIFRA

All pesticides must receive regulatory approval before their use.[4] 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," and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."[5] These requirements are crucial to ensure that pesticides do not unreasonably harm public health or the environment.

EPA must reevaluate pesticide registrations every 15 years.[6] As part of registration review, EPA may notify pesticide registrants of additional data needed to maintain the registration.[7] If a registrant fails to take appropriate steps to secure the required data, EPA may issue a notice of intent to suspend the registration.[8] Also prior to re-registering a pesticide, EPA releases updated risk assessments evaluating the pesticide's impacts on public health and the environment.[9] These documents form the basis for EPA's analysis of whether the pesticide will cause unreasonable adverse effects on the environment.

II. Flonicamid is Toxic to Pollinators.

Flonicamid is an insecticide that manages crop pests by provoking irreversible feeding cessation, causing insects to die of starvation or dehydration.[10] While its effects upon exposure are immediate, they are often not observed until many days later, after insects have starved. Based on this understanding, the chronic adult honeybee study submitted for flonicamid's registration review included an extended observation period designed to capture flonicamid's delayed toxicity.[11]

The new chronic adult honeybee study found that flonicamid is extremely toxic to adult bees. The second-lowest dose studied (0.44 µg/day) killed 60% of bees after the extended observation period.[12] Based on these results, EPA determined that the registered uses of

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[4] 7 U.S.C. § 136a(a).
[5] 7 U.S.C. § 136a(c)(5)(C)-(D).
[6] 40 C.F.R. § 155.40(a).
[7] 7 U.S.C. § 136a(c)(2)(B).
[8] *Id.*
[9] 40 C.F.R. § 155.53.
[10] Ecological Risk Assessment, EPA-HQ-OPP-2014-0777-0021, at 11.
[11] *Id.* at 32.
[12] *Id.* at 24.

flonicamid would expose bees to 17 to 51 times the amount of flonicamid that would cause substantial harm.[13] EPA also concluded that flonicamid drift presents significant risks to bees as far as 308 feet from the application site.[14]

The extended observation period was critical to understanding flonicamid's true impact on pollinators. During the extended observation period, "mortality continued to increase at all test concentrations in a dose dependent manner," confirming that prior studies without extended observation periods did not fully capture flonicamid's impacts on bees.[15] Moreover, mortality did not stabilize by the end of the extended observation period in the flonicamid arms of the study.[16] This result suggests that even the six-day extended observation period in the chronic adult honeybee study may not have been sufficient to measure flonicamid's full effects.

Despite these data, flonicamid is marketed as safe for pollinators. Flonicamid was discovered by ISK, a Japanese corporation, and it is marketed in the United States by FMC Corporation under the names Carbine, Beleaf, and Aria. ISK advertises flonicamid as having "no negative impact on pollinating insects or natural enemies."[17] Similarly, FMC asserts that flonicamid has "a minimal impact on many important beneficial insects, pollinators and predatory mites."[18] The brochures containing these statements do not cite any basis for these claims.

III. EPA Should Not Register New Uses of Flonicamid Until It Has Adequately Characterized and Mitigated Flonicamid's Risks to Pollinators.

In the draft ecological risk assessment, EPA determined, "[b]ased on the available data set," that flonicamid presents risks to bees.[19] However, EPA was unable to comprehensively characterize flonicamid's risks to pollinators because it did not receive all of the required data. Even though EPA requested that ISK submit all of this data in the data call, ISK submitted no contact exposure data, no residue data, and no Tier II studies.[20] Consequently, EPA concluded that "[a] full assessment of pollinator risk cannot be conducted until data are available to form the weight of evidence at the individual and colony level."[21]

If EPA finds that residential use of flonicamid on roses, flowers, shrubs, or small trees would expose pollinators to flonicamid, EPA must not register these new uses until ISK has

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[13] *Id*. at 33.
[14] *Id*. at 34 Table 8-3.
[15] *Id*. at 7.
[16] *Id*. at 25 Fig. 1.
[17] Flonicamid Brochure, *available at* https://www.iskweb.co.jp/products/pdf/flonicamid.pdf.
[18] Beleaf 50SG Insecticide, Strawberries Brochure, *available at* https://www.fmccrop.com/Portals/_default/fmc_pdf/2f4dd7d0d36e4925b4d089b729ac780a.pdf.
[19] Ecological Risk Assessment, at 35.
[20] Generic Data Call In, EPA-HQ-OPP-2014-0777-0017, at 26-28; Ecological Risk Assessment, at 26-27 Table 6-2.
[21] Ecological Risk Assessment, at 36.

submitted the required pollinator studies and EPA has mitigated any adverse impacts on pollinators. To register new uses of flonicamid, EPA must find that the uses will not cause unreasonable adverse effects on the environment.[22] Yet EPA itself found that it could not fully assess flonicamid's risks to pollinators because the necessary data are unavailable.[23] If EPA proceeds to register these new uses of flonicamid, these facts will be materially identical to those in litigation involving sulfoxaflor. There, the Ninth Circuit held that "EPA's decision to register sulfoxaflor was not supported by substantial evidence" because, "[w]ithout sufficient data, the EPA has no real idea whether sulfoxaflor will cause unreasonable adverse effects on bees, as prohibited by FIFRA."[24]

EPA can obtain the necessary pollinator data. FIFRA requires registrants to heed EPA's data calls.[25] If registrants do not provide the requested studies, EPA may suspend the pesticide registration.[26] EPA noted that it "received and provided comments on a registrant protocol for conducting a semi-field study," but it did not state whether ISK is conducting that study.[27] It also revealed that "[n]o pollen/nectar residue studies have been proposed or submitted to [EPA] at this time."[28] Data from these studies are essential to characterizing flonicamid's risks to pollinators, and therefore to determining whether flonicamid presents unreasonable adverse effects on the environment. EPA also cannot evaluate whether additional labeling restrictions are necessary without a full picture of flonicamid's adverse effects. EPA must gather the necessary data and describe and mitigate flonicamid's risks to pollinators before registering the proposed new uses of flonicamid.

IV. Conclusion

The California Attorney General's Office is committed to protecting all Californians' health and preserving California's exceptional natural resources. For the reasons discussed above, EPA cannot demonstrate that the new uses of flonicamid "will not generally cause unreasonable adverse effects on the environment" "when used in accordance with widespread and commonly recognized practice" until EPA can adequately characterize flonicamid's risks to pollinators.[29] The Attorney General of California therefore urges EPA to determine whether the new proposed uses of flonicamid would expose pollinators to flonicamid and, if so, collect data from the required studies of flonicamid's effects on pollinators so that it can adequately describe and mitigate flonicamid's risks to pollinators.

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[22] 7 U.S.C. § 136a(c)(5)(C)-(D).
[23] Ecological Risk Assessment, at 36.
[24] *Pollinator Stewardship Council v. U.S. E.P.A.*, 806 F.3d 520, 532 (9th Cir. 2015).
[25] 7 U.S.C. § 136a(c)(2)(B)
[26] *Id*.
[27] Ecological Risk Assessment, at 36.
[28] *Id*.
[29] 7 U.S.C. § 136a(c)(5).

Sincerely,

ROBERT D. SWANSON
Deputy Attorney General

For XAVIER BECERRA
Attorney General