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Eric Fox
Pesticide Re-Evaluation Division (7508P)
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-2014-0777

RE: Registration Review: Draft Human Health and/or Ecological Risk Assessments for Several Pesticides (Flonicamid)

Dear Mr. Fox:

On November 18, 2019, EPA released for public review draft human health, occupational and residential exposure, and ecological risk assessments for flonicamid.[1] The Attorney General of California has reviewed the draft risk assessments for flonicamid and submits these comments to the regulatory docket.

The 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. EPA now improperly proposes to move registration review forward despite finding that a "full assessment of pollinator risk cannot be conducted until data are available." EPA should revise the draft ecological risk assessment to remedy this data gap and recirculate it for further public comment.

I. Pesticide Registration under FIFRA

All pesticides must receive regulatory approval before their use.[2] 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

[1] EPA-HQ-OPP-2014-0777-0019, -0020, -0021.
[2] 7 U.S.C. § 136a(a).

cause unreasonable adverse effects on the environment."[3] 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.[4] As part of registration review, EPA may notify pesticide registrants of additional data needed to maintain the registration.[5] If a registrant fails to take appropriate steps to secure the required data, EPA may issue a notice of intent to suspend the registration.[6] Also prior to re-registering a pesticide, EPA releases updated risk assessments evaluating the pesticide's impacts on public health and the environment.[7] 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.[8] 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 this registration review included an extended observation period designed to capture flonicamid's delayed toxicity.[9]

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.[10] Based on these results, EPA determined that the registered uses of flonicamid would expose bees to 17 to 51 times the amount of flonicamid that would cause substantial harm.[11] EPA also concluded that flonicamid drift presents significant risks to bees as far as 308 feet from the application site.[12]

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.[13] Moreover, mortality did not stabilize by the end of the extended observation period in the flonicamid arms of the

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[3] 7 U.S.C. § 136a(c)(5)(C)-(D).
[4] 40 C.F.R. § 155.40(a).
[5] 7 U.S.C. § 136a(c)(2)(B).
[6] *Id*.
[7] 40 C.F.R. § 155.53.
[8] Ecological Risk Assessment, EPA-HQ-OPP-2014-0777-0021, at 11.
[9] *Id*. at 32.
[10] *Id*. at 24.
[11] *Id*. at 33.
[12] *Id*. at 34 Table 8-3.
[13] *Id*. at 7.

study.[14] 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."[15] Similarly, FMC asserts that flonicamid has "a minimal impact on many important beneficial insects, pollinators and predatory mites."[16] The brochures containing these statements do not cite any basis for these claims.

III. The Draft Ecological Risk Assessment Fails to Adequately Characterize Flonicamid's Risks to Pollinators.

"Based on the available data set," EPA determined that flonicamid presents risks to bees.[17] 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.[18] 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."[19]

EPA must demand that ISK submit the required pollinator studies. To register flonicamid, EPA must find that it will not cause unreasonable adverse effects on the environment.[20] Yet EPA itself found that it could not fully assess flonicamid's risks to pollinators because the necessary data are unavailable.[21] If EPA proceeds to re-register 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."[22]

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[14] *Id*. at 25 Fig. 1.
[15] Flonicamid Brochure, *available at* https://www.iskweb.co.jp/products/pdf/flonicamid.pdf.
[16] Beleaf 50SG Insecticide, Strawberries Brochure, *available at* https://www.fmccrop.com/Portals/_default/fmc_pdf/2f4dd7d0d36e4925b4d089b729ac780a.pdf.
[17] Ecological Risk Assessment, at 35.
[18] Generic Data Call In, EPA-HQ-OPP-2014-0777-0017, at 26-28; Ecological Risk Assessment, at 26-27 Table 6-2.
[19] Ecological Risk Assessment, at 36.
[20] 7 U.S.C. § 136a(c)(5)(C)-(D).
[21] Ecological Risk Assessment, at 36.
[22] *Pollinator Stewardship Council v. U.S. E.P.A.*, 806 F.3d 520, 532 (9th Cir. 2015).

EPA can obtain the necessary pollinator data. FIFRA requires registrants to heed EPA's data calls.[23] If registrants do not provide the requested studies, EPA may suspend the pesticide registration.[24] 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.[25] It also revealed that "[n]o pollen/nectar residue studies have been proposed or submitted to [EPA] at this time."[26] 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, describe flonicamid's risks to pollinators, and recirculate its draft ecological risk assessment before proposing to re-register 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, the draft ecological risk assessment for flonicamid cannot demonstrate that flonicamid "will not generally cause unreasonable adverse effects on the environment" "when used in accordance with widespread and commonly recognized practice."[27] The Attorney General of California therefore urges EPA to revise the draft ecological risk assessment to fully characterize flonicamid's risks to pollinators and recirculate for further public comment.

Sincerely,

ROBERT D. SWANSON
Deputy Attorney General

For XAVIER BECERRA
Attorney General

[23] 7 U.S.C. § 136a(c)(2)(B)
[24] *Id*.
[25] Ecological Risk Assessment, at 36.
[26] *Id*.
[27] 7 U.S.C. § 136a(c)(5).