XAVIER BECERRA
Attorney General

State of Californ
DEPARTMENT OF JUSTICE

1300 I STREET, SUITE 125
P.O. BOX 944255
SACRAMENTO, CA 94244-2550

Public: (916) 445-9555
Telephone: (916) 210-7808
Facsimile: (916) 327-2319
E-Mail: Robert.Swanson@doj.ca.gov

November 2, 2020

Alexandra Feitel
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: Pesticide Registration Review: Proposed Interim Decisions for Several Pesticides (Flonicamid)

Dear Ms. Feitel:

On September 2, 2020, EPA released for public review a Proposed Interim Registration Review Decision for flonicamid (PID).[1] The Attorney General of California has reviewed the PID and submits these comments to the regulatory docket.

The Attorney General of California previously submitted comments on EPA's draft ecological risk assessment for flonicamid.[2] Those comments noted that EPA had failed to collect data from required follow-up studies of flonicamid's impacts on pollinators, even though studies showed that flonicamid presents significant risks to pollinators and the risk assessment found that a "full assessment of pollinator risk cannot be conducted until data are available." The comments urged EPA to revise the draft ecological risk assessment to remedy the data gap and recirculate the risk assessment for further public comment.

In response, the PID states that the registrant has committed to conducting the additional, required pollinator studies, and that if any data from higher-tier studies changes any risk conclusions, EPA will address the issue in its final interim decision.[3] However, EPA has not committed to reviewing the data from higher-tier studies before it will issue a final interim decision. If EPA moves forward before it can sufficiently characterize flonicamid's risks to pollinators, it will violate the Federal Insecticide, Fungicide, and Rodenticide Act's (FIFRA) requirement that EPA determine flonicamid's registration will not cause unreasonable adverse

[1] PID, EPA-HQ-OPP-2014-0777-0032.
[2] EPA-HQ-OPP-2014-0777-0023.
[3] PID at 6.

environmental effects. EPA should review the follow-up studies, revise its ecological risk assessment, propose any necessary mitigation, and circulate its findings for public comment *before* issuing a registration decision.

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, commonly referred to as a "data call".[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. After receiving public comment on the updated risk assessments, EPA revises the risk assessments (if necessary) and publishes a proposed registration review decision, which includes any new restrictions or labeling changes.[10] Following a public comment period on the proposed registration review decision, EPA issues a final registration review decision, which completes the registration review proceeding.[11]

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.[12] 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

---

[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] *Id.*; 40 C.F.R. § 155.58.
[11] 40 C.F.R. § 155.58.
[12] Ecological Risk Assessment, EPA-HQ-OPP-2014-0777-0021, at 11.

review included an extended observation period designed to capture flonicamid's delayed toxicity.[13]

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.[14] 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.[15] EPA also concluded that flonicamid drift presents significant risks to bees as far as 308 feet from the application site.[16]

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.[17] Moreover, mortality did not stabilize by the end of the extended observation period in the flonicamid arms of the study.[18] 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. The PID states that ISK, the technical registrant, is conducting studies required by EPA's data call in to further investigate flonicamid's extended impacts on pollinators, including tier II colony studies.

Despite these data, flonicamid is marketed as safe for pollinators. Flonicamid was discovered by ISK, 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."[19] Similarly, FMC asserts that flonicamid has "a minimal impact on many important beneficial insects, pollinators and predatory mites."[20] The brochures containing these statements do not cite any basis for these claims.

III. EPA Must Adequately Characterize Flonicamid's Risks to Pollinators Before Issuing a Registration Decision.

To re-register flonicamid, FIFRA requires EPA to find that flonicamid "will not generally cause unreasonable adverse effects on the environment." Under *Pollinator Stewardship Council v. U.S. EPA*, 806 F.3d 520, 532 (9th Cir. 2015), EPA cannot make this determination without sufficient data to characterize a pesticide's risks to pollinators.

---

[13] *Id*. at 32.
[14] *Id*. at 24.
[15] *Id*. at 33.
[16] *Id*. at 34 Table 8-3.
[17] *Id*. at 7.
[18] *Id*. at 25 Fig. 1.
[19] Flonicamid Brochure, *available at* https://www.iskweb.co.jp/products/pdf/flonicamid.pdf.
[20] Beleaf 50SG Insecticide, Strawberries Brochure, *available at* https://www.fmccrop.com/Portals/_default/fmc_pdf/2f4dd7d0d36e4925b4d089b729ac780a.pdf.

Here, EPA lacks sufficient information to characterize flonicamid's risks to pollinators. EPA stated in its ecological risk assessment 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] EPA similarly discloses in the PID that "[a]dditional higher-tiered pollinator data required by the registration review [generic data call in] will be developed, which may change the agency's understanding of the risks of concern."[22]

Accordingly, EPA must review the forthcoming higher-tiered pollinator data *before* issuing an Interim Registration Review Decision. The PID states that higher-tiered pollinator data "will be considered prior to issuance of the Interim Decision *if available*,"[23] and the California Attorney General's Office understands that the higher-tiered pollinator data will not be available before EPA plans to issue its Interim Decision. EPA's non-committal suggestion that it will review the data "if available" undermines FIFRA's requirement that EPA adequately comprehend a pesticide's risks before registration. And once the registration review is complete, there is no guarantee ISK will finish its studies and submit higher-tiered pollinator data, especially if the data confirm that flonicamid presents significant risks to pollinators.

Moreover, the possibility that EPA will faithfully review the new ISK studies after the registration review is closed does not cure the defect. Outside formal registration review, EPA will not be required to review the new ISK studies in a timely manner. FIFRA also lacks any opportunity for public participation or legal recourse if EPA's consideration of ISK's studies or decision on mitigation is flawed. Deferring consideration of higher-tiered pollinator data until after registration review would frustrate FIFRA's intent to provide a transparent registration and risk evaluation process that allows for public input.

EPA states that its proposed interim decision includes the determination that "submission of higher-tier pollinator data are required."[24] But EPA decided over four years ago at the data call in stage of flonicamid's registration review that higher-tier pollinator data were required.[25] That registration review procedure—first issuing a data call in, then receiving and reviewing the data to produce an ecological risk assessment, and then issuing proposed and final registration decisions—ensures EPA has data *before* it has to make a registration decision. Especially where, as here, the partial data EPA possesses suggests that a pesticide's standard uses poses potential risks,[26] issuing a registration review decision despite significant data gaps violates FIFRA.[27]

The PID also proposes to add an advisory label statement warning that flonicamid "is moderately toxic to bees and other pollinating insects." The label advisory helps correct the impression—perpetuated by ISK's marketing—that flonicamid does not harm pollinators, but it

---

[21] Ecological Risk Assessment, at 36.
[22] PID at 16.
[23] *Id*. (emphasis added).
[24] *Id*. at 18.
[25] EPA-HQ-OPP-2014-0777-0017.
[26] *See, e.g.*, Ecological Risk Assessment, at 35; PID at 14.
[27] *Pollinator Stewardship Council*, 806 F.3d at 532.

does not compensate for EPA's data deficiencies. As EPA admits in the PID, without the required follow-up pollinator studies, EPA cannot know the degree to which flonicamid harms pollinators or calibrate the need for additional labeling restrictions.[28] In addition, the label advisory does not compel applicators to take any particular precautions. EPA should consider adopting additional mitigation, especially on an interim basis until it can determine the extent of flonicamid's adverse effects on pollinators.

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 has not demonstrated that flonicamid "will not generally cause unreasonable adverse effects on the environment" "when used in accordance with widespread and commonly recognized practice."[29] The Attorney General of California therefore urges EPA gather the necessary data, describe flonicamid's risks to pollinators, and recirculate its draft ecological risk assessment before re-registering flonicamid.

Sincerely,

ROBERT D. SWANSON
Deputy Attorney General

For XAVIER BECERRA
Attorney General

[28] PID at 14, 16.
[29] 7 U.S.C. § 136a(c)(5).