THE COMMONWEALTH OF MASSACHUSETTS
OFFICE OF THE ATTORNEY GENERAL
ONE ASHBURTON PLACE
BOSTON, MASSACHUSETTS 02108

MAURA HEALEY
ATTORNEY GENERAL

(617) 727-2200
(617) 727-4765 TTY
www.mass.gov/ago

May 4, 2020

Via Electronic Filing

EPA-HQ-OPP-2008-0844 (Imidacloprid Registration Review)
EPA-HQ-OPP-2011-0865 (Clothianidin Registration Review)
EPA-HQ-OPP-2011-0920 (Dinotefuran Registration Review)
EPA-HQ-OPP-2011-0581 (Thiamethoxam Registration Review)
EPA-HQ-OPP-2012-0329 (Acetamiprid Registration Review)

Mary Reaves, Acting Director
Pesticide Re-Evaluation Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: Notice of Availability and Request for Comments on EPA's Proposed Interim Registration Review Decisions for the Neonicotinoid Pesticides Imidacloprid, Clothianidin, Dinotefuran, Thiamethoxam, and Acetamiprid (85 Fed. Reg. 5,953; Feb. 3, 2020)

Dear Acting Director Reaves:

The Attorneys General of Massachusetts, New York, Hawai'i, Illinois, Maryland, Minnesota, Oregon, Washington, and the District of Colombia appreciate this opportunity to comment further on the U.S. Environmental Protection Agency's ("EPA") continuing reviews under Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")[1] of the registrations of five neonicotinoid insecticides: imidacloprid, clothianidin, thiamethoxam, dinotefuran, and acetamiprid (collectively, the "Registration Reviews").

In its notice dated February 3, 2020,[2] EPA requested comments on its proposed interim registration review decisions (the "PIDs") for imidacloprid, clothianidin, thiamethoxam, dinotefuran, and acetamiprid (collectively, the "Subject Neonicotinoid Insecticides") as an avenue for providing input for the agency to consider in issuing interim or final registration

[1] 7 U.S.C. § 136a(g).

[2] *See* 85 Fed. Reg. 5,953 (Feb. 3, 2020).

review decisions for the Subject Neonicotinoid Insecticides and a mechanism for initiating any necessary amendments to the PIDs.

On July 31, 2017, the Attorney General of New York filed comments (the "2017 New York AG Comments") on EPA's preliminary bee risk assessment for clothianidin and thiamethoxam,[3] which are incorporated by reference herein and attached hereto. And on April 20, 2018, the Attorneys General of Massachusetts, Hawai'i, Maryland, and the District of Columbia submitted comments (the "2018 Multistate AG Comments") on EPA's draft non-pollinator ecological risk assessment for the review of imidacloprid[4] and on EPA's draft human-health and non-pollinator ecological risk assessments for the reviews of clothianidin,[5] thiamethoxam,[6] and dinotefuran,[7] which comments are also incorporated by reference herein and attached hereto.

For the reasons discussed below, the PIDs are based on deficient risk assessments that, in their present form: (1) cannot support a finding that the Subject Neonicotinoid Insecticides "will not generally cause unreasonable adverse effects on the environment" under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136a(c)(5); and (2) cannot "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to these pesticides applied for food uses as required by the Food Quality Protection Act ("FQPA"), 21 U.S.C. § 346a(b)(2)(C)(ii).

First, the Final Bee Risk Assessments for clothianidin, thiamethoxam, and imidacloprid fail to examine risks to pollinators from exposure to treated seed dust created during the planting of neonicotinoid treated seeds, despite EPA's acknowledgement that seed treatment is the predominant use of these neonicotinoid insecticides and that dust from treated seeds is associated with numerous risks to honey bees and other pollinators.[8] Second, EPA failed to finalize its non-

---

[3] EPA, *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam* (Jan. 5, 2017), Doc. No. EPA-HQ-OPP-2011-0865-0173 [hereinafter Clothianidin and Thiamethoxam Preliminary Bee Risk Assessment].

[4] EPA, *Imidacloprid – Transmittal of the Preliminary Terrestrial Risk Assessment to Support the Registration Review* (Nov. 28, 2017), Docket No. EPA-HQ-OPP-2008-0844-1256.

[5] EPA, *Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support the Registration Review of Clothianidin* (Nov. 27, 2017), Doc. No. EPA-HQ-OPP-2011-0865-0242; EPA, *Clothianidin. Draft Human Health Risk Assessment in Support of Registration Review* (Sept. 7, 2017), Doc. No. EPA-HQ-OPP-2011-0865-0243.

[6] EPA, *Preliminary Risk Assessment to Support the Registration Review of Thiamethoxam* (Nov. 29, 2017), Doc. No. EPA-HQ-OPP-2011-0581-0093; EPA, *Thiamethoxam. Draft Human Health Risk Assessment for Registration Review* (Dec. 5, 2017), Doc. No. EPA-HQ-OPP-2011-0581-0096.

[7] EPA, *Preliminary Ecological Risk Assessment (excluding terrestrial invertebrates) for the Registration Review of Dinotefuran* (Nov. 28, 2017), Doc. No. EPA-HQ-OPP-2011-0920-0616; EPA, *Dinotefuran: Human Health Draft Risk Assessment for Registration Review* (Sept. 12, 2017), Doc. No. EPA-HQ-OPP-2011-0920-0620.

[8] The undersigned are concerned also with such seeds being considered treated articles by the agency, *see* 40 CFR 152.25(a), limiting the regulatory authority of EPA and the states to investigate and address exposures that may occur during planting where such planting is not considered the use of a pesticide. *See*

pollinator risk assessments, and its preliminary risk assessments do not adequately assess risks from the Subject Neonicotinoid Insecticides to aquatic ecosystems, soil ecosystems, and groundwater. Third, because EPA's risk assessments for the Subject Neonicotinoid Insecticides are partial and/or non-final, it is unlawful and arbitrary and capricious for EPA to base its cost-benefit analysis on those incomplete assessments in determining whether the pesticides satisfy the FIFRA standard for registration. Fourth, EPA's human health risk assessments for the Subject Neonicotinoid Insecticides are not finalized, and its preliminary risk assessments fail to protect the nation's most vulnerable populations, our children, from neonicotinoid exposure.

Accordingly, we urge EPA to conduct the necessary, thorough assessments of all risks associated with the Subject Neonicotinoid Insecticides, including by performing a full assessment of the risks from prophylactic use of seed treatments, and to finalize all risk assessments, with an additional opportunity for public comment, before making any pesticide registration decisions for the Subject Neonicotinoid Insecticides. Final and complete risk assessments must be developed for bees and other pollinators, non-pollinator species, and humans, before EPA issues interim or final registration review decisions and moves forward with reregistration of these pesticides. Failure to do so necessitates the cancelation or severe restriction of neonicotinoid use unless and until adequate, complete and final assessments are performed.

The Attorneys General submit the following comments for EPA's consideration in its ongoing analyses in connection with the Registration Reviews.

SUMMARY OF COMMENTS

Many of the undersigned expressed guarded optimism in the 2018 Multistate AG Comments about EPA's undertaking a much-needed review of the registrations of neonicotinoid insecticides that threaten significant harm to our states and appropriately acting to address those risks. However, the risk assessments that EPA has conducted to date for the Subject Neonicotinoid Insecticides are wholly inadequate to support the findings required under both FIFRA and FQPA.

FIFRA requires EPA to analyze and duly consider during the registration-review process the full suite of risks posed by the Subject Neonicotinoid Insecticides. EPA must ensure that each pesticide, when used in accordance with widespread and commonly recognized practice, "will not generally cause unreasonable adverse effects on the environment;" that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.[9] Under FIFRA, a pesticide product may be registered or

---

New York Attorney General Comments on Center for Food Safety Petition Seeking Formal Agency Interpretation for Planted Seeds Treated with Systemic Insecticides (83 Fed. Reg. 66,260) (Mar. 26, 2019), Doc. ID EPA-HQ-OPP-2018-0805-0083, https://www.regulations.gov/document?D=EPA-HQ-OPP-2018-0805-0083 (last accessed May 4, 2020).

[9] *See* 7 U.S.C. §§ 136(bb), 136a(c)(5), 136a(g). *See also Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015).

remain registered only if it meets this statutory standard for registration.[10]

As demonstrated in the 2017 New York AG Comments, the 2018 Multistate AG Comments, and further demonstrated below, including when used in accordance with common practice as a seed treatment, the Subject Neonicotinoid Insecticides are known to be highly toxic to bees and other pollinators, contributing to potentially catastrophic pollinator losses that threaten our states' agricultural economies and the food supply, the health and welfare of our residents,, while also being harmful to fish, amphibians, birds, bats, aquatic invertebrates, and other wildlife. They threaten the health of our lakes, streams, and rivers. Further, the use of neonicotinoids on food crops, their environmental persistence, presence in drinking water sources, and possible binding to human nicotinic acetylcholine receptors raise concerns for potential adverse human health impacts from chronic exposures.[11]

Accordingly, EPA cannot support a finding under FIFRA that continued extensive use of the Subject Neonicotinoid Insecticides "will not generally cause unreasonable adverse effects on the environment," and to date EPA has not conducted risk assessments adequate to find otherwise. On the contrary, the significant risks identified to date posed by the Subject Neonicotinoid Insecticides appear to outweigh the benefits of at least many, if not most, uses—a conclusion that is underscored by a continuing litany of actions by states, retailers, citizen groups, and other countries around the world to limit neonicotinoid insecticide use and mitigate associated environmental harms, including harms to honey bees and other pollinators.

Similarly, EPA's risk assessments fail to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to these pesticides as required by FQPA.[12] EPA's draft human health risk assessments illegally eliminate the tenfold safety factor for the protection of infants and children for all five Subject Neonicotinoid Insecticides without considering updated scientific research on human health risk, and without subjecting them to the Endocrine Disruptor Screening Program ("EDSP") or assessing their cumulative impact as required by the FQPA.

These comments proceed as follows. In Part I, we describe the standard for EPA's review of the registrations of the Subject Neonicotinoid Insecticides. In Part II, we provide a summary of our states' interests with regard to the Registration Reviews. In Part III, we discuss the need for stricter federal control of the Subject Neonicotinoid Insecticides to meet federal policy goals, protect states, and buttress state pollinator-protection actions. In Part IV, we provide information about the consensus among governments and major retailers that the risks associated with these pesticides outweigh their benefits. And in Part V we analyze the severe and unacceptable risks posed by neonicotinoid insecticides to pollinator and non-pollinator species across ecosystems, the ubiquitous use and known adverse impacts of seeds treated with the insecticides coupled with

---

[10] *See* 85 Fed. Reg. at 5,954.

[11] National Toxicology Program, U.S. Dep't of Health and Human Services, *Neonicotinoid Pesticides & Human Health Outcomes*, https://ntp.niehs.nih.gov/whatwestudy/assessments/noncancer/ongoing/neonicotinoid/index.html (last accessed May 4, 2020).

[12] 21 U.S.C. § 346a(b)(2)(C)(ii).

the failures of the agency adequately to examine the associated risks, the requirements for the agency to assess risks to protect threatened and endangered species and to consider cumulative, synergistic, and aggregate exposure risks, and finally, the failures of the agency properly to apply the FQPA safety factor to protect vulnerable populations in its registration review.

There is compelling evidence linking neonicotinoid insecticides to severe, unacceptable risks to bees and other pollinators, as well as risks to other wildlife, ecosystems and human health, and EPA has failed to complete adequate risk assessments on which to reregister the Subject Neonicotinoid Insecticides. The agency must not reregister the Subject Neonicotinoid Insecticides for their various uses unless and until adequate assessments are completed. In the absence of adequate information establishing that the various uses meet the standards for registration, these registrations should be suspended. EPA already has cancelled registrations for certain uses of products with the neonicotinoid insecticides thiamethoxam, clothianidin, and imidacloprid,[13] albeit at the registrants' own request, and we urge the agency based on science similarly to act to severely restrict or cancel additional registrations for the Subject Neonicotinoid Insecticides, including unnecessary applications and other uses that pose particular risk to human health, pollinators and aquatic and soil ecosystems.

I. Standard for Registration Review

Under FIFRA, every pesticide distributed or sold in the United States, including neonicotinoid insecticides, must be registered by EPA (with limited exceptions).[14] "A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used."[15] The purpose of the registration process is "to protect man and his environment."[16]

FIFRA requires EPA to review pesticide registrations at least every fifteen years to "assess any changes that may have occurred since EPA's last registration decision" and "determine . . . whether the insecticide still satisfies the FIFRA standard for registration."[17] EPA can register a pesticide only if EPA "determines that, when considered with any restrictions

---

[13] *See* EPA, *Product Cancellation Order for Certain Pesticide Registrations*, 84 Fed. Reg. 22, 841 (May 20, 2019), https://www.govinfo.gov/content/pkg/FR-2019-05-20/pdf/2019-10447.pdf (last accessed May 4, 2020).

[14] *See* 7 U.S.C. § 136a(a): "[n]o person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter." Insecticides, including each of the Subject Neonicotinoid Insecticides, are a class of pesticides used specifically to target, manage, and kill insects. *See id.* § 136 (defining "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer," with certain exceptions not applicable here).

[15] *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010).

[16] S. REP. NO. 92-838 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 3993.

[17] 40 C.F.R. § 155.53(a); *see also id.* § 155.40(a)(1) ("Registration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment."); *see also* 7 U.S.C. § 136a(g)(1)(A).

imposed . . . it will perform its intended function without unreasonable adverse effects on the environment" and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."[18] "Unreasonable adverse effects on the environment" are defined as "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any insecticide, or (2) a human dietary risk . . . inconsistent with [federal standards]."[19]

FIFRA's "unreasonable adverse effects" language creates a "risk-benefit" standard wherein EPA must weigh the relative risks and benefits of the use of the pesticides and evaluate whether, on balance, the benefits of the use outweigh risks to humans and the environment.[20] EPA must base its risk evaluation on sufficient data and cannot rely on ambiguous or inconclusive studies to support a conclusion that a pesticide does not cause unreasonable adverse effects.[21] If a pesticide under review "fails to satisfy the FIFRA standard for registration, the product's registration may be subject to cancellation."[22]

EPA commences a registration review by opening a public docket containing "information that will assist the public in understanding the types of information and issues that EPA may consider in the course of the registration review," including any "[r]isk assessment documents."[23] EPA then solicits public comment on the registration review docket, and "interested persons may identify any additional information they believe EPA should consider in the course of the registration review."[24] The registration review docket remains open during the pendency of the review process, until EPA has completed all actions required for a final decision.[25]

---

[18] 7 U.S.C. § 136a(c)(5); *see also Reckitt Benckiser Inc.*, 613 F.3d at 1133.

[19] 7 U.S.C. § 136(bb).

[20] *See, e.g., Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 532 (9th Cir. 2001) (quoting *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984)) ("FIFRA registration is a cost-benefit analysis that no unreasonable risk exists to man or the environment . . . ."); *Pollinator Stewardship Council*, 806 F.3d at 522-23 (quoting *Washington Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005)) ("FIFRA uses a 'cost-benefit analysis to ensure that there is no unreasonable risk created for people or the environment from a pesticide.'").

[21] *See Pollinator Stewardship Council*, 806 F.3d at 531-32 (vacating EPA's unconditional registration of the neonicotinoid sulfoxaflor where approval decision was not supported by substantial evidence).

[22] 40 C.F.R. § 155.40(a)(2); *see also* 7 U.S.C. § 136d(b) (EPA may commence action to cancel or reclassify a registration if it appears that common use of the pesticide "generally causes unreasonable adverse effects on the environment."); *Envtl. Defense Fund, Inc. v. EPA*, 510 F.2d 1292, 1296 n.4 (D.C. Cir. 1975) (quoting *Envtl. Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 594 (D.C. Cir. 1971)) (EPA must commence a cancellation or reclassification proceeding "whenever there is a substantial question about the safety of a registered pesticide").

[23] 40 C.F.R. § 155.50(a).

[24] *Id.* § 155.50(b).

[25] *See id.* § 155.58(c).

The federal FQPA of 1996[26] amended both FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA)[27] and was passed for the purpose of assuring that pesticide residues on foods are "safe" when considering aggregate and cumulative human exposure scenarios (via food, water, and other human exposures). FFDCA Section 408a(b) identifies the safety standard that must be met and states that EPA may leave in effect a tolerance for a pesticide residue on food *only if* the EPA Administrator determines that the tolerance is safe:

> Standard. The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on food *only if* the Administrator determines that the tolerance is safe. The Administrator *shall modify or revoke a tolerance if the Administrator determines it is not safe*.[28]

The EPA Administrator's determination of safety means that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.[29] In determining allowable levels of pesticide residues in food, EPA must, among other things, perform a comprehensive assessment of each pesticide's risks, considering: aggregate exposure (from food, drinking water, and residential uses); cumulative effects from all pesticides sharing a common mechanism of toxicity; possible increased susceptibility of infants and children; and possible endocrine or estrogenic effects.

II. States' Interests

Our states continue to have a significant interest in ensuring that the Registration Reviews are conducted in accordance with FIFRA and protect our pollinators, ecosystems, and the health of our residents from the risks posed by the Subject Neonicotinoid Insecticides.

Honey bees and other pollinators, including wild bees, bats, and birds, play an essential role in crop production.[30] Pollinators are critical to both small local farms and large national farming operations, and to the production of food consumed by people as well as livestock, domestic pets, and wild animals. The U.S. Department of Agriculture (USDA) reports that bee pollination of agricultural crops accounts for about one-third of the U.S. diet, contributing to the production of a diverse range of high-value fruits, vegetables, tree nuts, forage crops, some field crops, and other specialty crops.[31] Honey bee pollination contributes more than fifteen billion

---

[26] P.L. 104-70, signed into law by President Clinton on Aug. 3, 1996.

[27] 21 U.S.C. §§ 301, *et seq.*, as amended.

[28] *Id.* § 346a(b)(2)(A)(i).

[29] *Id.* § 346a(b)(2)(A)(ii).

[30] *See generally* L.A. Garibaldi et al., *Wild Pollinators Enhance Fruit Set of Crops Regardless of Honey Bee Abundance*, 339 SCIENCE 1608 (2013); Natural Resources Defense Council, *Busy as a Bee: Pollinators Put Food on the Table* (2015), https://www.nrdc.org/sites/default/files/bee-deaths-FS.pdf (last accessed May 4, 2020).

[31] *See* R. Johnson et al., *Bee Health: Background and Issues for Congress*, Congressional Research Serv. (Jan. 20, 2015) at 5, fas.org/sgp/crs/misc/R43191.pdf (last accessed May 4, 2020); *see also* Michael

dollars in value to U.S. agricultural crops each year.[32]

Alarmingly, the critically important ecological services provided by pollinators are in jeopardy due to significant pollinator declines in recent years. Between 2012 and 2019, the national annual colony losses ranged from 33.2% to 45.2%.[33]

In 2015, the USDA and EPA declared the national honey bee colony losses unacceptable and set a ten-year goal to reduce losses during winter to no more than 15%.[34] Data points to no progress towards meeting that goal. As reported by the University of Maryland, between April 2018 and April 2019, U.S. beekeepers lost approximately 41 percent of honey bee colonies, and experienced the highest recorded rate of winter losses.[35] Losses to U.S. commercial beekeepers,

---

Wines, *Mystery Malady Kills More Bees, Heightening Worry on Farms*, N.Y. TIMES (Mar. 28, 2013).

[32] *See* Presidential Memorandum – Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators (June 20, 2014), https://obamawhitehouse.archives.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b (last accessed May 4, 2020) [hereinafter Federal Pollinator Memorandum].

[33] Total national honey bee loss from 2012-2013 was 45.2%: N.A. Steinhauer et al., *A National Survey of Managed Honey Bee 2012-2013 Annual Colony Losses in the USA: Results from the Bee Informed Partnership 2012-2013*, 53 J. OF APICULTURAL RESEARCH 1-18 (2014).

Total national honey bee loss from 2013-2014 was 34.1%: K.V. Lee et al., *A National Survey of Managed Honey Bee 2013-2014 Annual Colony Losses in the USA*, 46 APIDOLOGIE 292-305 (2015).

Total national honey bee loss from 2014-2015 was 40.6%: N. Seitz et al., *A National Survey of Managed Honey Bee 2014-2015 Annual Colony Losses in the USA*, 54 J. OF APICULTURAL RESEARCH 292-304 (2016).

Total national honey bee loss from 2015-2016 was 40.5%: K. Kulhanek et al., *A National Survey of Managed Honey Bee 2015-2016 Annual Colony Losses in the USA*, 56 J OF APICULTURAL RESEARCH 328-340 (2017).

Total national honey bee loss from 2016-2017 was 33.2%: N. Steinhauer et al., *Honey Bee Colony Losses 2016-2017: Preliminary Results*, https://beeinformed.org/2017/05/25/2016-2017-loss-results-thank-you-to-all-survey-participants/ (last accessed May 4, 2020).

Total national honey bee loss from 2017-2018 was 40.1%: S. Bruckner et al., *United States Honey Bee Colony Losses 2017-2018: Preliminary Results*, https://beeinformed.org/wp-content/uploads/2019/11/2017-2018-Abstract.pdf (last accessed May 4, 2020).

Total national honey bee loss from 2018-2019 was 40.7 %: S. Bruckner et al., *2018-2019 Honey Bee Colony Losses in the United States: Preliminary Results*, https://beeinformed.org/wp-content/uploads/2019/11/2018_2019-Abstract.pdf (last accessed May 4, 2020).

[34] USDA & EPA Pollinator Health Task Force, *National Strategy to Promote the Health of Honey Bees and Other Pollinators*, https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf (last accessed May 4, 2020).

[35] University of Maryland, *U.S. Beekeepers Lost Over 40 Percent of Colonies Last Year, Highest Winter Losses Ever Recorded: Results Point to a Need for Increased Research, Extension, and Best Management Practices*, SCIENCEDAILY (June 19, 2019), www.sciencedaily.com/releases/2019/06/190619142532.htm

according to the USDA, "far exceed the historical rate . . . and represent a threat to both beekeepers and to those agriculture crops that rely upon pollination as a production input."[36] In addition to the risks to food production, these bee losses have a significant direct economic impact as well, translating to billions of dollars of costs borne by beekeepers.[37]

Recent pollinator declines[38] coincide with dramatically increased use[39] and toxicity loading of neonicotinoid insecticides on agricultural lands and surrounding areas.[40] Neonicotinoid insecticides are a class of systemic pesticides: water-soluble pesticides that once absorbed by the treated plant, moves throughout the plant's vascular system, exposing insects feeding on the plant—including those drinking guttation fluid and obtaining nectar—to the insecticide. Neonicotinoids affect the central nervous system of insects, with resulting nervous stimulation, paralysis, and death depending on the level of exposure. As highly water-soluble insecticides, they also readily leach off agricultural fields and are transported into surface water, ground water and wetlands with ease.[41]

Neonicotinoid insecticides were first registered for use in the United States in the mid-1990s and are now abundant in the environment across most of the country. EPA has approved hundreds of neonicotinoid-containing products and authorized broad use of these products in residential and commercial settings, including agricultural use on nearly all major U.S. crops. In some reported years, more than four million pounds of neonicotinoid insecticides are applied to U.S. cropland[42] to protect against sap-sucking insects and plant-feeding insects, and use, including seed treatments, is only projected to grow. Much of the use of neonicotinoid insecticides in agriculture is considered "prophylactic," meaning the toxic insecticide is applied

---

(last accessed May 4, 2020).

[36] USDA, *Report on the National Stakeholders Conference on Honey Bee Health*, National Honey Bee Health Stakeholder Conference Steering Committee (2012), at 1.

[37] *See id.* at 1-2.

[38] David Goulson et al., *Bee Declines Driven by Combined Stress from Parasites, Pesticides, and Lack of Flowers.* 347 SCIENCE 6229 (2015).

[39] *See* Margaret R. Douglas & John F. Tooker, *Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides and Preemptive Pest Management in U.S. Field Crops*, 49 ENVTL. SCI. & TECH. 5088 (2015).

[40] Michael DiBartolomeis et al., *An Assessment of Acute Insecticide Toxicity Loading (AITL) of Chemical Pesticides Used on Agricultural Land in the United States,* 14 PLoS ONE 1 (2019).

[41] T.J. Wood & D. Goulson, *The Environmental Risks of Neonicotinoid Pesticides: A Review of the Evidence Post 2013* 24 ENVTL. SCI. & POLLUTION RESEARCH INT'L 17285 (2017).

[42] U.S. Geological Survey, *Estimated Annual Agricultural Pesticide Use – Pesticide Use Maps – Thiamethoxam* (2017), https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2014&map=THIAMETHOXAM&hilo=L&disp=Thiamethoxam (last accessed May 4, 2020); U.S. Geological Survey, *Estimated Annual Agricultural Pesticide Use – Pesticide Use Maps – Imidacloprid* (2017), https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2014&map=IMIDACLOPRID&hilo=L (last accessed May 4, 2020).

prior to any experienced pest problem (the primary example being as a seed treatment).[43] Neonicotinoid insecticides are also approved for a wide variety of non-agricultural uses, including use in residential settings, such as on lawns, flowering trees and shrubs, and gardens; in building materials; and in treatments for domestic pets.

Manufacturers promoted neonicotinoid insecticides as a safer alternative for wildlife because these insecticides were thought to be less toxic to birds and mammals than older classes of chemicals. However, research shows neonicotinoids are highly toxic to many non-target species. The environmental risks of neonicotinoid insecticides are now a significant global concern, prompting calls for neonicotinoid insecticide bans, and state and international action to limit neonicotinoid insecticide use.[44] Studies have found increasing evidence that neonicotinoid insecticides are harmful not only to pollinators but also to a broad range of terrestrial and aquatic wildlife, threatening the health and functioning of our natural ecosystems.[45] In addition, though there is little research on the human-health risks of chronic exposure to neonicotinoid insecticides, studies raise concerns about significant impacts such as nervous system disorders and developmental impacts to infants and children.[46]

As described below, each of our states has a significant interest in ensuring that in the course of the Registration Reviews, EPA fulfills its responsibilities under FIFRA and FQPA and takes appropriate action to protect our state's resources, residents, wildlife, and agricultural economy from the risks posed by the Subject Neonicotinoid Insecticides.

Massachusetts

Pollinators play a critical role in supporting Massachusetts' economy and the health and welfare of Massachusetts residents. For centuries, Massachusetts' agricultural economy, which includes more than 7,750 farms and 523,000 acres of farmland, has been a vital source of job opportunities, land preservation, and valuable commodities such as the state's native cranberry.[47] Nearly half of the state's agricultural production relies on its rich diversity of pollinator species. Massachusetts is home to an estimated 380 wild bee species and 120 butterfly species, including

---

[43] Kevin Johnson et al., *Probability of Cost-Effective Management of Soybean Aphid (Hemiptera: Aphididae) in North America*, 102 J. OF ECON. ENTOMOLOGY 2101 (2009); Adeney de Fraitas Bueno et al., *Effects of Integrated Pest Management, Biological Control and Prophylactic Use of Insecticides on the Management and Sustainability of Soybeans*, 30 CROP PROTECTION 937 (2011); Douglas & Tooker, *supra* note 39; David Goulson, *An Overview of the Environmental Risks Posed by Neonicotinoid Insecticides*, 50 J. OF APPLIED ECOLOGY 977 (2013), https://besjournals.onlinelibrary.wiley.com/doi/full/10.1111/1365-2664.12111 (last accessed May 4, 2020).

[44] *See infra* at 16-23.

[45] *See infra* at 29-31.

[46] *See infra* at 31-32.

[47] *See* APIARY PROG. WORKING GROUP, DIV. OF CROP & PEST SERV., MASS. DEP'T OF AGRIC. RES., MASSACHUSETTS POLLINATOR PROTECTION PLAN 3 (2017), https://www.mass.gov/files/documents/2017/06/zw/pollinator-plan.pdf (last accessed May 4, 2020) [hereinafter MA Pollinator Plan].

some protected species,[48] as well as numerous managed pollinator species.[49]

In recent years, Massachusetts has experienced declines in pollinator populations that threaten the economic and environmental health of our state. In the 2015/2016 season, Massachusetts beekeepers reported an annual loss of 55.75 percent of honey bee colonies—which is the highest level of bee loss in New England and among the top 10 percent of losses across the nation.[50] State surveys indicate that on average, beekeepers lost 30 percent of their honey bee colonies that season, with some counties reporting losses as high as 41 percent.[51]

Following guidance from the federal government, the Massachusetts Department of Agricultural Resources ("MDAR")[52] finalized its *Massachusetts Pollinator Protection Plan* ("MA Pollinator Plan") in 2017. The MA Pollinator Plan is designed to improve the health of pollinators by promoting best management practices and facilitating collaboration on solutions to protect Massachusetts' critical pollinator populations.[53] The MA Pollinator Plan links recent alarming colony losses to pesticide use (which the plan notes is one of "the major threats facing pollinators"),[54] and sets forth wide-ranging guidelines for beekeepers, pesticide applicators, land managers and farmers, nurseries and landscapers, and homeowners and gardeners.[55]

The Massachusetts Attorney General's Office has also responded to the risks posed by pesticides. In 2016, Attorney General Maura Healey pursued enforcement action against Bayer CropScience LP for unfair or deceptive practices in marketing the company's lawn and garden products containing imidacloprid and clothianidin. The Attorney General alleged that Bayer CropScience LP violated the state's Consumer Protection Act[56] by failing to disclose harms to bees and making misleading claims regarding its neonicotinoid insecticide products, including that the products were "environmentally friendly" and using them was akin to "taking a daily vitamin." In settlement, Bayer CropScience LP agreed to pay $75,000 and reform its advertising

---

[48] The Massachusetts Division of Fisheries and Wildlife and the Natural Heritage and Endangered Species Program have listed seven species of wild bees and nineteen species of butterflies and moths as "of concern," endangered, or threatened. The Natural Heritage and Endangered Species Program has identified pesticides as a key threat to the state's imperiled pollinators. *See id.* at 6-8.

[49] Managed species include, *e.g.*, honey bees, bumble bees, leafcutting bees, and orchard bees. *See id.* at 5.

[50] *See id.* at 6-7.

[51] *See id.* at 7.

[52] MDAR's Pesticide Enforcement Program is the designated lead state agency for enforcement of FIFRA and the Massachusetts Pesticide Control Act. *See* MASS. GEN. LAWS ch. 132B; 333 MASS. CODE REGS. 1-14. MDAR's pollinator programs include, e.g., investigating bee kills, collecting and analyzing data on pollinator health, and overseeing education programs. *See* MA Pollinator Plan, *supra* note 47, at 11-13, 24-25.

[53] MA Pollinator Plan, *supra* note 47, at 3.

[54] *See id.* at 7.

[55] *Id.* at 13-24.

[56] MASS. GEN. LAWS ch. 93A.

and branding practices for neonicotinoid products in Massachusetts.[57]

The Massachusetts legislators have also recognized the grave risks posed by neonicotinoids and developed pioneering legislation that would impose strict state-level controls on the application of bee-toxic pesticides. For example, House Bill 763[58] would limit distribution of neonicotinoid-containing substances primarily to certified commercial applicators, certified private applicators, and licensed applicators; allow only such qualified applicators to spray, release, deposit, or apply neonicotinoids on any property within the Commonwealth; and require applicators to provide notice to property owner. House Bill 763 is currently moving through the legislative process with broad support and in November 2019 was favorably reported out of committee.

New York

The economy of New York State includes a robust agricultural sector, with over 35,000 farms covering approximately 7.3 million acres, or nearly one-quarter of the state's land area.[59] The State is a leading producer of specialty crops that require or benefit from pollination by insects, such as apples, pears, cherries, strawberries, pumpkins, squash, beans and cucumbers. These pollination-dependent crops contribute $1.2 billion annually to the state's agricultural economy, with the Western honey bee (Apis mellifera) providing 50% of crop pollination services in the State.[60]

Some crops widely grown in New York, such as corn, involve the use of substantial quantities of neonicotinoid pesticides, including use of treated seeds. Indeed, based on EPA's own estimation that nearly all corn seed planted in the United States is treated with clothianidin or thiamethoxam,[61] virtually all of the approximately one million acres of corn grown annually across New York likely is planted with seeds treated with one of these two neonicotinoids,[62] despite the fact that clothianidin is not registered for agricultural use by the New York State Department of Environmental Conservation (NY DEC).[63] During its registration review, NY

---

[57] *See* Assurance of Discontinuance, *Commonwealth of Massachusetts v. Bayer CropScience LP*, Civil Action No. 16-3269G (Suffolk Cty. Super. Ct. Oct 26, 2016).

[58] *Available at* https://malegislature.gov/Bills/191/H763 (last accessed May 4, 2020).

[59] Office of the New York State Comptroller, *Agriculture in New York State* (Sept. 2018), at 1, https://www.osc.state.ny.us/reports/economic/agriculture-report-2018.pdf (last accessed May 4, 2020).

[60] NY DEC & NY Ag & Markets, *New York State Pollinator Protection Plan Update* (June 2018), at 8, https://agriculture.ny.gov/system/files/documents/2019/06/pollinator-report.pdf (last accessed May 4, 2020) [hereinafter Plan Update].

[61] Clothianidin and Thiamethoxam Preliminary Bee Risk Assessment, *supra* note 3, at 6-7 & Table 2.6. EPA estimates that 45-65% of all U.S. corn acres are planted with clothianidin treated seed and 26-45% of U.S. corn acres with thiamethoxam treated seed.

[62] USDA, Nat'l Ag. Statistics Serv., https://quickstats.nass.usda.gov/results/A7A4336B-3873-36A4-B92B-2F7C8B97FB9C. USDA estimates for New York State: 1,080,000 acres of corn planted with corn in 2015, 1,100,000 acres in 2016 and 1,000,000 acres in 2017.

[63] The NY DEC has not registered clothianidin for any agricultural use. NY DEC, *Letter Re: Withdrawal*

DEC determined that "based on the high toxicity of clothianidin and the potential long-term chronic effects to honey bees, environmental persistence, possible role as an endocrine disrupter, chronic toxic risk to non-endangered and endangered small birds, and acute/chronic toxicity to non-endangered and endangered mammals, [clothianidin] should not be accepted for registration in New York State." [64]

At the same time, many of New York's other economically important crops depend upon insect pollination, either from approximately 80,000 managed pollinator colonies in the State, or from New York's 450 wild pollinator species.[65] Both commercial and wild bee colonies have experienced the precipitous loss over the past several years. From 2017 to 2018 alone, New York beekeepers experienced a 40.43% total annual colony loss,[66]and overall colony losses of commercial migratory bees based in the State have exceeded 70%.[67]

In an effort to address these catastrophic pollinator losses, in 2016 the NY DEC and the New York State Department of Agriculture and Markets (NY Ag & Markets) developed the "New York State Pollinator Protection Plan," which aims to "promote the health and recovery of pollinator populations in New York State in order to sustain the state's robust agricultural economy and unparalleled natural resources."[68] The Plan has been updated to reflect the numerous initiatives undertaken and proposed by various State entities seeking to alleviate this persistent problem. Despite these efforts, the updated Plan cites research at Cornell University confirming previous reports that approximately *half* the honey bee colonies present in New York were lost in each of the three previous years.[69] Additional research being undertaken by Cornell University includes the potential negative impacts on pollinators from certain insecticides.[70]

Hawai'i

As recently as 2018, there were over 400 registered beekeepers in Hawai'i. A recent needs assessment survey conducted by the University of Hawai'i found that one third of beekeepers in the state depend upon the sale of honey or honey bee queens as at least a portion of their income. Honey was ranked as a top 20 commodity in Hawai'i in 2017,[71] and according to

---

of Application for Registration of the New Product Poncho 600 (EPA Reg. No. 264-789-7501), Which Contains the New Active Ingredient Clothianidin (Nov. 16, 2005).

[64] *Id.*

[65]NY DEC & NY Ag & Markets, *New York State Pollinator Protection Plan,* (June 2016), at 5-6 https://www.dec.ny.gov/docs/administration_pdf/nyspollinatorplan.pdf (last accessed May 4, 2020).

[66]Bee Informed Partnership, *2017/18 Total Annual All Colony Loss*, https://bip2.beeinformed.org/loss-map/ (last accessed May 4, 2020).

[67] *New York State Pollinator Protection Plan*, *supra* note 65, at 5.

[68]*Id.* at 1.

[69]*Plan Update, supra* note 60, at 1.

[70]*Id.* at 12.

[71] *See* https://www.nass.usda.gov/Statistics_by_State/Hawaii/Publications/Annual_Statistical_Bulletin/2017/201

the National Agricultural Statistics Service, 17,000 honey-producing colonies statewide produced on average 103 pounds of honey each, the highest in the nation.[72] The resulting value of $3.362 million is likely a gross underestimation of honey revenues generated by beekeepers, as specialty honeys produced from *ʻōhiʻa* lehua retail for $20/pound and mixed wildflower honeys retail higher than the clover honey produced in the mainland U.S.

The honey bee queen rearing industry in Hawaiʻi is the largest in the world, and is essential to the success of mainland U.S. and Canadian beekeeping operations. Due to the subtropical climate, queen rearing, which otherwise only occurs in the spring, can occur during winter months and approximately ten large queen-breeding companies on Oʻahu and Hawaiʻi islands ship tens of thousands of queen bees to North American beekeepers every spring to replace winter dead-outs which in the past have topped 30%. The Hawaiʻi Department of Agriculture estimates this industry as being worth $10 million annually. While this is likely a gross underestimation of the value of queen breeding in Hawaiʻi, *it is invaluable to North American beekeeping where roughly 70% of queens originate from the state of Hawaiʻi.*

Honey bee pollination services are also essential for increasing yields and profitability of the state's major specialty cash crops. In 2017, macadamia nut and coffee were valued at $53.9 million and $43.8 million, respectively.[73] Due to the relatively high stocking density of colonies near arable land areas resulting from geographic constraints and high nectar plant availability, farmers do not presently pay for pollination services.

In addition to honey bees, there are 63 species of native bees, all belonging to the genus *Hylaeus* (Colletidae),[74] though several are thought to be extinct and seven are currently listed as federally endangered.[75] They have close plant-pollinator associations with native plants across the islands. Species ranges extend from coastal to inland to mountainous areas, frequently overlapping with honey bees and the other 18 introduced bee species across the archipelago.

In recognition of the vital role that pollinators, and honey bees in particular, play in the agricultural economy of the Hawaiʻian Islands and the threat that neonicotinoids pose to local bee colonies, the Hawaiʻi Legislature introduced Senate Bill 445 in 2019.[76] This bill, if it becomes law, would make it necessary to obtain a permit prior to applying any neonicotinoid, including planting treated (i.e., neonicotinoid-coated) seeds.

7HawaiiTop20Commodities.pdf (last accessed May 4, 2020).

[72] *Available at* https://downloads.usda.library.cornell.edu/usda-esmis/files/hd76s004z/v979vm595/dn39xk32q/hony0320.pdf (last accessed May 4, 2020).

[73] *See supra* note 71.

[74] H.V. Daly & K.N. Magnacca, *Insects of Hawaii: Hawaiian Hylaeus (Nesoprosopis) Bees (Hymenoptera: Apoidea)* (University of Hawaii Press, Honolulu, HI, 2003).

[75] U.S. Fish and Wildlife Service, *Endangered and Threatened Wildlife and Plants; Endangered Status for 49 Species from the Hawaiian Islands* (2016), at 67786-67860.

[76] *See* https://capitol.hawaii.gov/measure_indiv.aspx?billtype=SB&billnumber=445&year=2020 (last accessed May 4, 2020).

Illinois

Illinois farmland covers 27 million acres—about 75 percent of the State's total land area.[77] Illinois is a leading producer of soybeans and corn. The State's climate and varied soil types enable farmers to also grow many other agricultural commodities, including wheat, oats, sorghum, hay, fruits, and vegetables. Illinois also produces several specialty crops, such as buckwheat and horseradish. These crops involve the use of substantial quantities of neonicotinoid pesticides, including use of treated seeds. According to the United States Department of Agricultural Statistics Services ("USDA-NASS"), as of April 2019, Illinois had more than 71,000 farms.[78] Marketing of Illinois' agricultural commodities generates more than $19 billion annually.

There are approximately 400 to 500 species of native bees in Illinois.[79] Bumble bees, carpenter bees, plasterer bees, cuckoo bees, mason bees, leafcutter bees, sweat bees and mining bees are types of native bees in Illinois. Under the Illinois Bees and Apiaries Act, the Illinois Department of Agriculture has the power to inspect bees, colonies, and apiaries (510 ILCS 20/2-4) and is required to annually report its findings (510 ILCS 20/3). The most recent report stated that 4,551 beekeepers manage 32,268 colonies in 6,202 apiaries in Illinois.[80] In Illinois, colonies are being increasingly used due to lack of feral colonies and the importance of pollination. Furthermore, honeybee exposure to pesticides has at times had "catastrophic impacts" on Illinois' pollinators.[81]

District of Columbia

The District of Columbia (District) is vitally interested in ensuring that EPA performs the FIFRA Registration Reviews for the Subject Neonicotinoid Insecticides appropriately and considers the results from recent scientific studies and assessments that demonstrate adverse impacts of the Subject Neonicotinoid Insecticides. The District is primarily an urban environment, but within that environment, the District has expansive parks, an impressive tree canopy, miles of shore, numerous buildings with green roofs, open space, and many avid gardeners. The District is home to approximately 130 native bee species. Four of these species

---

[77] Illinois Dep't of Ag., *Facts About Illinois Agriculture*, https://www2.illinois.gov/sites/agr/About/Pages/Facts-About-Illinois-Agriculture.aspx (last accessed May 4, 2020).

[78] USDA-NASS, *2019 State Agriculture Overview*, https://www.nass.usda.gov/Quick_Stats/Ag_Overview/stateOverview.php?state=ILLINOIS (last accessed May 4, 2020).

[79] Illinois Dep't of Natural Resources, *Native Bees,* https://www2.illinois.gov/dnr/education/Pages/PollinatorNativeBees.aspx (last accessed May 4, 2020).

[80] Illinois Dep't of Ag., *FY 2019 Apiary Inspection Annual Report*, https://www2.illinois.gov/sites/agr/Insects/Bees/Documents/FY19ApiaryAnnualReport.pdf (last accessed May 4, 2020).

[81] *Id*. at 2.

are designated as Species of Greatest Conservation Need in the 2015 Wildlife Action Plan,[82] and these species and their critical habitats are managed by the District's Department of Energy & Environment (DOEE). In addition, one of them, the rusty patched bumble bee, is an endangered species.

In 2016 the District had the distinction of being proclaimed a Bee City USA in part due to the efforts of the DOEE to promote pollinators through pollinator seed giveaways, native meadow creation, and educational outreach. Although the District has no commercial agriculture or commercial beekeeping for pollination services or honey production, the DOEE has created a Pollinator Protection Plan that focuses not only on the protection of managed pollinators, but also on the protection of all pollinators in the District. The goal of this Plan is to engage non-profit organizations, government agencies, businesses, pesticide applicators, beekeepers, educational institutions, and the general public in the promotion and protection of pollinators by helping people understand pollinators' importance and how there can be a home for them in the District's urban environment.

In further promoting the District's interest in the health of pollinators and the potential impacts to human health and the environment, the DOEE is in the process of publishing a proposed rulemaking that will add the Subject Neonicotinoids and other pesticides to the list of District Restricted-Use Pesticides (DRUP). A pesticide that is on the DRUP list is subject to a number of use restrictions, including purchase and use only by a DOEE-licensed applicator. The DOEE started this rulemaking effort in part due to the extensive scientific and toxicological assessments and corresponding legislation adopted by the State of Maryland and the European Union.[83]

III. Stricter Federal Controls Are Needed to Fulfill Federal Policy Goals, Protect States from the Unreasonable Risks of Neonicotinoid Insecticides, and Buttress State Action to Protect Pollinators.

Since 2014, it has been the express policy of the federal government to promote the health of pollinators, including by avoiding pesticide uses that would aggravate already severe pollinator losses, and to support state efforts to develop and implement their own pollinator protection plans.[84] Given that states and EPA have invested considerable resources to advance the federal policy of protecting pollinators from the damaging effects of pesticides, it would be

---

[82] *Available at* https://doee.dc.gov/service/2015-district-columbia-wildlife-action-plan (last accessed May 4, 2020).

[83] *See, e.g.,* MD. DEP'T OF LEGIS. SERVS., POLLINATOR HEALTH AND THE USE OF NEONICOTINOIDS IN MARYLAND (2015), http://mgaleg.maryland.gov/pubs/legislegal/2015-pollinator-health.pdf (last accessed May 4, 2020); Eur. Comm'n, *Pesticides and Bees* https://ec.europa.eu/food/animals/live_animals/bees/pesticides_en (last accessed May 4, 2020); COMMISSION IMPLEMENTING REGULATION (EU) 2013 O.J. (L 139) NO 485, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:139:0012:0026:EN:PDF (last accessed May 4, 2020).

[84] *See* Federal Pollinator Memorandum, *supra* note 32.

wholly unreasonable for EPA now to undermine this policy by reregistering the continued extensive use of the Subject Neonicotinoid Insecticides without conducting adequate risk assessments of the grave risks to pollinators in our states.

In 2014, then President Obama issued a memorandum entitled *Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators*[85] ("Federal Pollinator Memorandum"), which recognized recent severe pollinator losses and established an interagency Pollinator Health Task Force. The Pollinator Health Task Force was charged with developing a National Pollinator Health Strategy ("Federal Pollinator Strategy") that sets forth plans for research, public education, and public-private partnerships.[86] The Federal Pollinator Memorandum further required the Pollinator Health Task Force member agencies, including EPA, to develop and implement plans to enhance pollinator habitat and incorporate consideration of pollinator health into certain agency decision-making processes. Additionally, the Federal Pollinator Memorandum required all executive departments and agencies to take appropriate action to protect pollinators, including "avoiding the use of pesticides in sensitive pollinator habitats."[87]

The Federal Pollinator Strategy finalized by the Pollinator Health Task Force in 2015 states that:

> **[m]itigating the effects of pesticides on bees is a priority for the Federal government**, as both bee pollination and insect control are essential to the success of agriculture. . . . [T]he Federal government seeks to create physical and temporal space between the use of pesticides and those areas and times when pollinators are present.[88]

The Federal Pollinator Strategy further details actions that EPA will take by 2020 to protect pollinators as directed by the Federal Pollinator Memorandum. Among other actions, the Federal Pollinator Strategy states that EPA will "[r]estrict the use of pesticides that are acutely toxic to bees," including by potentially restricting uses of pesticides that pose a particular risk to pollinators, such as foliar (leaf) application during bloom periods.[89] Notably, the Federal Pollinator Memorandum specifically required EPA to "assess the effect of pesticides, including neonicotinoids, on bee and other pollinator health,"[90] and the Federal Pollinator Strategy cites the Registration Reviews as a key implementation action.[91]

---

[85] *Id.*

[86] *See* POLLINATOR HEALTH TASK FORCE, NATIONAL STRATEGY TO PROMOTE THE HEALTH OF HONEY BEES AND OTHER POLLINATORS (2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf (last accessed May 4, 2020).

[87] Federal Pollinator Memorandum, *supra* note 32.

[88] POLLINATOR HEALTH TASK FORCE, *supra* note 92, at 47 (emphasis added).

[89] *Id.* at 49.

[90] Federal Pollinator Memorandum, *supra* note 32.

[91] POLLINATOR HEALTH TASK FORCE, *supra* note 92, at 47, 48-49, 52.

The Federal Pollinator Memorandum also specifically required EPA to "engage" states and tribes "in the development of State and tribal pollinator protection plans[.]"[92] As described in these comments, many of our states and other jurisdictions across the country have developed such plans and are taking other action to strictly control bee-toxic chemicals and promote pollinator health.[93] For instance, at least six states have enacted policies to protect their valuable pollinators from neonicotinoid insecticides and others are in process (*see* **Error! Reference source not found.**).[94]

Table 1. Examples of State Policies Regarding Neonicotinoid Insecticides (all last accessed May 4, 2020)

State	Neonicotinoid Legislation
Arizona	**Senate Bill 1289 (2020) (*pending*)** prohibits the sale of neonicotinoid pesticides unless the person is licensed to sell a restricted use pesticide and restricts the use of neonicotinoid pesticides to certified applicators, farmers, and veterinarians, except for the use of certain pet care, personal care, and pest control products.
California	**Assembly Bill 1789 (2014)**[95] required the Department of Pesticide Regulation to reevaluate neonicotinoid insecticides by July 1, 2018, and thereafter "adopt any control measures necessary to protect pollinator health."
Colorado	**House Bill 1180 (2020) (*pending*)** requires the Commissioner of Agriculture to adopt rules to regulate the use of neonicotinoid pesticides, and that the Commissioner's rules exempt use of indoor pest control, personal care, and pet care products from restricted use unless the Commissioner determines that another commercially available product is as or more effective.

[92] Federal Pollinator Memorandum, *supra* note 32.

[93] *See generally* NAT'L CONFERENCE OF STATE LEGISLATURES, POLLINATOR HEALTH (2016), http://www.ncsl.org/research/environment-and-natural-resources/pollinator-health.aspx (last accessed May 4, 2020) (listing state legislation supporting research on issues related to pollinator health, protecting pollinators from pesticides, protecting and restoring pollinator habitat, educating the public about the role of pollinators, or supporting local beekeepers). *See also supra* Part II.

[94] In addition, in 2007, New York State denied applications for registration of four new pesticide products containing clothianidin based on concerns regarding impacts to non-target aquatic species and non-target pollinators. *See* Letter from NY DEC to Arysta Life Science North America Corp. (July 17, 2007).

[95] *Codified at* CAL. FOOD & AGRIC. CODE § 12838.

State	Neonicotinoid Legislation
Connecticut	**Senate Bill 231 (2016)**[96] prohibited applying neonicotinoid insecticides to certain plants; required the Department of Energy and Environmental Protection to classify certain neonicotinoid insecticides as "restricted use" pesticides; required the Department of Agriculture to develop best practices for minimizing the release of dust from neonicotinoid-treated seeds; and encouraged protection and restoration of pollinator habitat.
Delaware	**House Bill 317 (2020) (*pending*)** prohibits the use of neonicotinoids outdoors on public land owned or maintained by the State, classifies neonicotinoids as "restricted use" pesticides, and limits use to certified applicators.
Hawai'i	**Senate Bill 445 (2019) (*pending*)** prohibits application of neonicotinoid insecticides without a permit after June 30, 2020 to protect honeybees and other pollinators.
Illinois	**House Bill 3636 (2019) (*pending*); House Bill 4381 (2020) (*pending*)** authorize the Director of the Department of Agriculture to classify pesticides as restricted use pesticides, including those containing neonicotinoids, and prohibit any pesticide containing a neonicotinoid from being used outdoors on any public land or maintained by the state, except for use in structural pest control or abatement of a certain pest species.
Maine	**House Bill 1484; Legislative Document 2083 (2020) (*pending*)** requires the Board of Pesticides Control to annually publish certain information regarding pesticides and to prohibit certain uses of neonicotinoids.
Maryland	**Senate Bill 198 (2016)**[97] limited the sale of neonicotinoid insecticides to establishments that sell restricted use pesticides and generally restricted neonicotinoid use to certified applicators, farm employees, and veterinarians. Upon completion of EPA's Registration Reviews, the Department of Agriculture is required to review the state's pesticide laws and regulations and recommend changes to protect pollinators.
Massachusetts	**House Bill 763 ("An Act to Protect Massachusetts Pollinators") (2019) (*pending*)** limits distribution of neonicotinoid-containing substances primarily to certified commercial applicators, certified private applicators, and licensed applicators. It also allows only such applicators to spray, release, deposit, or apply neonicotinoids on any property within the Commonwealth, and requires applicators to provide certain notice to property owners.
	Senate Bill 463 (2019) (*pending*) prohibits distribution of all neonicotinoids and neonicotinoid-containing substances, except neonicotinoid-treated nursery plants, and prohibits the spray, release, deposit, or application of any neonicotinoid on any property within the Commonwealth.

[96] 2016 CONN. PUB. ACTS 16-17.

[97] *Codified at* MD. CODE ANN., AGRIC. §§ 5-2A-01 *et seq.*

State	Neonicotinoid Legislation
Minnesota	**Executive Order 16-07 (Aug. 25, 2016)** directed the Department of Agriculture to require a "verification of need" prior to the use of neonicotinoid insecticides, where appropriate, and to implement restrictions on pesticide product labels to protect pollinators; required the Department of Natural Resources to develop an integrated pest management strategy for public lands; and encouraged protection and restoration of pollinator habitat
	House Bill 721 (2019) (*pending*); House Bill 1656 (2019) (*pending*); Senate Bill 2107 (2019) (*pending*); and House Bill 3657 (2020) (*pending*) prohibit neonicotinoid insecticides from being used by any person in a wildlife management area.
	House Bill 2647 (2019) (*pending*) appropriates $400,000 to the Board of Regents of the University of Minnesota to study the presence of neonicotinoids in wild white-tailed deer in Minnesota.
	House Bill 1252 (2019) (*pending*); Senate Bill 2576 (2019) (*pending*) increase the pesticide gross sales fee for neonicotinoid pesticides and require revenues from this additional fee to be dedicated to pollinator habitat and research account.
	House Bill 1255 (2020) (*pending*) authorizes cities to adopt pesticide control ordinances requiring warning signs for pesticide application or prohibiting application of certain pesticides.
Missouri	**House Bill 2441 (2020) (*pending*)** prohibits any person from applying any glyphosate or neonicotinoid pesticide by using any type of ground, water, or aerial equipment using motorized, mechanical or pressurized power to apply the pesticide; and allows the Department of Agriculture to issue civil penalties.
	House Bill 2292 (2020) (*pending*) restricts the sale of neonicotinoid insecticides to retailers who also sell restricted use pesticides and restricts the use of neonicotinoid pesticides to pesticide applicators, operators, and technicians; farmers; and veterinarians.
New Hampshire	**House Bill 646 (2019) (*pending*)** defines "bee-toxic pesticide," restricts the use of bee-toxic pesticides, and requires certain state agencies to create and publish a list of best practices for the agricultural industry and the general public to transition away from the use of bee-toxic pesticides.
New Jersey	**Senate Bill 1016 (2020) (*pending*)** directs the Department of Environmental Protection (NJ DEP) to classify neonicotinoid pesticides as restricted use pesticides, which would restrict use to certified and licensed pesticide applicators. It also directs NJ DEP to study, and authorizes NJ DEP to restrict, systemic insecticides.
	Assembly Bill 2070 (2020) (*pending*) directs NJ DEP to classify neonicotinoid pesticides as restricted use pesticides, which would restrict use to certified and licensed pesticide applicators.
	Assembly Bill 2848 (2020) (*pending*) prohibits application of neonicotinoids on state, county, or municipal property.

State	Neonicotinoid Legislation
	Assembly Bill 2075 (2020) (*pending*) prohibits sale of milkweed plants treated with certain pesticides.
New York	**Senate Bill 5816 ("Birds and Bees Protection Act") (2019) (*pending*)** prohibits the sale of certain pesticides; requires the commissioner of environmental conservation to report on the use of certain pesticides; requires the Department of Environmental Conservation (NY DEC) to consider a strategy for the development of pollinator friendly lands; and requires the NY DEC to distribute information to protect migratory birds. It also requires the NY DEC to make recommendations to the department of transportation on the species of plantings and the application of pesticides.
	Assembly Bill 7639A ("Birds and Bees Protection Act") (2019) (*pending*) prohibits the sale of certain pesticides and requires the commissioner of environmental conservation to report on the use of certain pesticides; requires the NY DEC to consider a strategy for the development of pollinator friendly lands; and requires the NY DEC to distribute information to protect migratory birds.
	Senate Bill 1074 (2019) (*pending*) prohibits the distribution, sale, or use within the state–or delivering for transportation or transport in intrastate commerce of–neonicotinoids.
	Assembly Bill 8116 (2019) (*pending*) prohibits any person from using any pesticide containing neonicotinoids.
North Carolina	**House Bill 559 (2019); Senate Bill 496 (2019) ("The Pollinator Protection Act") (*pending*)** prohibits the sale of any neonicotinoid pesticide to members of the public at retail, unless the seller is authorized to sell a restricted use pesticide; and prohibits the use of neonicotinoid pesticides except by licensed applicators, farmers, and veterinarians.
Oregon	**House Bill 4139 (2014)**[98] required Oregon State University, in consultation with the State Department of Agriculture, to develop educational materials measures that pesticide applicators can take to protect pollinator health, which shall be included as part of the education required for the pesticide applicator licensing examination.
	Administrative Rule No. 603-057-0388 (2015) prohibits the use of any product containing clothianidin, dinotefuran, imidacloprid, or thiamethoxam on *Tilia* species (e.g., linden trees), which are highly attractive to bees.
Rhode Island	**House Bill 7425 (2020); Senate Bill 2403 (2020) (*pending*)** prohibit the purchase, possession, or use of all neonicotinoids on any land for any purposes within the state.

[98] OR. REV. STAT. § 634.045.

State	Neonicotinoid Legislation
Tennessee	**Senate Bill 2580 (2020); House Bill 2422 (2020) (*pending*)** prohibit the sale of any plant or seed treated with a neonicotinoid pesticide unless such plant is labeled with a warning regarding neonicotinoids' effects on bees, and prohibit the use of neonicotinoid pesticides except by certified applicators, farmers, and veterinarians.
Vermont	**House Bill 759 (2020) (*pending*)** requires any use of neonicotinoid-treated article seed to be authorized by the Secretary of Agriculture, Food and Markets.
	Senate Bill 266 (2020) (*pending*) prohibits the sale, distribution, or use of any neonicotinoid-treated article seed in the state, except as authorized by the Secretary of Agriculture, Food and Markets upon a determination that a threat to Vermont crops exists that requires the use of a neonicotinoid-treated article.
	House Bill 268 (2019) (*pending*) limits the retail sale of neonicotinoid pesticides to pet care products, personal care products, and indoor pest control products, and requires the retail sale of neonicotinoid pesticides to be authorized by the Secretary of Agriculture, Food and Markets upon a determination that a threat to human health, natural resources, biota, or crops exists that requires the use of a neonicotinoid pesticide.
	House Bill 869 (2014)[99] required the Secretary of Agriculture Food, and Markets to evaluate whether neonicotinoid insecticides are safe and not harmful to human health or the health of Vermont's pollinators.

Ongoing state-level actions to mitigate the threats of neonicotinoid insecticides evidence a growing, widespread consensus that these chemicals pose unreasonable risks and should be strictly curtailed. However, only EPA has the power to limit the use of neonicotinoid insecticides throughout the United States. Given how neonicotinoid insecticides can and do adversely affect pollinating insects, other species, and ecosystems in ways that have serious consequences without respect to state borders, unless EPA takes appropriate action to strictly control them, neonicotinoid insecticide use will continue to undermine state initiatives—as well as federal policy goals—to protect our pollinators, other natural resources, and economies from adverse environmental effects.

IV. Actions by Other Governments and Major Retailers Evidence a Watershed Consensus That the Risks of Neonicotinoid Insecticides Outweigh Benefits.

Science-based state actions by other governments to limit neonicotinoid insecticide use—and the net benefits associated with those limits—provide further evidence that extensive use of neonicotinoid insecticides poses unreasonable environmental risks.

The most significant actions by other governments to restrict neonicotinoids have come from the EU and Canada. In 2013, the EU severely restricted the use of pesticides containing

[99] 2014 Vt. Legis. Serv. 159.

three neonicotinoids—clothianidin, imidacloprid and thiamethoxam—on flowering crops upon which bees feed.[100] These limitations were subsequently expanded to all field crops in April 2018,[101] which followed an assessment by the European Food Safety Authority of more than 1,500 studies of the effects of clothianidin, imidacloprid, and thiamethoxam, concluding that most uses of neonicotinoid insecticides pose a risk to wild bees and honeybees.[102] Later in 2018, France enacted more protective measures, banning the use of seven neonicotinoids within its borders beginning September 1, 2018, with limited exceptions until July 1, 2020.[103] Most recently, the EU decided not to renew approval of a fourth neonicotinoid, thiacloprid in January 2020.[104]

In April 2019, Canada completed a re-evaluation of clothianidin, imidacloprid, and thiamethoxam's effects on bees and other pollinators, announcing that it would cancel some uses of these pesticides and amend some existing restrictions on their use over a two-year period.[105] Quebec and Ontario have already imposed restrictions on neonicotinoid insecticides, and Montreal banned all uses of neonicotinoid insecticides within city limits in 2015.

Governments are not the only entities responding to calls from the public for action against neonicotinoid insecticides. More than 140 companies have eliminated or limited neonicotinoid pesticides in their supply chains, including major retailers such as Rite Aid, Aldi, Kroger, Costco, Ace Hardware, Lowe's Home Depot, Walmart, and True Value.[106] For example, Ace Hardware announced in 2018 that is has "removed neonics from ninety-five percent of its

---

[100] Damian Carrington, *Bee-Harming Pesticides Banned in Europe*, THE GUARDIAN (Apr. 29, 2013), https://www.theguardian.com/environment/2013/apr/29/bee-harming-pesticides-banned-europe (last accessed May 4, 2020).

[101] Erik Stokstad, *European Union Expands Ban of Three Neonicotinoid Pesticides*, SCIENCE (Apr. 27, 2018), https://www.sciencemag.org/news/2018/04/european-union-expands-ban-three-neonicotinoid-pesticides (last accessed May 4, 2020).

[102] *See* Press Release, European Food Safety Auth., *Neonicotinoids: Risks to Bees Confirmed* (Feb. 28, 2018), https://www.efsa.europa.eu/en/press/news/180228 (last accessed May 4, 2020).

[103] *Neonicotinoids to Be Banned in France from September 1*, THE CONNEXION (Aug. 29, 2018), https://www.connexionfrance.com/French-news/Neonicotinoids-pesticides-to-be-banned-in-France-from-September-1-2018 (last accessed May 4, 2020) (discussing French ban of acetamiprid, clothianidin, dinotefuran, imidacloprid, nitenpyram, thiacloprid, and thiamethoxam).

[104] Robin Emmott, *EU Commission Bans Bayer Pesticide Linked to Harming Bees*, REUTERS (Jan. 13, 2020), https://www.reuters.com/article/us-eu-bayer-pesticide/eu-commission-bans-bayer-pesticide-linked-to-harming-bees-idUSKBN1ZC136 (last accessed May 4, 2020); *see also* Eur. Comm'n, *Neonicotinoids*, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en (last accessed May 4, 2020) (summarizing status of neonicotinoids in the EU from 2013 to present).

[105] News Release, Health Canada, *Health Canada Releases Final Pollinator Re-Evaluation Decisions for Neonicotinoid Pesticides* (Apr. 11, 2019), https://www.canada.ca/en/health-canada/news/2019/04/some-cancellations-and-new-restrictions-to-protect-bees-and-other-pollinators.html (last accessed May 4, 2020).

[106] Friends of the Earth, *Retailer Commitments on Pesticides and Pollinator Health*, https://foe.org/nursery-retailer-commitments/ (last accessed May 4, 2020).

insecticide product offerings," and "[a]ll of its private label lawn and garden products are neonic-free."[107]

EPA should follow Europe's and Canada's lead in recognizing that risks to pollinators necessitate swift federal action to severely curtail the use of neonicotinoid insecticides and should propose to restrict severely or cancel uses of the Subject Neonicotinoid Insecticides, including unnecessary uses and other uses that pose particular risk to pollinators and aquatic environments, based on adequate and complete risk assessments.

V. Analysis

A. The Subject Neonicotinoid Insecticides Pose Severe, Unacceptable Risks to the Environment.

Following the submission of the 2017 NY AG Comments and 2018 Multistate AG Comments, the science establishing that the Subject Neonicotinoid Insecticides pose unreasonable risks to pollinators, other wildlife, human health, and state agricultural economies, has strengthened and only increases the urgency with which EPA must comprehensively and adequately assess the risks of these insecticides under FIFRA and FQPA.

At the time of the 2017 and 2018 comments, a robust body of research already demonstrated that neonicotinoid insecticides are toxic to bees, causing a variety of adverse sublethal effects that reduce the survival of colonies and the survival of wild bees,[108] and that neonicotinoid insecticides also pose risks to other wildlife, including fish, amphibians, birds, aquatic invertebrates, and bats. While there was not much by way of studies assessing human health effects of chronic exposure to neonicotinoid insecticides, the existing data indicated a risk of potentially serious harms. Since April 2018, the science demonstrating the severe toxicity of these neonicotinoid has developed, further supporting significant agency action to protect pollinators, other wildlife, ecosystems, and people, from the risks associated with exposure to these pesticides.

To date, the dockets for the Registration Reviews for the Subject Neonicotinoid Insecticides do not include a single risk assessment document that is comprehensive and complete, despite the fifteen risk assessments that are underway. For example, of these fifteen

---

[107] *Id.*

[108] *See, e.g.*, A. Decourtye & J. Devillers, *Ecotoxicity of Neonicotinoid Insecticides to Bees*, 683 ADV. EXP. MED. BIOL. 85 (2010); Richard J. Gill et al., *Combined Pesticide Exposure Severely Affects Individual- and Colony-Level Traits in Bees*, 491 NATURE 105 (2012); P.R. Whitehorn et al., *Neonicotinoid Pesticide Reduces Bumble Bee Colony Growth and Queen Production*, 356 SCIENCE 351 (2012). *See also* EPA, Press Release, *EPA Releases the First of Four Preliminary Risk Assessments for Insecticides Potentially Harmful to Bees* (Jan. 6, 2016), https://archive.epa.gov/epa/newsreleases/epa-releases-first-four-preliminary-risk-assessments-insecticides-potentially-harmful.html (last accessed May 4, 2020) (summarizing EPA's preliminary finding that "imidacloprid potentially poses risk to hives" and exposure to imidacloprid at a common level has likely adverse effects, "includ[ing] decreases in pollinators as well as less honey produced").

risk assessments, eleven are designated as merely preliminary assessments, and four are improperly characterized as final notwithstanding that they do not assess the risk associated with the predominant mode of application for the pesticide (seed treatment). Moreover, for all five Subject Neonicotinoid Insecticides, EPA concedes that it has limited usage data on non-agricultural use sites of the chemical,[109] and often has no recent usage data on agricultural uses of the chemical.[110] Accordingly, EPA's publication of the PIDs is grossly premature as they do not reflect assessments EPA is legally mandated to perform to adequately assess the risks presented by the Subject Neonicotinoid Insecticides.

The demonstrated significant risks presented by the continued use of the Subject Neonicotinoid Insecticides appear clearly to outweigh the benefits of at least many, if not most, uses of the pesticides. Accordingly, EPA cannot support a finding under FIFRA that continued extensive use of the Subject Neonicotinoid Insecticides "will not generally cause unreasonable adverse effects on the environment."[111]

1. Neonicotinoid Insecticides Are Ubiquitous in the Environment, Posing a Chronic Threat to Wildlife and Humans.

As a consequence of their chemical characteristics and common application practices, neonicotinoid insecticides are pervasive in the environment, posing a chronic threat to pollinators and other animals.

Neonicotinoid insecticides are the most extensively applied insecticides in the United States by land area.[112] Neonicotinoid product application typically involves spraying or injecting a plant, inundating soil, or treating plant seeds. Because of the systemic nature of neonicotinoid, a treated seed or plant absorbs the insecticide into its roots, tissues and vascular systems poisoning target insects, but also rendering its pollen, nectar and guttation fluid a risk to non-target insects.[113]

Neonicotinoid insecticides remain in the environment long after they are applied, and can

---

[109] EPA, *Imidacloprid Proposed Interim Registration Review Decision* (Jan. 2020), Doc. No. EPA-HQ-OPP-2008-0844-1619, at 15 [hereinafter Imidacloprid PID]; EPA, *Clothianidin and Thiamethoxam Proposed Interim Registration Review Decision* (Jan. 2020), Docket IDs EPA-HQ-OPP-2011-0865-1190 & EPA-HQ-OPP-2011-0581-0362, at 17 [hereinafter Clothianidin and Thiamethoxam PID]; EPA, *Dinotefuran Proposed Interim Registration Review Decision* (Jan. 2020), Docket ID EPA-HQ-OPP-2011-0920-0765, at 14 [hereinafter Dinotefuran PID]; EPA, *Acetamiprid Proposed Interim Registration Review Decision* (Jan. 2020), Doc. No. EPA-HQ-OPP-2012-0329-0064, at 9 [hereinafter Acetamiprid PID].

[110] *E.g.*, the latest available data for seed treatment usage for clothianidin and thiamethoxam dates to 2014 (Clothianidin & Thiamethoxam PID at 17 and 18, respectively); for seed treatment usage for imidacloprid to 2015 (Imidacloprid PID at 14); and for agricultural usage of dinotefuran to 2017, with "usage . . . increasing over time" (Dinotefuran PID at 14).

[111] *See* 7 U.S.C. § 136a(c)(5).

[112] *See* CTR. FOR FOOD SAFETY, NET LOSS: ECONOMIC EFFICACY AND COSTS OF NEONICOTINOID INSECTICIDES USED AS SEED COATINGS: UPDATES FROM THE UNITED STATES AND EUROPE 1 (2016) [hereinafter NET LOSS REPORT].

[113] Wood & Goulson, *supra* note 41.

be found in pollen, dust, sediment, water, soils, and untreated vegetation.[114] On average, ninety-five percent of the active ingredient in neonicotinoid insecticides remains in the environment after application. When sprayed, neonicotinoid-containing products drift via air to nearby soils, water, and other plants. Neonicotinoid insecticides also are highly water soluble and therefore move and spread easily throughout the environment via groundwater and surface waters. The U.S. Geological Service's recent national-scale study of U.S. streams found at least one neonicotinoid present in sixty-three percent of surveyed streams, in both urban and agricultural areas; and the top four most commonly detected neonicotinoid insecticides were the four chemicals currently under EPA review.[115] The drift, aquatic transport, and persistence of neonicotinoid insecticides in the environment is especially concerning considering that several neonicotinoid-containing products approved by EPA for homeowner use in gardens and lawns, and on ornamental trees have manufacturer-recommended application rates that are sometimes 120 times higher than rates approved for use on agricultural crops—higher application rates that are both unnecessary for adequate pest control and more detrimental to pollinators. In general, neonicotinoid insecticides are applied at much higher rates to plants in greenhouses and nurseries and trees in urban areas than to field crops.[116]

There is no escape from these toxic chemicals. Pollinators are chronically exposed to neonicotinoid insecticides via a number of pathways, including direct ingestion of neonicotinoid-laced pollen, nectar, and guttation from commercial crops, dust from the planting of neonicotinoid-treated seeds, and from backyard lawns, gardens and ornamental plantings where neonicotinoid-containing lawn and garden products have been used.[117] Research shows that bees are drawn to pollen and plant fluids containing neonicotinoid insecticides such as imidacloprid and thiamethoxam as they are to pollen and plant fluids that do not contain such pesticides and cannot limit their exposure to these chemicals.[118] Research also shows that "set-aside" strips of

---

[114] For example, recent research has documented high levels of neonicotinoid contamination in vegetation in rural areas near fields treated with neonicotinoid insecticides. *See, e.g.*, C. Botias et al., *Neonicotinoid Residues in Wildflowers, a Potential Route of Chronic Exposure for Bees*, 49 ENVTL. SCI. TECH. 12731 (2016); Arthur David et al., *Widespread Contamination of Wildflower and Bee-Collected Pollen with Complex Mixtures of Neonicotinoids and Fungicides Commonly Applied to Crops*, 88 ENV'T INT'L 169 (2016).

[115] Michelle L. Hladik & Dana W. Kolpin, *First National-Scale Reconnaissance of Neonicotinoid Insecticides in Streams Across the USA,* 13 ENVTL. CHEMISTRY 12 (2015) (detecting neonicotinoid insecticides in surveyed U.S. streams, including imidacloprid (detected 37 percent of the time), clothianidin (24 percent), thiamethoxam (21 percent), and dinotefuran (13 percent)).

[116] L. Pisa et al., *An Update of the Worldwide Integrated Assessment (WIA) on Systemic Insecticides, Part 2: Impacts on Organisms and Ecosystems*, ENVTL. SCI. & POLLUTION RESEARCH (July 25, 2017), https://link.springer.com/content/pdf/10.1007/s11356-017-0341-3.pdf (last accessed May 4, 2020).

[117] Other pathways include exposure to treated seed fragments during planting. At least one researcher believes high fructose corn syrup made from corn treated with neonicotinoid insecticides (which is commonly fed to bees by commercial beekeepers) may contain small concentrations of neonicotinoid insecticides and constitute another exposure route. *See* Chensheng Lu, Kenneth M. Warchol, & Richard A. Callahan, In situ *Replication of Honey Bee Colony Collapse Disorder*, 65 BULLETIN OF INSECTOLOGY 99 (2012).

[118] Sebastien C. Kessler et al., *Bees Prefer Foods Containing Neonicotinoid Pesticides*, 521 NATURE 74

untreated pollinator-friendly vegetation near treated fields fail to provide pollinators relief from neonicotinoid exposures.[119]

Moreover, humans are chronically exposed to neonicotinoid insecticides in the natural environment; in the built environment, where neonicotinoid-containing products are used; and in the water and food supplies.[120] Notably, because of the systemic nature of neonicotinoid insecticides, some of the insecticides cannot be washed off the surface of foods prior to consumption. The most recent pesticide monitoring study by the U.S. Food and Drug Administration found neonicotinoid residues in a variety of different foods found in the human diet. Imidacloprid was the second most frequently occurring pesticide residue in the study, found in approximately thirty percent of samples. Thiamethoxam and clothianidin were also present in approximately eleven percent of samples.[121] In addition, a recent worldwide survey of neonicotinoids in honey found at least one of five tested neonicotinoid insecticides (acetamiprid, clothianidin, imidacloprid, thiacloprid, and thiamethoxam) in 75 percent of honey samples, with 10 percent of samples containing four or five of the compounds.[122] Neonicotinoid-containing products are also approved for a variety of residential uses and other uses that result in exposures of vulnerable populations such as children and pregnant women. For instance, imidacloprid is permitted for use on lawns, golf courses, and ornamental plantings; as a wood preservative and termiticide in dwellings, fence posts, decks, utility poles, and other structures; and in domestic pet treatments.[123]

2. *Neonicotinoid Insecticides Are Highly Toxic to Pollinators and Impair Bee Colony Success.*

There is no question that neonicotinoid insecticides are highly toxic to bees. By design, neonicotinoid insecticides are poisons engineered to kill insects and invertebrates. Even at minuscule doses, neonicotinoid insecticides cause bees to experience convulsions, paralysis, and death. And exposure during brood or early-adult development has been shown to reduce brain

---

(2015).

[119] *See* Christina L. Mogren & Jonathan G. Lundgren, *Neonicotinoid-Contaminated Pollinator Strips Adjacent to Cropland Reduce Honey Bee Nutritional Status*, 6 SCIENTIFIC REPORTS 1 (2016).

[120] In addition, some pesticide handlers and agricultural workers experience occupational exposure. *See* Memorandum from Jennifer R. Tyler et al., Off. of Pesticide Programs, EPA, to Russell Wasem & Susan Lewis, Special Review & Reregistration Div., EPA, at 6 (Dec. 3, 2008), Doc. ID. EPA-HQ-OPP-2008-0844-0004 [hereinafter Imidacloprid Human Health Assessment Scoping Document].

[121] U.S. FOOD & DRUG ADMIN., PESTICIDE RESIDUE MONITORING PROGRAM FISCAL YEAR 2015 PESTICIDE REPORT 27 (2017), https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm2006797.htm (last accessed May 4, 2020). *See also* AM. BIRD CONSERVANCY, NEONICOTINOID INSECTICIDES HARMFUL TO BIRDS AND BEES FOUND IN CONGRESSIONAL CAFETERIA FOOD (2015), https://abcbirds.org/wp-content/uploads/2017/02/Congressional-report_Pesticides_FINAL_7-30.pdf (last accessed May 4, 2020). (finding that more than 90 percent of food samples taken from Congressional cafeterias contain neonicotinoid insecticides).

[122] E.A.D. Mitchell et al., *A Worldwide Survey of Neonicotinoids in Honey*, 358 SCIENCE 109 (2017).

[123] *See* Imidacloprid Human Health Assessment Scoping Document, *supra* note 126, at 1, 4-5.

growth and impairs adult learning.[124] Research also shows that bees exposed to neonicotinoid insecticides (including in field-realistic conditions and doses) experience increased mortalities and a number of sublethal adverse effects that impair colony success and increase biodiversity loss.[125] Sublethal adverse effects include:

- neuromuscular impairments;
- disorientation and difficulties navigating back to the hive;
- reduced foraging efficiency;
- increased worker mortality;
- impaired memory, learning, and ability to communicate properly with other bees in the colony;
- reduction in breeding success and colony growth;
- reductions in queen production and survivorship;
- decrease in metabolic efficiency;
- immune suppression; and
- increased susceptibility to disease and parasites.[126]

The Directorate-General for Internal Policies of the European Parliament issued a report in 2012 concluding that "there is no safe level of exposure [of neonicotinoid insecticides], as even tiny amounts of systemic insecticides can have negative effects in the long term . . . the

---

[124] *See, e.g.,* Dylan B. Smith et al., *Insecticide Exposure During Brood or Early-Adult Development Reduces Brain Growth and Impairs Adult Learning in Bumblebees,* PROCEEDINGS OF THE ROYAL SOCIETY B, BIOLOGICAL SCIENCES (Mar. 4, 2020), https://royalsocietypublishing.org/doi/10.1098/rspb.2019.2442 (last accessed May 4, 2020).

[125] *See, e.g.*, Ben A. Woodstock et al., *Impacts of Neonicotinoid Use on Long-Term Population Changes in Wild Bees in England*, 7 NATURE COMMUNICATIONS (2016); JENNIFER HOPWOOD ET AL., XERCES SOC'Y, HOW NEONICOTINOIDS CAN KILL BEES: THE SCIENCE BEHIND THE ROLE THESE INSECTICIDES PLAY IN HARMING BEES (2d ed. 2016).

[126] *See, e.g.*, Gill et al., *supra* note 114; Whitehorn et al., *supra* note 114; Pisa et al., *supra* note 122; Annely Brandt et al., *Immunosuppression in Honeybee Queens by the Neonicotinoids Thiacloprid and Clothianidin*, 7 SCIENTIFIC REPORTS (2017); Javier Hernandez Lopez et al., *Sublethal Pesticide Doses Negatively Affect Survival and the Cellular Responses in American Foulbrood-Infected Honeybee Larvae*, 7 SCIENTIFIC REPORTS (2017); Nadejda Tsvetkov et al., *Chronic Exposure to Neonicotinoids Reduces Honey Bee Health Near Corn Crops*, 356 SCIENCE 1395 (2017); B.A. Woodcock et al., *Country-Specific Effects of Neonicotinoid Pesticides on Honey Bees and Wild Bees*, 356 SCIENCE 1393 (2017); Claudia Dussaubat et al., *Combined Neonicotinoid Pesticide and Parasite Stress Alter Honeybee Queens' Physiology and Survival*, 6 SCIENTIFIC REPORTS (2016); Lars Straub et al., *Neonicotinoid Insecticides Can Serve as Inadvertent Insect Contraceptives*, 283 PROCEEDINGS OF THE ROYAL SOC'Y B (2016); Judy Wu-Smart & Maria Spivak, *Sub-Lethal Effects of Dietary Neonicotinoid Insecticide Exposure on Honey Bee Queen Fecundity and Colony Development*, 6 SCIENTIFIC REPORTS (2016); Mohamed Alburaki et al., *Neonicotinoid-Coated Zea mays Seeds Indirectly Affect Honeybee Performance and Pathogen Susceptibility in Field Trials*, 10 PLOS ONE (2015); Maj Rundlof et al., *Seed Coating with a Neonicotinoid Insecticide Negatively Affects Wild Bees*, 521 NATURE 77 (2015); Daren M. Eiri & James C. Nieh, *A Nicotinic Acetylcholine Receptor Agonist Affects Honey Bee Sucrose Responsiveness and Decreases Waggle Dancing*, 215 J. EXPERIMENTAL BIOLOGY 2022 (2012); Erik Stokstad, *Field Research on Bees Raises Concern about Low-Dose Pesticides*, News & Analysis, 335 SCIENCE 1555 (2012).

damage neonicotinoids cause to the central nervous system of insects is both irreversible and cumulative."[127] Moreover, the combined effect of neonicotinoid insecticides and other stressors, which commonly occurs in agricultural areas, can amplify threats to pollinators.[128] Research strongly indicates that exposure to neonicotinoid insecticides is a factor in overall pollinator decline because it impairs the resilience and survival of colonies, and renders pollinators more susceptible to other threats.[129] Exposure to neonicotinoid insecticides may also play a contributing role in the sudden and total collapse of hives known as Colony Collapse Disorder.[130] Furthermore, the demonstrated adverse synergistic and cumulative effects of insecticides in the environment suggest that research and risk assessments to date may have underestimated the real-world adverse effects of neonicotinoid insecticides.[131]

A growing body of research also links neonicotinoid use to impacts to other pollinators including declines in butterflies.[132] Neonicotinoid exposure is considered a contributing factor in the decline of the monarch butterfly[133] with neonicotinoid contaminated milkweed growing adjacent to agricultural fields being of concern.[134] Other non-bee pollinators including hover flies and bee flies (Bombyliidae family) are demonstrated crop pollinators in agricultural settings.[135]

---

[127] EUR. PARL., DIRECTORATE-GENERAL FOR INTERNAL POLICIES, EXISTING SCIENTIFIC EVIDENCE OF THE EFFECTS OF NEONICOTINOID PESTICIDES ON BEES 15 (2012),https://www.europarl.europa.eu/RegData/etudes/IDAN/2012/492465/IPOL-ENVI_NT(2012)492465_EN.pdf (last accessed May 4, 2020).

[128] Simone Tosi et al., *Neonicotinoid Pesticides and Nutritional Stress Synergistically Reduce Survival in Honey Bees*, 284 PROCEEDINGS OF THE ROYAL SOCIETY B: BIOLOGICAL SCI. (2017).

[129] *See* Francisco Sanchez-Bayo et al., *Are Bee Diseases Linked to Pesticides? – A Brief Review*, 89-90 ENV'T INT'L 7 (2016).

[130] *See* Lu, Warchol, & Callahan, *supra* note123.

[131] *See* CTR. FOR BIOLOGICAL DIVERSITY, TOXIC CONCOCTIONS: HOW THE EPA IGNORES THE DANGERS OF PESTICIDE COCKTAILS (2016) (arguing that EPA has failed to adequately analyze the risks associated with the synergistic effects of chemical mixtures in the environment, including neonicotinoid products); Tsvetkov et al., *supra* note 132.

[132] *See, e.g.*, M.L. Forister et al., *Increasing Neonicotinoid Use and the Declining Butterfly Fauna of Lowland California*, 12 BIOLOGY LETTERS (2016); J.R. Pecanka & J.G. Lundgren, *Non-Target Effects of Clothianidin on Monarch Butterflies*, 102 THE SCI. OF NATURE 1270 (2015); V. Krischik et al., *Soil-Applied Imidacloprid Translocates to Ornamental Flowers and Reduces Survival of Adult* Coleomegilla maculata, Harmonia axyridis, *and* Hippodamia convergens *Lady Beetles, and Larval* Danaus plexippus *and* Vanessa cardui *Butterflies*, 10 PLOS ONE 0119133; Pisa et al., *supra* note 122 (reviewing studies concluding that the use of studied neonicotinoid insecticides "cause negative effects on the most common butterfly families, such as reduced survival rate, feeding interruption, and alteration of oviposition behavior"); NET LOSS REPORT, *supra* note 118, at 16-17.

[133] W.E. Thogmartin et al., *Monarch Butterfly Population Decline in North America: Identifying the Threatening Processes*, 4 R. SOC. OPEN. SCI. 170760 (2017).

[134] J.R. Pecenka & J.G. Lundgren, *Non-target effects of clothianidin on monarch butterflies*, 102 SCI. NAT. 19 (2015).

[135] A. Klein et al., *Wild Pollination Services to California Almond Rely on Semi-Natural Habitat*, 49 J. OF APPLIED ECOLOGY 723-732 (2012); K.A. Orford et al., *The Forgotten Flies: The Importance of Non-*

3. *Neonicotinoid Insecticides Have Other Adverse Ecological Effects and Risks that Underscore the Need for Stricter Federal Limits.*

The risks posed by neonicotinoid insecticides extend well beyond pollinating insects. The scientific literature connects neonicotinoid exposure in terrestrial and aquatic environments to mortality and sublethal effects, such as feeding inhibition, impaired movement, reduced fecundity, body size reductions, and immune suppression, in a host of species, including fish, amphibians, birds, bats, and aquatic invertebrates such as insects and crabs.[136]

The well-documented declines of terrestrial insect abundance across North America is of great concern.[137] Such decline can reduce the decomposition capacity of ecosystems and also disrupt the food chain, leading to losses of birds, amphibians, and bats that feed on those invertebrates.[138]

Neonicotinoid impacts to aquatic ecosystems are particularly troubling. Monitoring studies have documented "world-wide contamination of creeks, rivers and lakes" by

---

Syrphid Diptera as Pollinators, 282 PROC. R. SOC. B 20142934 (2015).

[136] *See, e.g.*, Rosemary Mason et al., *Immune Suppression by Neonicotinoid Insecticides at the Root of Global Wildlife Declines*, 1 J. ENVTL. IMMUNOLOGY & TOXICOLOGY 3 (2013). Francisco Sanchez-Bayo et al., *Contamination of the Aquatic Environment with Neonicotinoids and Its Implications for Ecosystems*, 4 FRONTIERS IN ENVTL. SCI. 1, art. 71 (2016); CTR. FOR FOOD SAFETY, WATER HAZARD – AQUATIC CONTAMINATION BY NEONICOTINOID INSECTICIDES IN THE UNITED STATES (2015); Francisco Sanchez-Bayo, *The Trouble with Neonicotinoids*, 346 SCIENCE 806 (2014); Pisa et al., *supra* note 122. *See also* Order, *Ellis v. Housenger*, Case No. 13-cv-01266-MMC, Doc. 269 (N.D. Cal. May 8, 2017) (holding, in response to claims from beekeepers, environmental groups, food safety advocates, and consumer advocates that EPA failed to protect wildlife from pesticides containing clothianidin or thiamethoxam, that EPA unlawfully issued registrations for fifty-nine pesticides without consulting with the U.S. Fish and Wildlife Service as required by the Endangered Species Act); Compl., *Natural Resources Defense Council v. Pruitt*, Case No. 17-cv-2034 (D.D.C. Oct 2, 2017) (alleging that EPA failed to properly evaluate the impacts of hundreds of neonicotinoid products on threatened and endangered species, including pollinator species, and seeking to vacate the registrations of insecticide products containing acetamiprid, dinotefuran, and imidacloprid).

[137] R. van Klink et al., *Meta-Analysis Reveals Declines in Terrestrial But Increases in Freshwater Insect Abundances*, 368 SCIENCE 417-420 (2020).

[138] *See* DR. PIERRE MINEAU & CYNTHIA PALMER, AMERICAN BIRD CONSERVANCY, THE IMPACT OF THE NATION'S MOST WIDELY USED INSECTICIDES ON BIRDS (Mar. 2013), https://abcbirds.org/wp-content/uploads/2015/05/Neonic_FINAL.pdf (last accessed May 4, 2020); Sanchez-Bayo et al., *supra* note 142. *See also* Pisa et al., *supra* note 122 ("The consequences of losing the invertebrate fauna due to continuous exposure to ubiquitous residues of neonicotinoids and fipronil are . . . far reaching and cannot be ignored any longer"); Agence France-Presse, *'Catastrophe' as France's Bird Population Collapses Due to Pesticides*, GUARDIAN (Mar. 20, 2018), https://www.theguardian.com/world/2018/mar/21/catastrophe-as-frances-bird-population-collapses-due-to-pesticides (last accessed May 4, 2020) (describing two recent studies by France's National Museum of Natural History and National Centre for Scientific Research documenting significant declines in bird populations across France, in some cases by more than two-thirds, which researchers speculate are connected to neonicotinoid insecticide use).

neonicotinoid insecticides.[139] Although initial studies suggested that neonicotinoid insecticides would not have major impacts on aquatic environments, later studies have since found that aquatic organisms are "much more sensitive" to neonicotinoid insecticides than standard test species.[140] Furthermore, "[d]iscrepancies between the acute and chronic sensitivity of species can lead to water quality benchmarks that are under-protective, especially for low-level chronic exposures."[141] According to Sanchez-Bayo et al. (2016),

> [o]ne particular aspect of neonicotinoids became apparent only after years of testing: median toxicity values varied significantly depending on the time of exposure. . . . Neonicotinoids bind irreversibly to the nicotinic acetylcholine receptors (nAChR) embedded in the synaptic membranes of neurons, and their activation elicits a continuous electric impulse that eventually leads to the death of the neuron. The neuronal death toll accumulates as more and more chemical molecules bind to other nAChRs until the organism cannot cope with the damage and dies . . . . Aquatic organisms are constantly being exposed to residues of chemicals present in water, a medium from which they cannot escape. The time to reach the organism's death threshold depends on the internal concentration of insecticide, which in turn depends on its external concentration and the kinetics and detoxification ability of each species . . . .[142]

Sanchez-Bayo et al. (2016) concludes that "[t]he decline of many populations of invertebrates, due mostly to the widespread presence of waterborne residues and the extreme chronic toxicity of neonicotinoids, is affecting the structure and function of aquatic ecosystems."[143]

Another recent review of neonicotinoid insecticides in surface waters finds "[s]trong evidence exists that water-borne neonicotinoid exposures are frequent, long-term, and at levels . . . which commonly exceed several existing water quality guidelines" and "neonicotinoids in surface waters worldwide are well within the range where both short- and long-term impacts on aquatic invertebrate species are possible . . . ."[144]

In general, there is increasingly strong evidence that neonicotinoid insecticides disrupt important ecosystem functioning and services such as pollination, nutrient cycling, and pest and

---

[139] Sanchez-Bayo et al., *supra* note 142.

[140] *See id. See also* Pisa et al., *supra* note 122; SARAH HOYLE & AIMEE CODE, XERCES SOC'Y, NEONICOTINOIDS IN CALIFORNIA'S SURFACE WATERS: A PRELIMINARY REVIEW OF POTENTIAL RISK TO AQUATIC INVERTEBRATES (2016), at 12, https://xerces.org/sites/default/files/2018-05/16-050_01_XercesCAAquaticNeonics_Dec2016_Final.pdf (last accessed May 4, 2020) (concluding that "[i]n the case of imidacloprid, there is strong evidence that the EPA aquatic life benchmarks are under-protective of invertebrates.").

[141] HOYLE & CODE, *supra* note 146, at 12

[142] Sanchez-Bayo et al., *supra* note 142.

[143] *Id.; see also generally* HOYLE & CODE, *supra* note 146.

[144] Christy A. Morrissey et al., *Neonicotinoid Contamination of Global Surface Waters and Associated Risk to Aquatic Invertebrates: A Review*, 74 ENV'T INT'L 291 (2015).

weed control, as well as ecosystem resilience.[145] The toxicological risk to both terrestrial and aquatic ecosystems and birds has led the American Bird Conservancy to call for suspension of all applications of neonicotinoids until independent review, and an outright ban on neonicotinoid insecticides as seed treatments.[146]

4. Evidence of Potential Serious Risks to Human Health Should Lead EPA to Take a Precautionary Approach and Restrict Neonicotinoid Insecticide Use.

As noted above, neonicotinoid insecticides are ubiquitous in the environment, including in our groundwater, our surface waters, and the food we eat. Yet, there is very little research on the human-health risks of chronic exposure to these chemicals. What limited data does exist is alarming; neonicotinoid insecticides have been shown to disrupt mammalian nerve cell activity, raising concerns about significant human-health impacts such as nervous system disorders and developmental impacts to infants and children.

According to a review of the risks of neonicotinoid exposure to human health published by Cimino et al. in 2017 (the "Cimino study"),[147] neonicotinoid insecticides have been linked to adverse effects in vertebrates, and recent studies show adverse effects on mammals even at sublethal doses, including nerve cell effects that play a role in central nervous system disorders such as Alzheimer's disease, Parkinson's disease, schizophrenia, and depression. The Cimino study concludes that "there remains a paucity of data on neonic exposure and human health. Given the widespread use of neonics in agriculture and household products and its increasing detection in U.S. food and water, more studies on the human health effects of chronic (non-acute) neonic exposure are needed."[148]

In light of the dearth of studies about the impacts of neonicotinoid insecticides on human health—and acknowledging the critical need for additional studies regarding chronic neonicotinoid insecticide exposure, in particular—EPA should restrict product use pending research that demonstrates a lack of significant adverse human health effects. FIFRA requires EPA to base its risk evaluation on sufficient data, and any determination by EPA that the Subject Neonicotinoid Insecticides pose reasonable risks to human health would not be supported by substantial evidence.[149] As in *Pollinator Stewardship Council v. EPA*, "[t]he limitations of the underlying data in this case mean that no such conclusion can be reached."[150]

---

[145] *See* Pisa et al., *supra* note 122; HOYLE & CODE, *supra* note 146; J.L. Pestana et al., *Structural and Functional Responses of Benthic Invertebrates to Imidacloprid in Outdoor Stream Mesocosms*, 157 ENVTL. POLLUTION 2328 (2009).

[146] MINEAU & PALMER, *supra* note 144.

[147] *See* Andria M. Cimino et al., *Effects of Neonicotinoid Pesticide Exposure on Human Health: A Systematic Review,* 125 ENVTL. HEALTH PERSPECTIVES 155 (2017), http://dx.doi.org/10.1289/EHP515.

[148] *Id.* at 160.

[149] *See Pollinator Stewardship Council*, 806 F.3d at 532 ("Without sufficient data, the EPA has no real idea whether [a pesticide] will cause unreasonable adverse effects . . . as prohibited by FIFRA.").

[150] *Id.* at 531.

B. Widespread Use and Recognized Adverse Impacts of Seeds Treated with Neonicotinoids to Bees and Other Pollinators, Ecosystems and Humans.

1. Seed Treatment Is the Predominant Use of Neonicotinoids in the United States.

The Clothianidin and Thiamethoxam Final Bee Risk Assessment[151] reveals that seed treatments constitute the most significant agricultural use of clothianidin and thiamethoxam, when considering annual pounds of active ingredient. Clothianidin seed treatment usage is estimated at 1,458,000 pounds of active ingredient per year, whereas 25,000-35,500 pounds per year are used in foliar and soil agricultural applications. Thiamethoxam seed treatment usage is estimated at 792,000 pounds per year, whereas 121,000-132,500 pounds per year are used in foliar and soil applications.[152] Clothianidin and thiamethoxam seed treatment annual use is thus at least thirteen times greater than both foliar and soil agricultural use combined. The Imidacloprid Proposed Interim Decision states "the largest agricultural use for imidacloprid, in terms of active ingredient applied, has been in the form of seed treatments," with an annual average of 700,000 pounds used for seed treatment, versus an annual average of 800,000 pounds for foliar and soil application combined.[153] While EPA usage reporting data appears inconsistent across all five neonicotinoids, when reported agricultural seed treatment and foliar and soil applications are considered for the remaining two neonicotinoids,[154] the combined annual seed treatment agricultural use for all five neonicotinoids is still approximately three times greater than both foliar and soil use combined.[155]

Additionally, the assessment for clothianidin and thiamethoxam shows that the number of acres planted with treated seeds for predominantly agricultural commodities is also significant. For example, in 2017, for corn and soybean crops—the two most widely planted crops in the United States—EPA estimated that an average of 61,367,600 acres of treated corn seed were planted out of 87,668,000 total acres planted, while 13,277,075 acres of treated soybean seed

---

[151] EPA, *Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam* (Jan. 14, 2020), Doc. No. EPA-HQ-OPP-2011-0865-1164 [hereinafter Clothianidin and Thiamethoxam Final Bee Risk Assessment].

[152] *Id.* at 45-46, Tbls. 2.6, 2.7.

[153] Imidacloprid PID, *supra* note 115, at 14.

[154] EPA, *Final Bee Risk Assessment to Support the Registration Review of Dinotefuran* (Jan. 14, 2020), Doc. No. EPA-HQ-OPP-2011-0920-0761, at 26-27, Tbl. 2.3 (reporting over 21,000 pounds used for foliar and soil application, and none for seed treatment); Acetamiprid PID, *supra* note 115, at 9 (reporting over 80,000 pounds used over a 5-year period).

[155] Estimates were made using imidacloprid PID usage values, by conservatively assuming all dinotefuran and acetamiprid usage is foliar and soil application only, and by using the maximum value from EPA's estimated range of foliar and soil application for clothianidin and thiamethoxam. Following, approximately 1,006,000 pounds of neonicotinoid insecticide is applied to crops via foliar and soil application, whereas approximately 2,950,000 pounds of neonicotinoid insecticide is applied to seeds before planting.

were planted out of 75,869,000 total acres planted.[156] For all agricultural uses of imidacloprid, the number of acres planted with treated seeds has increased, from 5 million acres in 1998 to approximately 30 million acres in 2012.[157]

Neonicotinoid insecticide use as seed treatment is pervasive, preemptively used on 34-44% of soybeans and 79-100% of corn.[158] Despite the prophylactic use of treated seeds, such use may not improve soybean crop production or crop yields compared to areas planted with non-treated seeds.[159] On October 15, 2014, EPA released an analysis questioning the benefits of treated soybean seeds and concluding that treated soybeans "provide negligible overall benefits to soybean production in most situations . . . in most cases there is no difference in soybean yield when soybean seed was treated with neonicotinoids versus not receiving any insect control treatment."[160] Even after further review and consideration of public input, EPA still was unable to justify prophylactic use of seed treatment on soybeans, instead identifying areas of the country where seed treatments may be justified.[161] Multiple studies have bolstered evidence that prophylactic use of seed treatment on soybeans does not improve yield,[162] and that using an integrated pest management approach is more beneficial or cost effective for farmers.[163] Studies have also shown no crop yield benefit of planting neonicotinoid-treated corn seed.[164]

2. *Dust from Seeds Treated with Neonicotinoids Causes Adverse Effects on Non-Target Species, Such as Bees.*

---

[156] Clothianidin and Thiamethoxam Final Bee Risk Assessment, *supra* note 157, at 48, Tbl. 2.8.

[157] EPA, *Final Bee Risk Assessment to Support the Registration Review of Imidacloprid* (Jan. 14, 2020), Doc. No. EPA-HQ-OPP-2008-0844-1611, at 48 [hereinafter Imidacloprid Final Bee Risk Assessment].

[158] Douglas & Tooker, *supra* note 39.

[159] Goulson, *supra* note 41.

[160] EPA, *Benefits of Neonicotinoid Seed Treatments to Soybean Production* (Oct. 15, 2014), https://www.epa.gov/sites/production/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf (last accessed May 4, 2020).

[161] EPA, *Biological and Economic Analysis Division (BEAD) Response to Public Comments Submitted in Response to BEAD's Assessment Entitled "Benefits of Neonicotinoid Seed Treatments to Soybean Production" Dated October 15, 2014* (Dec. 5, 2017) Doc. No. EPA-HQ-OPP-2014-0737-0948 at 43, 54.

[162] Michael Seagraves & Jonathan Lundgren, *Effects of Neonicotinoid Seed Treatments on Soybean Aphid and Its Natural Enemies*, 85 J. OF PEST SCI. 125 (2012); Brian P. McCornack & David W. Ragsdale, *Efficacy of Thiamethoxam to Suppress Soybean Aphid Populations in Minnesota Soybean*, 5 PEST MGMT. NETWORK 1. (2006); William J. Cox et al., *Planting Date and Seed Treatment Effects on Soybean in the Northeastern United States*, 100 AGRONOMY J. 1662 (2008); Wayne J. Ohnesorg et al., *Impact of Reduced-Risk Insecticides on Soybean Aphid and Associated Natural Enemies*, 102 J. OF ECON. ENTOMOLOGY 1816 (2009).

[163] de Fraitas Bueno et al., *supra* note 43; Johnson et al., *supra* note 43.

[164] Christian H. Krupke et al., *Planting of Neonicotinoid-Treated Maize Poses Risks for Honey Bees and Other Non-Target Organisms Over a Wide Area Without Consistent Crop Yield Benefit*, 54 J. OF APPLIED ECOLOGY 1449 (2017).

The final bee risk assessments for clothianidin, thiamethoxam, and imidacloprid in particular cite to several studies that reflect the exposure impacts from seed treatments.[165] Additional field studies not included in the assessments also demonstrate that exposure to the dust of neonicotinoid treated seeds causes significant harm to pollinator health, including decreased survival of bees and fitness of colonies,[166] reduction of overwintering success and colony reproduction, [167] damage to the brains of bee workers,[168]and fatalities from bees coming in contact with abraded seed dust, especially in high humidity environments.[169] Studies also show that abraded, pesticide-laden seed dust migrates off the agricultural field during the planting process, contaminating nearby grass and flowers,[170] and that seed treatment is an important route of exposure in bees, on par with oral consumption of contaminated pollen and nectar.[171]

Scientific articles also document that neonicotinoids are extensively and prophylactically used worldwide, and despite the attempt to mitigate pesticide loss, only a small percentage of neonicotinoid active ingredients on treated seeds is absorbed by the agricultural crop planted. The remainder of the active ingredient can migrate off-field. For example:

- Douglas and Tooker (2015) shows that neonicotinoids are the most widely used class of insecticides worldwide, and "virtually all" neonicotinoids applied to maize, soybeans, and wheat were as seed treatments.[172]
- Tsvetkov et al. (2017) confirms that the use of dust-reducing seed lubricants during planting does not prevent exposure to a toxicologically significant level of neonicotinoids into the air.[173] Further, both clothianidin and thiamethoxam show synergistic effects and become nearly twice as toxic to bees when the bees are also exposed to a commonly used fungicide.

---

[165] Clothianidin and Thiamethoxam Final Bee Risk Assessment, *supra* note 157, at 58; Imidacloprid Final Bee Risk Assessment, *supra* note 163, at 38.

[166] Tsvetkov et al., *supra* note 132, at 1395.

[167] Ben A. Woodcock et al., *supra* note 132.

[168] Melanie K. Schirrmann et al., *Global Transcriptomic Effects of Environmentally Relevant Concentrations of the Neonicotinoids Clothianidin, Imidacloprid, and Thiamethoxam in the Brain of Honey Bees (Apis Mellifera)*, 53 ENVTL. SCI. & TECH. 7534 (2018)

[169] Matteo Marzaro et al., *Lethal Aerial Powdering of Honey Bees with Neonicotinoids from Fragments of Maize Seed Coat*, 46 ENVTL. SCI. & TECH.2592 (2011); Vincenzo Girolami et al., *Fatal Powdering of Bees in Flight with Particulates of Neonicotinoids Seed Coating and Humidity Implication*, 136 J. APPLIED ENTOMOLOGY 17 (2012).

[170] Moreno Greatti et al., *Presence of the a.i. Imidacloprid on Vegetation Near Corn Fields Sown with Gaucho Dressed Seeds*, 59 BULLETIN OF INSECTOLOGY 99 (2006).

[171] Fabio Sgolastra et al., *Pesticide Exposure Assessment Paradigm for Solitary Bees*, 48 ENVTL. ENTOMOLOGY 22 (2019).

[172] Douglas & Tooker, *supra* note 39.

[173] Tsvetkov et al., *supra* note 132, at 1395.

- Hladik et al. (2018) found "only a small portion (on average 5%) of the neonicotinoid coating being absorbed by the crop" leaving "~95% of the active ingredient available in the soil and soil water or lost as dust during planting."[174]
- Chan et al (2019) found soil was the most important route of neonicotinoid exposure for the ground-nesting hoary-squash bee. When soil, pollen and nectar neonicotinoid exposures were combined for this bee, the concentrations could be lethal.[175]
- Alford and Krupke (2019) found high concentrations of neonicotinoid concentrations directly leaching off of agricultural fields with drain tiles, thereby demonstrating that aquatic ecosystems, rather than the target crop, are a "key environmental sink" for neonicotinoids on crop seed.[176]
- Xue et al. (2015) call for the assessment of risk from seed treatment, stating because "results unequivocally show that well over 95% of the exposure to non-target organisms for neonicotinoid insecticide seed treatment use originates from the exhaust during planting, a risk assessment model that follows the residues from this point source, using a mass balance approach, to exposure sites in the ecosystem adjacent to and near maize production should and can be developed."[177]

Given evidence within the scientific literature that most of the neonicotinoid on a treated seed is not taken up by the plant and has been repeatedly demonstrated to migrate off-field, it is reasonable to assume that most of neonicotinoid contamination in non-target environments originates from the predominant type of application—seed treatment. Off-field migration of neonicotinoids causes harm to ecological and hydrological resources. Neonicotinoid pollution of aquatic ecosystems, surface waters, groundwater and sediments is persistent and accumulating, as demonstrated here:

- Goulson (2013) found typically more than 90% of neonicotinoid seed treatment active ingredient enters the soil, where it can persist and accumulate in soil and leach into nearby waters, threatening non-target soil and aquatic organisms.[178]
- Hladik and Kolpin (2016) detected neonicotinoids in 53% of 149 samples collected from streams across the United States; imidacloprid, clothianidin and thiamethoxam were the most frequently detected. Mixtures or two or more neonicotinoids were commonly detected and clothianidin and thiamethoxam were positively correlated to agricultural areas.[179]

---

[174] Michelle L. Hladik et al., *Environmental Risks and Challenges Associated with Neonicotinoid Insects*, 52 ENVTL. SCI. & TECH. 3329 (2018).

[175] D.S.W. Chan et al., *Assessment of Risk to Hoary Squash Bees (*Peponapis pruinosa*) and Other Ground-Nesting Bees from Systemic Insecticides in Agricultural Soil*, 9 Scientific Reports 11870 (2019).

[176] Adam M. Alford & Christian H. Krupke, *Movement of the Neonicotinoid Seed Treatment Clothianidin Into Groundwater, Aquatic Plants and Insect Herbivores*, 53 ENVTL. SCI. & TECH. 14368 (2019).

[177] Yingen Xue et al., *Quantifying Neonicotinoid Insecticide Residues Escaping During Maize Planting with Vacuum Planters*, 49 ENVTL. SCI. &TECH. 13003 (2015).

[178] Goulson, *supra* note 41.

[179] Hladik & Kolpin, *supra* note 121, at 12.

- Morrissey et al. (2015) report that neonicotinoids are persistent, have high leaching and runoff potential, and are highly toxic to a broad range of invertebrate. They determined that neonicotinoids represent a risk to surface waters and the associated aquatic and terrestrial fauna that surface water ecosystems support.[180]
- Kuechle et al. (2019) demonstrate widespread impacts to floodplain wetlands across Missouri. Of the 149 surface water samples, 60% of samples were found to have at least one neonicotinoid; Imidacloprid and thiamethoxam were the most commonly detected in surface water.[181]
- In a meta-analysis of insecticides in U.S. surface waters, Wolfram et al (2018) found that regulatory threshold levels (Clothianidin – 11 ug/L; Thiamethoxam – 17.5 ug/L; Imidacloprid – 0.385 ug/L) for neonicotinoids were exceeded in 22.4% of 388 freshwater samples.[182]
- Yamamuro et al. (2019) report that aquatic systems in Japan are threatened by toxicity and persistence of neonicotinoids, which cascade to higher trophic levels. They attribute neonic application to an 83% decrease in spring zooplankton biomass, and collapse of the smelt harvest (>90% decrease) in Lake Shinji, Japan. The authors reason that fishery yields are indirectly reduced by decreasing abundances of invertebrates.[183]

C. EPA Fails to Adequately Examine the Risks to Bees, Other Pollinators, and Other Species from Exposure to Neonicotinoids.

The final bee risk assessments completely fail to examine risks to bees and other pollinators from exposure to neonicotinoids from the predominant use of the insecticides, treated seeds. EPA failed to finalize its non-pollinator risk assessments and ecological risk assessments, and the preliminary risk assessments are grossly inadequate in assessing off-field risk of neonicotinoids to terrestrial and aquatic ecosystems.

1. EPA Completely Fails to Assess Risk to Bees and Other Pollinators from Seed Treatment.

The final bee risk assessments "intended to account for the major routes of pesticide exposure that are relevant to bees (i.e. through diet and contact)."[184] Nonetheless, although seed treatments are the predominant application method for clothianidin thiamethoxam and imidacloprid, and their assessments identify abraded seed coat dust as an "important route of

[180] Morrissey et al., *supra* note 150.

[181] Kyle J. Kuechle et al., *Factors Influencing Neonicotinoid Insecticide Concentrations in Floodplain Wetland Sediments Across Missouri*, 53 ENVTL. SCI. & TECH. 10591 (2019).

[182] Jakob Wolfram et al., *Meta-Analysis of Insecticides in U.S. Surface Waters: Status and Future Implications*, 52 ENVTL. SCI. & TECH. 14452 (2018).

[183] Masumi Yamamuro et al., *Neonicotinoids Disrupt Aquatic Food Webs and Decrease Fishery Yields*, 366 SCIENCE 620 (2019).

[184] Clothianidin and Thiamethoxam Final Bee Risk Assessment, *supra* note 157, at 60.

exposure" and "route of concern,"[185] the assessments fail to examine the risks associated with contact with, and off-site movement of, seed coat dust and residue.

Rather, EPA said "exposure through consumption of residues in nectar and pollen [is] expected to be the dominant route"[186] and "consistent with the 2014 risk assessment guidance" for seed treatment "it is assumed that contact exposure on the treated field would be negligible."[187] EPA's 2014 guidance does not provide evidence to support this assumption,[188] but rather admits that the guidance "does not include quantification of exposures via contact with dust from seed treatments" or, for that matter, "via consumption of water from surface water, puddles, dew, droplet formation on leave and guttation fluid."[189]

EPA must assess the potential risks of all recognized exposure routes. Academic experts assert that such risk assessments can be performed.[190] Clearly, an exposure route that is, according to EPA itself, the predominant application method of clothianidin, thiamethoxam and imidacloprid by volume of active ingredient, should be incorporated throughout these assessments.

2. *EPA Relies on Unidentified Mitigation Measures that May Be Ineffective Absent a Complete Assessment of Risks from Treated Seeds.*

In its final bee risk assessments, EPA justifies its exclusion of seed treatment as an exposure pathway by positing that EPA may require mitigation measures. But largely those measures are not identified in the assessment, and the mitigation measures that are identified raise further questions of risk.[191] After conceding in the assessment that: "[e]xposure of bees to clothianidin and thiamethoxam via drift of abraded seed coat dust, is considered a route of concern given that bee kill incidents have been associated with planting of clothianidin- or thiamethoxam-treated corn,"[192] EPA continues:

---

[185] *Id.* at 58, 30; Imidacloprid Final Bee Risk Assessment, *supra* note 163, at 38, 306.

[186] Imidacloprid Final Bee Risk Assessment, *supra* note 163, at 29.

[187] *Id.* at 80.

[188] EPA merely adopts the assumption as fact by stating "[r]elatively speaking, exposures from foliar and soil applications are greater compared to those from seed treatments." Clothianidin and Thiamethoxam Preliminary Bee Risk Assessment, *supra* note 3, at 365.

[189] EPA, *Guidance for Assessing Pesticide Risks to Bees* (June 19, 2014), https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf (last accessed May 4, 2020).

[190] *See supra* note 183 and accompanying text.

[191] EPA's PIDs for acetamiprid, clothianidin, imidacloprid, and thiamethoxam recommend a mitigation measure for farmers to reduce the exposure of wildlife to excess neonicotinoid treated seeds that remain after planting by burying the unused seeds away from bodies of water. This disposal practice has the potential to contaminate groundwater, which may ultimately feed a surface water body and unnecessarily expose aquatic life. *See, e.g.*, Clothianidin and Thiamethoxam PID, *supra* note 115, at 67, 86.

[192] Clothianidin and Thiamethoxam Final Bee Risk Assessment, *supra* note 157, at 30; *see also* Imidacloprid Final Bee Risk Assessment, *supra* note 163, at 306 (stating that "Exposure of bees to

> *However, the Agency is working with different stakeholders to identify best management practices and to promote technology-based solutions that reduce this potential route of exposure.* To date, the Agency has not developed an approach to quantify this exposure route. Therefore, this exposure route was not quantitatively considered in this assessment."[193]

Thus, EPA's final bee risk assessments expressly and unambiguously conclude not only that the agency does not have sufficient information about the pathways for this exposure "route of concern" but that EPA does not even have a plan for obtaining that crucial information. Obtaining and analyzing such exposure data is a sine qua non for any meaningful risk assessment and without it EPA cannot make defensible registration decisions.

3. EPA Fails to Adequately Protect Aquatic Resources.

There are many formulations of neonicotinoid insecticides, including soluble liquids, soluble granules, water-dispersible granules, and flowable concentrates. Neonicotinoids are readily soluble in water, are applied through a variety of aerial and ground methods, including airblast sprayers, chemigation and soil drenching, and as a seed treatment, and generally are considered persistent in aquatic environments.[194] Many of the Subject Neonicotinoid Insecticides have been widely detected in surface waters, sediments and groundwater, contamination that can be either directly tied to neonicotinoid seed treatment or otherwise having seed-treatment uses as a major contributing factor to the aquatic contamination.[195] Moreover, concentrations of concern to many sensitive aquatic species, as well as regulatory guidelines currently used in the U.S., have been found or have been exceeded in U.S. surface waters.[196, 197] These studies are particularly instructive:

---

imidacloprid via drift of abraded seed coat dust, is also considered a route of concern. Risk are demonstrated by several bee kill incidents reported at the time of corn planting.")

[193] Clothianidin and Thiamethoxam Final Bee Risk Assessment, *supra* note 157, at 30 (emphasis added); Imidacloprid Final Bee Risk Assessment, supra note 163, at 306 (emphasis added).

[194] *See, e.g.*, Imidacloprid PID, *supra* note 115, at 27.

[195] *See* Kuechle et al., *supra* note 187; *See* Wolfram et al., *supra* note 188.

[196] *See* Wolfram et al., *supra* note 188; EPA, *2019 OPP Aquatic Life Benchmarks for Freshwater Organisms*, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/aquatic-life-benchmarks-and-ecological-risk (last accessed May 4, 2020).

[197] In 2017, EPA significantly reduced its aquatic life benchmark for imidacloprid (the level of the insecticide in water thought to be safe for aquatic life) from 1.05 micrograms per liter ("µg/L") to 0.010 µg/L. *See* Minnesota Dep't of Health, *Imidacloprid and Groundwater* (Mar. 2019), https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/imidainfo.pdf (last accessed May 4, 2020). Accordingly, in most states, detections of imidacloprid in surface waters have been above USEPA's revised aquatic life benchmark for aquatic life. This notwithstanding, EPA has not required any corresponding mitigation measures on pesticide labels or otherwise to protect aquatic organisms.

- Van Dijk et al (2013) found significant impact from imidacloprid concentrations in surface waters, on five orders of macro-invertebrates.[198]
- Raby et al (2018) tested 21 aquatic invertebrate species and found the lethal concentration to neonicotinoids for many sensitive species was very low, often times just parts per billion.[199]
- Roessick et al (2013) and Alexander et al. (2007, 2008) found mayfly and caddisfly were sensitive to neonicotinoid exposure, with mayflies in particular, sensitive to long term exposure to low levels of imidacloprid.[200]
- Alford and Krupke (2019) determined that aquatic plants such as duckweed, could take up neonicotinoids from contaminating surface water. When aphids consumed the duckweed, the neonicotinoid was then passed on to them.[201]

Unfortunately, the PIDs fail adequately to assess these risks and, accordingly, cannot begin to address them.

4. *EPA Employs a Faulty Risk Benefit Approach.*

Without having assessed the *risk* to bees from their contact with clothianidin, thiamethoxam, and imidacloprid through dust-off during planting, it is not possible for EPA to reasonably determine whether mitigation will reduce risk associated with exposure to treated seeds below levels of concern.

Importantly, at least one federal appeals court has rejected a substantially similar approach as EPA has taken in its risk assessments for the Subject Neonicotinoids *See Pollinator Stewardship Council v. EPA,* 2015 U.S. App. LEXIS 19945, at *17-21 (9th Cir. Nov. 12, 2015). In that case, the court vacated EPA's registration of another pesticide, sulfoxaflor, in part because EPA had improperly relied on un-assessed mitigation measures to justify its registration of sulfoxaflor, which EPA had previously classified as "very highly toxic to bees." The court found that EPA's decision to register sulfoxaflor was not supported by substantial evidence on the record. Specifically, the court held that the "lack of any meaningful study of the effects of the mitigation measures" warranted remand to the agency. *Id.* at *23. The court further found that "*[w]ithout sufficient data, the EPA has no real idea whether sulfoxaflor will cause unreasonable adverse effects on bees, as prohibited by FIFRA." Id.* at *25 (emphasis added.) The Ninth Circuit's reasoning in that case applies with equal force here. Measures EPA relies on to reduce risks must be preceded by an examination of the actual risks to be mitigated.

---

[198] Tessa C. Van Dijk et al., *Macro-Invertebrate Decline in Surface Water Polluted With Imidacloprid*, 8 PLOS ONE 1 (2013).

[199] Melanie Raby et al., *Acute Toxicity of Six Neonicotinoid Insecticides to Freshwater Invertebrates: Aquatic Toxicity of Neonicotinoid Insecticides*, 37 ENVTL. TOXICOLOGY & CHEMISTRY 1430 (2018).

[200] Ivo Roessick et al., *The Neonicotinoid Imidacloprid Shows High Chronic Toxicity to Mayfly Nymphs*, 32 ENVTL. TOXICOLOLGY & CHEMISTRY 1096 (2013); Alexa C. Alexander et al., *Emergent Body Size of Mayfly Survivors*, 53 FRESHWATER BIOLOGY 171 (2008).

[201] Alford & Krupke, *supra* note 182.

Moreover, peer-reviewed studies previously cited raise concerns that mitigation measures envisioned by EPA may not be effective in reducing the risk of exposure. In fact, a study referenced by EPA within the Final Bee Risk Assessments[202] states:

> [A]nalytical results regarding factor emissions, air concentration of insecticide around the drilling machine and consequent bee contamination, reveal that all kinds of the tested seed coatings (also those more recently proposed) do not prevent the dispersion of large amounts of micrometric particles containing the insecticide, producing lethal exposure of [sic] flying bees. Moreover, the modifications of the air outlet of drilling machines so far adopted seem to have a limited effect on both the factor emission and the effective bee contamination.

While mitigation should certainly be part of the solution for reducing risks from pesticide use,[203] without a full assessment of the risks the mitigation measures aim to alleviate, as well as a much better understanding of the efficacy of the mitigation measures, reliance on mitigation cannot support reregistration. Indeed, under FIFRA's cost-benefit standard for determining whether a pesticide poses unreasonable adverse effects, the risks to pollinators associated with neonicotinoid use as a seed treatment, let alone other risks to humans and the environment, appear to outweigh the benefit of such use, which EPA can determine only if it actually assesses the risk associated with dust-off from treated seeds.

D. EPA Must Base its Registration Review Decisions in Risk Assessments Adequate to Protect Threatened and Endangered Species.

EPA's risk-review analyses to date for the Subject Neonicotinoid Insecticides fall far short of what is needed to register these highly toxic pesticides in accordance with protecting threatened and endangered species. Under Section 7 of the Endangered Species Act (ESA),[204] EPA is statutorily obligated to consult with the U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service (NMFS).[205] Absent acting on such shared information, EPA cannot meet its FIFRA obligations to ensure that any registered use of the pesticide will not unreasonably adversely affect the environment as is the agency's charge under Section 3(c)(5) of FIFRA.[206]

---

[202] Andrea Tapparo et al., *Assessment of the Environmental Exposure of Honey Bees to Particulate Matter Containing Neonicotinoid Insecticides Coming from Corn-Coated Seeds*, 46 ENVTL. SCI. & TECH. 2592 (2012).

[203] For instance, in 2016 the Province of Ontario, Canada, included mitigation within their action plan for clothianidin, thiamethoxam, and imidacloprid. Notably, Ontario's plan aims to reduce the use of neonicotinoid-treated com and soybean seeds by 80%. Ministry of Agriculture, Food, and Rural Affairs *Ontario's Pollinator Health Action Plan* (2016), https://www.vaughan.ca/cityhall/environmental_sustainability/General%20Documents/Ontario%20Pollinator%20Health%20Action%20Plan.pdf (last accessed May 4, 2020).

[204] 16 U.S.C. § 1531 *et seq.*

[205] 16 U.S.C. § 1536.

[206] 7 U.S.C. § 136a(c)(5).

Of particular note, in 2017, the U.S. Fish and Wildlife Service listed a bumblebee species, the rusty patched bumblebee (*Bombus affinis*), as endangered for the first time. The population of this once-common bumblebee has declined nearly 90 percent since the 1990s and is now on the brink of extinction.[207]

E. EPA Fails to Assess Cumulative, Synergistic, and Aggregate Risks of Exposure to Neonicotinoids.

As EPA has recognized,[208] EPA's approach to all pesticide risk assessments under FIFRA is to use the same risk assessment techniques that it developed in implementing FQPA, whether the risk assessment falls under FQPA or not, so long as application of the technique is consistent with good scientific practice and is not otherwise prohibited by law. This includes: (i) using an additional safety/uncertainty factor to protect children; (ii) considering aggregate exposures to pesticides from multiple sources; and (iii) considering cumulative effects that may occur from exposure to multiple pesticides with a common mechanism of toxicity.

As pointed out in the 2017 New York AG Comments, EPA's risk assessments fail to evaluate the cumulative and synergistic risks of simultaneous exposures to multiple neonicotinoids and other insecticides, herbicides, fungicides and other chemicals used in agricultural production,[209] a fatal shortfall not addressed in the subject PIDs. This notwithstanding, for example, both clothianidin and thiamethoxam become nearly twice as toxic to bees when the bees are also exposed in the field to a commonly used fungicide.[210] Moreover, the U.S. Geological Survey has established through in-field studies that nearly half of native bees tested have been exposed to at least two or more pesticides,[211] and a Government Accountability Office report call on EPA to identify the most common mixtures of pesticides used on crops to enable EPA to assess the cumulative or synergistic effects of commonly used pesticide mixtures on bees.[212]

And EPA's assessments to date fail to evaluate the risk of other exposure combinations, for example aggregate risks of exposure through multiple routes, e.g., treated seed planting and foliar spray, and cumulative risk of exposure to more than one neonicotinoid, which EPA has

---

[207] *See* Michael Greshko, *First U.S. Bumblebee Officially Listed as Endangered*, NAT'L GEOGRAPHIC (Mar. 22, 2017), https://news.nationalgeographic.com/2017/03/bumblebees-endangered-extinction-united-states/ (last accessed May 4, 2020).

[208] *See*, *e.g.*, EPA, Revised Methods for Worker Risk Assessments (last updated Apr. 19, 2019), https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/revised-methods-worker-risk-assessment (last accessed May 4, 2020).

[209] *See* Tsvetkov et al., *supra* note 132, at 1395.

[210] *Id.*

[211] Michelle L. Hladik et al., *Exposure to Native Bees Foraging in Agricultural Landscape to Current-Use Pesticides*, 542 SCIENCE OF THE TOTAL ENV'T 469 (2016).

[212] U.S. Gov't Accountability Office, *Bee Health: USDA and EPA should Take Additional Actions to Address Threats to Bee Populations* (Feb. 2016).

conceded it is not conducting.[213]

F. EPA Fails to Protect Vulnerable Populations as Required by FQPA.

In the PIDs, EPA has failed in each case to comply with requirements of FQPA to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to the respective pesticides.[214] It is well understood and documented that unborn fetuses, infants and children are disproportionately impacted by pesticide exposure in general, and for this reason FQPA *mandates* the application of an additional tenfold safety factor for the protection of infants and children (the "FQPA 10X safety factor") in determining whether particular exposures are safe. And the safety factor can be reduced or eliminated "*only if, on the basis of reliable data*, such margin will be safe for infants and children."[215] FQPA also requires the Administrator to consider, *inter alia*, "available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity," as well as information "on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects."[216]

EPA's review illegally eliminates the FQPA 10X safety factor for all five of the Subject Neonicotinoid Insecticides without meeting these statutory requirements. Each of the assessments in the respective Draft Human Health Risk Assessments (except for dinotefuran) cites studies showing increased susceptibility of the young to toxic impacts of exposure. In every case, critical "reliable data" is absent from the assessment of human health risks, and therefore EPA lacks a basis on which to eliminate the FQPA safety factor. Specifically, EPA has (1) refused to update its Draft Human Health Risk Assessments in light of more recent scientific research on human health risk; (2) failed to subject the subject pesticides to the legally-mandated Endocrine Disrupter Screening Program; and (3) failed to assess the cumulative impact of the neonicotinoids that have a common mechanism of toxicity as required by the FQPA. EPA must not—and cannot legally—proceed to finalize its Registration Review Decisions for the five subject pesticides without complying with these mandates.

1. EPA Fails to Consider Recent Research Regarding Human Health Risks of Neonicotinoid Exposure.

There have thus far been few studies of the health effects on humans of neonicotinoid exposure, but the scientific community is showing increased interest in studying these effects as neonicotinoid use has skyrocketed, increasing humans' chronic exposure. Recent studies have now demonstrated widespread human exposure to neonicotinoids. One study found evidence that roughly half of people over three years old had recently been exposed to neonicotinoids, with

---

[213] *See e.g.*, Clothianidin and Thiamethoxam Preliminary Bee Risk Assessment, *supra* note 3, at 5. ("although both chemicals are assessed here individually, a cumulative risk assessment is not conducted.")

[214] 21 U.S.C. § 346a(b)(2)(C)(ii).

[215] *Id.* (emphasis supplied).

[216] 21 U.S.C. § 346a(b)(2)(D).

young people exposed to the highest concentration.[217] In another study, Japanese researchers found toxic metabolites (i.e., partially metabolized molecules) of acetamiprid in newborns, suggesting that neonicotinoids and their metabolites are transferred from pregnant women to their fetuses.[218] Other studies have documented neonicotinoid contamination in tap water,[219] as well as in common foods such as apples, cherries, honey, strawberries, and baby food.[220]

The Cimino study, a systematic review of human population studies on the human health effects of neonicotinoid exposure published in 2017,[221] suggests a variety of adverse health effects from neonicotinoid exposure in humans. The article reviewed numerous studies of the effects of neonicotinoids, similar to the effects of nicotine, on mammalian neuroreceptors that "are of critical importance to human brain function, especially during development and for memory, cognition, and behavior," and alteration of which "plays a role in several central nervous system disorders, including Alzheimer's disease, Parkinson's disease, schizophrenia, and depression."[222] Other studies have found adverse reproductive and developmental effects in mammals such as reduced sperm production and function, reduced pregnancy rates, higher rates of embryo death, stillbirth, premature birth, and reduced weight of offspring.[223] These serious impacts on mammals prompted a review of human population studies, some of which "reported associations between chronic neonic exposure and adverse developmental outcomes or a symptom cluster including neurological effects."[224] The authors conclude that "there remains a paucity of data on neonic exposure and human health. Given the widespread use of neonicotinoids in agriculture and household products and its increasing detection in U.S. food and water, more studies on the human health effects of chronic (non-acute) neonicotinoid exposure are needed."[225]

---

[217] Maria Ospina et al., *Exposure to Neonicotinoid Insecticides in the U.S. General Population: Data From the 2015–2016 National Health and Nutrition Examination Survey*, 176 ENVTL. RESEARCH 108555 (2019), https://www.sciencedirect.com/science/article/abs/pii/S0013935119303524 (last accessed May 4, 2020).

[218] G. Ichikawa et al., *LC-ESI/MS/MS Analysis of Neonicotinoids in Urine of Very Low Birth Weight Infants at Birth*, PLOS ONE (2019), https://www.ncbi.nlm.nih.gov/pubmed/31260498 (last accessed May 4, 2020).

[219] Kathryn Klarich Wong et al., *Chlorinated Byproducts of Neonicotinoids and Their Metabolites: An Unrecognized Human Exposure Potential?*, 6 ENVTL. SCI. & TECH. LETTERS 98 (2019), https://pubs.er.usgs.gov/publication/70201737 (last accessed May 4, 2020).

[220] Hillary Craddock et al., *Trends in Neonicotinoid Pesticide Residues in Food and Water in the United States, 1999-2015*, ENVTL. HEALTH (2019), https://www.ncbi.nlm.nih.gov/pubmed/30634980 (last accessed May 4, 2020).

[221] Cimino, et al., *supra* note 153.

[222] *Id.* at 156.

[223] *Id.* at 156

[224] *Id.* at 160.

[225] *Id.*

In light of the demonstrated need for further study of the human health effects of neonicotinoid exposure, the 2018 Multistate AG Comments cited the Cimino study and urged EPA to restrict product use pending further study of such effects.[226] In its PIDs, EPA fails to explain whether or how it intends to consider the newer studies before finalizing the neonicotinoid registration reviews. In response to the 2018 Multistate AGs Comments, EPA's Health Effects Division ("HED") merely cites an ongoing literature review by the National Toxicology Program, after completion of which HED would determine "which of these studies are relevant to its risk assessment" and "if the studies can be used in its risk assessment."[227] Without updating its human health risk assessments to include full consideration of recent studies, EPA does not have "reliable data" on which to base reduction or elimination of the FQPA 10X safety factor.

2. *EPA Unlawfully Eliminates the FQPA 10X Safety Factor in the Face of Evidence of Increased Pre- and Post-natal Susceptibility in Its Own Human Health Risk Assessments.*

Each of the Human Health Draft Risk Assessments ("DRAs") for the subject neonicotinoids reduces the FQPA safety factor from 10X to 1X, thus, eliminating the FQPA safety factor. At the same time, each DRA (except the one for dinotefuran) cites evidence of increased adverse effects of exposure prenatally and in the young in the studies it uses to establish safe levels of exposure.[228]In the clothianidin, thiamethoxam and imidacloprid DRAs, EPA states that its "degree of concern" for these effects is "low." In the acetamiprid DRA, there is no comment on this evidence at all.

EPA cannot legally eliminate the FQPA 10X safety factor when its own cited studies confirm increased susceptibility of infants and children to toxic effects—a "low degree of concern" for identified developmental toxic effects does not equate to "safety," and EPA's rationale turns the FQPA mandate on its head. The FQPA requires that a 10X factor of safety be applied as the default position, and allows for its elimination *only* upon an affirmative showing that a lower factor will be safe based on reliable evidence. EPA states that it "uses a weight-of-evidence approach to determine whether the FQPA [safety factor] should be retained at 10X or reduced to 1X."[229] Using that standard, the evidence compels retention of the full 10X safety factor.

---

[226] 2018 Multistate AG Comments at 18.

[227] EPA, *Clothianidin. Response to Comments on HED's Draft Human Health Risk Assessment in Support of Registration Review, and an Updated Poultry House Assessment*, Docket ID EPA-HQ-OPP-2011-0865-1162.

[228] EPA, *Acetamiprid Human Health Draft Risk Assessment for Registration Review*, Docket ID EPA-HQ-OPP-2012-0329-0025, at 19; EPA, *Clothianidin Draft Human Health Risk Assessment in Support of Registration*, Docket ID EPA-HQ-OPP-2011-0865-0243, at 15; EPA, *Thiamethoxam, Draft Human Health Risk Assessment for Registration Review*, Docket ID EPA-HQ-OPP-2011-0581-0096, at 19; EPA, *Imidacloprid, Human Health Draft Risk Assessment (DRA) for Registration Review*, Docket ID EPA-HQ-OPP-2008-0844-1235, at 16.

[229] EPA, *Imidacloprid. Draft Human Health Risk Assessment [DRA] for Registration Review – Response to Comments*, Docket ID EPA-HQ-OPP-2008-0844-1613, at 7.

3. *EPA Cannot Dispense with Application of the FQPA 10X Safety Factor Without Completing the Endocrine Disruptor Screening Program*

The PIDs for the Subject Neonicotinoid Insecticides acknowledge that they have not been subjected to the EDSP, a legal requirement for registration under the FQPA.[230] In each PID, EPA states that it "is making no human health or environmental safety findings associated with the EDSP screening" of the subject neonic.[231]

Despite that language in its PID, imidacloprid was in fact the subject of a "Tier 1" Endocrine Screening, which concluded in 2015 that "Imidacloprid demonstrates no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways *in vivo* in mammals or wildlife."[232] This conclusion has been criticized for ignoring a number of adverse developmentally-related endocrine effects identified in studies included in EPA's own screening.[233] At least one additional study also provided evidence that imidacloprid is an endocrine disrupting chemical.[234] A robust screening of potential endocrine disruptor effects of all the subject neonicotinoids would be required *before* EPA could make a lawful determination regarding the application of the FQPA 10X safety factor.

Endocrine disruption is intrinsically developmental in nature, with a disproportionate impact on the unborn and the young through sexual maturity. The results of the yet-to-be-completed endocrine screenings for the respective neonicotinoids are an essential element of the "reliable data" without which EPA cannot dispense with full application of the FQPA 10X safety factor.

4. *EPA Has Failed to Determine that the Subject Neonicotinoid Insecticides Share a Common Mechanism of Toxicity and Unlawfully Failed to Consider Their Cumulative Effects*

EPA has failed to identify neonicotinoids as a cumulative assessment group with a common mechanism of toxicity. This failure is inexplicable, since EPA itself describes the mechanism of toxicity of each neonicotinoid the same way. In the imidacloprid PID, the pesticide is identified as "an N-nitroguanidine neonicotinoid insecticide, which causes irreversible blockage of the postsynaptic nicotinic acetylcholine receptors."[235]The Clothianidin and Thiamethoxam PID describes these pesticides as "systemic, neonicotinoid insecticides . . . that act on the nicotinic acetylcholine receptors (nAChRs) of the central nervous system of

---

[230] *See* note 222 *supra* and accompanying text.

[231] Clothianidin and Thiamethoxam PID, *supra* note 115, at 76; Imidacloprid PID, *supra* note 115, at 58-59; Dinotefuran PID, *supra* note 115, at 45; Acetamiprid PID, *supra* note 115, at 24.

[232] EDSP, *Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals*, Docket ID EPA-HQ-OPP-2008-0844-0137, at 31.

[233] NRDC, *Comments on the Imidacloprid Human Health Draft Risk Assessment for Registration Review*, Docket ID EPA-HQ-OPP-2008-0844-1253, at 11.

[234] *Id.*

[235] Imidacloprid PID, *supra* note 115, at 4.

insects."[236] Dinotefuran "acts on the neonicotinoid acetylcholine receptors (nAChRs) of the central nervous system of insects."[237] Although acetamiprid "is a chloropyridinyl neonicotinoid, distinct from the nitroguanidine neonicotinoids (imidacloprid, clothianidin, dinotefuran, and thiamethoxam), . . . [a]ll neonicotinoids function by binding to nicotinic acetylcholine receptors in the post-synaptic neurons of an insect's central nervous system."[238] Notably, all the neonicotinoids that are the subject of this review are within the same Mode of Action subclass 4A identified by the Insecticide Resistance Action Committee (IRAC), a technical subgroup of the agrochemical industry association, CropLife.[239]

The FQPA recognizes that assessment of the cumulative effects of exposure to these neonicotinoids is essential, since infants and children may well, in the real world, be exposed to multiple neonicotinoids at once. Given the obvious commonality of their mechanism of toxicity and EPA's failure to assess the cumulative effects of exposure, EPA cannot legally conclude that "on the basis of available data, [the removal of the 10X factor] will be safe for infants and children."

In sum, in the absence of reliable data, including updated health risk studies, endocrine disruption screening, and the cumulative impact of exposure to neonicotinoids with a common mechanism of toxicity, EPA is required to apply the 10X factor to account for the increased susceptibility of infants and children. EPA must not conclude the registration process for these neonicotinoids without finalizing Human Health Risk Assessments that fully assess these missing data to conclusively determine whether application of a reduced safety factor will be safe for infants and children in each case.

CONCLUSION

As EPA continues to evaluate the environmental effects of imidacloprid, clothianidin, thiamethoxam, dinotefuran, and acetamiprid, we urge EPA to conduct the necessary rigorous analysis to thoroughly consider the severe risks that these pesticides pose to our states' economies, food supplies, public health, and natural resources. Accordingly, we urge EPA to thoroughly assess the risks posed by the Subject Neonicotinoid Insecticides, including finalizing all associated risk assessments and fully assessing risk from prophylactic use of seed treatments. Final and complete risk assessments must be developed for bees, other pollinators, non-pollinator species, and humans, with an additional opportunity for public comment, before interim decisions may be issued and before these pesticides may be reregistered for use in the U.S. Without the necessary data to support reregistration, EPA should cancel or severely restrict the registrations for the ongoing uses of the Subject Neonicotinoid Insecticides until adequate, complete and final assessments are performed and thereafter EPA must cancel or severely restrict the registrations as necessary to protect the environment.

---

[236] Clothianidin and Thiamethoxam PID, *supra* note 115, at 5.

[237] Dinotefuran PID, *supra* note 115, at 4.

[238] Acetamiprid PID, *supra* note 115, at 4-5.

[239] *See* https://www.irac-online.org/modes-of-action/ (last accessed May 4, 2020).

We would be pleased to work with you as EPA continues its Registration Reviews. Please do not hesitate to contact us if you wish to engage us further in this important effort.

Sincerely,

/s/ I. Andrew Goldberg
I. Andrew Goldberg
Assistant Attorney General
Environmental Protection Division
MASSACHUSETTS OFFICE OF THE ATTORNEY GENERAL
One Ashburton Place, 18th Floor
Boston, Massachusetts 02108
(617) 727-2200

/s/ Morgan A. Costello
Morgan A. Costello
Assistant Attorney General
Karen R. Kaufmann
Volunteer Assistant Attorney General
Jennifer Nalbone
Environmental Scientist
Environmental Protection Bureau
NEW YORK OFFICE OF THE ATTORNEY GENERAL
The Capitol
Albany, New York 12224
(518) 776-2392

/s/ Wade H. Hargrove III
Wade H. Hargrove III
Deputy Attorney General
Health and Human Services Division
HAWAI'I DEPARTMENT OF THE ATTORNEY GENERAL
465 South King Street, Room 200
Honolulu, Hawaii 96813
(808) 586-4070

/s/ Joshua M. Segal
Joshua M. Segal
Special Assistant Attorney General
MARYLAND OFFICE OF THE ATTORNEY GENERAL
200 St. Paul Place
Baltimore, Maryland 21202
(410) 576-6446

/s/ Daniel Rottenberg
Daniel Rottenberg
Assistant Attorney General
ILLINOIS ATTORNEY GENERAL'S OFFICE
69 W. Washington St., 18th Floor
Chicago, IL 60602
(312) 814-3369

/s/ Peter N. Surdo
Peter N. Surdo
Special Assistant Attorney General
MINNESOTA OFFICE OF THE ATTORNEY GENERAL
445 Minnesota Street Suite 900
Saint Paul, Minnesota 55101
(651) 757-1061

/s/ Steve Novick
Steve Novick
Special Assistant Attorney General
Natural Resources Section | General Counsel Division
OREGON DEPARTMENT OF JUSTICE
100 SW Market
Portland, Oregon 97201
(971) 673-1891

/s/ Kelly Thomas Wood
Kelly Thomas Wood
Assistant Attorney General
Environmental Protection Division
WASHINGTON ATTORNEY GENERAL'S OFFICE
800 5th Ave Suite 2000, TB-14
Seattle, Washington 98104
(206) 326-5493

/s/ David S. Hoffman
David S. Hoffmann
Assistant Attorney General
Social Justice Section
OFFICE OF THE ATTORNEY GENERAL FOR THE DISTRICT OF COLUMBIA
441 Fourth Street N.W., Suite 650 North
Washington, D.C. 20001
(202) 442-9889

Attachments

1) 2018 Multistate AG Comments
2) 2017 New York AG Comments

THE COMMONWEALTH OF MASSACHUSETTS
OFFICE OF THE ATTORNEY GENERAL
ONE ASHBURTON PLACE
BOSTON, MASSACHUSETTS 02108

MAURA HEALEY
ATTORNEY GENERAL

(617) 727-2200
(617) 727-4765 TTY
www.mass.gov/ago

April 20, 2018

Via Electronic Filing

EPA-HQ-OPP-2008-0844 (Imidacloprid Registration Review)
EPA-HQ-OPP-2011-0865 (Clothianidin Registration Review)
EPA-HQ-OPP-2011-0920 (Dinotefuran Registration Review)
EPA-HQ-OPP-2011-0581 (Thiamethoxam Registration Review)

Yu-Ting Guilaran, Director
Pesticide Re-Evaluation Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: Notice of Availability and Request for Comments on EPA's Risk Assessments and Benefits Assessments for the Registration Reviews of Imidacloprid, Clothianidin, Thiamethoxam, and Dinotefuran (82 Fed. Reg. 60,599 (Dec. 21, 2017))

Dear Director Guilaran:

The Attorneys General of Massachusetts, Hawaii, Maryland, and the District of Columbia appreciate this opportunity to comment on the U.S. Environmental Protection Agency's ("EPA") reviews under Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")[1] of the registrations of four neonicotinoid insecticides: imidacloprid, clothianidin, thiamethoxam, and dinotefuran (collectively, the "Registration Reviews").

In its notice dated December 21, 2017,[2] EPA requested comments on its draft non-pollinator ecological risk assessment for the review of imidacloprid[3] and on its draft human-health and non-pollinator ecological risk assessments for the reviews of clothianidin,[4]

[1] 7 U.S.C. § 136a(g).

[2] *See* 82 Fed. Reg. 60,599 (Dec. 21, 2017).

[3] Keith Sappington, Mohammed Ruhman, & Justin Housenger, *Imidacloprid – Transmittal of the Preliminary Terrestrial Risk Assessment to Support the Registration Review* (Nov. 28, 2017), EPA Docket No. EPA-HQ-OPP-2008-0844-1256.

[4] Michael Wagman, Amy Blankinship, & Chuck Peck, *Preliminary Aquatic and Non-Pollinator Terrestrial Risk*

thiamethoxam,[5] and dinotefuran.[6] These preliminary risk assessments supplement EPA's previously published draft pollinator ecological risk assessments,[7] and draft aquatic ecological and human-health risk assessments for imidacloprid.[8] The notice also requested comments on EPA's assessments of the benefits of neonicotinoid insecticide use on cotton[9] and citrus.[10] These benefits assessments supplement EPA's 2014 assessment of the benefits to soybean production of neonicotinoid insecticide seed treatments.[11]

The Attorneys General submit the following comments for EPA's consideration in its ongoing analyses in connection with the Registration Reviews.

SUMMARY OF COMMENTS

The undersigned Attorneys General are pleased that EPA is undertaking a much-needed review of the registrations of imidacloprid, clothianidin, thiamethoxam, and dinotefuran (collectively "the Subject Neonicotinoid Insecticides")—four toxic neonicotinoid insecticides that threaten significant harm to our states. We urge EPA to act promptly based on science to severely cancel or restrict uses of these insecticides, including unnecessary applications and other uses that pose particular risk to pollinators and aquatic environments, such as seed coatings, cosmetic uses, uses on non-crop plants, and application during bloom periods.

Assessment to Support the Registration Review of Clothianidin (Nov. 27, 2017), Doc. No. EPA-HQ-OPP-2011-0865-0242; Danette Drew et al., *Clothianidin. Draft Human Health Risk Assessment in Support of Registration Review* (Sept. 7, 2017), Doc. No. EPA-HQ-OPP-2011-0865-0243.

[5] Ryan Mroz, Christopher M. Koper, & Kristina Garber, *Preliminary Risk Assessment to Support the Registration Review of Thiamethoxam* (Nov. 29, 2017), Doc. No. EPA-HQ-OPP-2011-0581-0093; Margarita Collantes et al., *Thiamethoxam. Draft Human Health Risk Assessment for Registration Review* (Dec. 5, 2017), Doc. No. EPA-HQ-OPP-2011-0581-0096.

[6] Elizabeth Donovan & Rochelle F.H. Bohaty, *Preliminary Ecological Risk Assessment (excluding terrestrial invertebrates) for the Registration Review of Dinotefuran* (Nov. 28, 2017), Doc. No. EPA-HQ-OPP-2011-0920-0616; Julie L. Van Alstine et al., *Dinotefuran: Human Health Draft Risk Assessment for Registration Review* (Sept. 12, 2017), Doc. No. EPA-HQ-OPP-2011-0920-0620.

[7] Justin Housenger, Keith Sappington, & Mohammed Ruhman, *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid* (Jan. 4, 2016), Doc. No. EPA-HQ-OPP-2008-0844-0140; Michael Wagman et al., *Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam* (Jan. 5, 2017), Doc. No. EPA-HQ-OPP-2011-0865-0173; Frank Farruggia et al., *Draft Assessment of the Potential Effects of Dinotefuran on Bees* (Jan. 5, 2017), Doc. No. EPA-HQ-OPP-2011-0920-0014.

[8] Keith Sappington. Mohammed Ruhman, & Justin Housenger, *Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid* (Dec. 22, 2016), Doc. No. EPA-HQ-OPP-2008-0844-1086; Jennifer R. Tyler et al., *Imidacloprid: Human Health Draft Risk Assessment for Registration Review* (June 22, 2017), Doc. No. EPA-HQ-OPP-2008-0844-1235.

[9] K. Welch & TJ. Wyatt, *Benefits of Neonicotinoid Insecticide Use in the Pre-Bloom and Bloom Periods of Cotton* (Nov. 21, 2017), Doc. No. EPA-HQ-OPP-2011-0865-0246.

[10] K. Welch & D. Sells, *Benefits of Neonicotinoid Insecticide Use in the Pre-Bloom and Bloom Periods of Citrus* (Nov. 21, 2017), Doc. No. EPA-HQ-OPP-2011-0865-0245.

[11] Clayton Myers & Elizabeth Hill, *Benefits of Neonicotinoid Seed Treatments to Soybean Production* (Oct. 15, 2014), *available at* https://www.epa.gov/sites/production/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf.

Under FIFRA, EPA must analyze and duly consider during the registration-review process the full suite of risks posed by the Subject Neonicotinoid Insecticides. EPA must ensure the Subject Neonicotinoid Insecticides "will not generally cause unreasonable adverse effects on the environment," taking into consideration each insecticide's relative economic, social, and environmental costs and benefits.[12] If EPA determines that the common use of an insecticide "generally causes unreasonable adverse effects on the environment," FIFRA authorizes EPA to take action to cancel or modify the registration of the insecticide.[13]

As demonstrated below, the Subject Neonicotinoid Insecticides are known to be highly toxic to bees and other pollinators, contributing to potentially catastrophic pollinator losses that threaten our states' agricultural economies, the health and welfare of our residents, and the food supply. In addition, these insecticides are harmful to fish, amphibians, birds, bats, aquatic invertebrates, and other wildlife. They threaten the health of our lakes, streams, and rivers, while also posing risks to human health.

For these reasons, EPA cannot support a finding under FIFRA that continued extensive use of imidacloprid, clothianidin, thiamethoxam, and dinotefuran "will not generally cause unreasonable adverse effects on the environment."[14] On balance, the significant risks posed by the Subject Neonicotinoid Insecticides outweigh the benefits of at least many, if not most, uses—a conclusion that is underscored by a litany of actions by states, retailers, citizen groups, and other countries around the world to limit neonicotinoid insecticide use and mitigate associated environmental harms.

These comments proceed as follows. In Part I, we describe the standard for EPA's Registration Reviews of the Subject Neonicotinoid Insecticides. In Part II, we provide a summary of our states' interests with regard to the Registration Reviews. In Part III, we offer analysis supporting our call for EPA to cancel or severely restrict uses of the Subject Neonicotinoid Insecticides. This Part III analysis starts with a description of how the Subject Neonicotinoid Insecticides are ubiquitous in the environment. We then summarize recent science on the severe risks the Subject Neonicotinoid Insecticides pose to pollinators, ecosystems, and human health. Finally, the analysis outlines actions by the federal government, states, other countries, and major retailers to control and mitigate neonicotinoid insecticide use, which evidence a consensus that the risks of neonicotinoid insecticides outweigh the benefits. In light of the compelling evidence linking neonicotinoid insecticides to severe, unacceptable risks, we conclude that EPA's evaluation of the costs and benefits of the Subject Neonicotinoid Insecticides must lead EPA to determine that uses of each of the Subject Neonicotinoid Insecticides should be cancelled or severely restricted.

---

[12] *See* 7 U.S.C. §§ 136(bb), 136a(c)(5), 136a(g). *See also Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015).

[13] *See* 7 U.S.C. §§ 136a(c)(5), 136d(b).

[14] *See id.* § 136a(c)(5) ("The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed . . . it will not generally cause unreasonable adverse effects on the environment.").

I. Standard for Registration Review

Under FIFRA, every pesticide distributed or sold in the United States, including neonicotinoid insecticides, must be registered by EPA (with limited exceptions).[15] "A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used."[16] The purpose of the registration process is "to protect man and his environment."[17]

FIFRA requires EPA to review pesticide registrations at least every fifteen years to "assess any changes that may have occurred since EPA's last registration decision" and "determine . . . whether the insecticide still satisfies the FIFRA standard for registration."[18] EPA can register a pesticide only if EPA "determines that, when considered with any restrictions imposed . . . it will perform its intended function without unreasonable adverse effects on the environment" and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."[19] "Unreasonable adverse effects on the environment" are defined as "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any insecticide, or (2) a human dietary risk . . . inconsistent with [federal standards]."[20] In other words, EPA must weigh the relative risks and benefits of the pesticides and evaluate whether, on balance, the benefits of the use outweigh risks to humans and the environment.[21] EPA must base its risk evaluation on sufficient data and cannot rely on ambiguous or inconclusive studies to support a conclusion that a pesticide does not cause unreasonable adverse effects.[22] If a pesticide under review "fails to satisfy the FIFRA standard for registration, the product's registration may be subject to cancellation . . . ."[23]

---

[15] *See id.* § 136a(a). Insecticides are a class of pesticides used specifically to target, manage, and kill insects. *See id.* § 136 (defining the term "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer," with certain exceptions).

[16] *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010).

[17] S. REP. NO. 92-838 (1972), *reprinted in* 1972 U.S.C.C.A.N. 3993, 3993.

[18] 40 C.F.R. § 155.53(a). *See also id.* § 155.40(a)(1) ("Registration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment."); 7 U.S.C. § 136a(g)(1)(A).

[19] 7 U.S.C. § 136a(c)(5). *See Reckitt Benckiser Inc.*, 613 F.3d at 1133.

[20] 7 U.S.C. § 136(bb).

[21] *See Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 532 (9th Cir. 2001) ("FIFRA registration is a cost-benefit analysis that no unreasonable risk exists to man or the environment . . . ." (quoting *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984))); *Pollinator Stewardship Council*, 806 F.3d at 522–23 ("FIFRA uses a 'cost-benefit analysis to ensure that there is no unreasonable risk created for people or the environment from a pesticide.'" (quoting *Washington Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005))).

[22] *See Pollinator Stewardship Council*, 806 F.3d at 531–32 (vacating EPA's unconditional registration of the neonicotinoid insecticide sulfoxaflor where approval decision was not supported by substantial evidence).

[23] 40 C.F.R. § 155.40(a)(2). *See also* 7 U.S.C. § 136d(b) (EPA may commence action to cancel or reclassify a registration if it appears that common use of the pesticide "generally causes unreasonable adverse effects on the environment."); *Envtl. Defense Fund, Inc. v. EPA,* 510 F.2d 1292, 1296 n.4 (D.C. Cir. 1975) (EPA must commence

EPA commences a registration review by opening a public docket containing "information that will assist the public in understanding the types of information and issues that EPA may consider in the course of the registration review," including any "[r]isk assessment documents."[24] EPA then solicits public comment on the registration review docket, and "interested persons may identify any additional information they believe EPA should consider in the course of the registration review."[25] The registration review docket remains open during the pendency of the review process, until EPA has completed all actions required for a final decision.[26]

II. States' Interests

Our states have a significant interest in ensuring that the Registration Reviews are conducted in accordance with FIFRA and in protecting our pollinators, ecosystems, and the health of our residents from the risks posed by the Subject Neonicotinoid Insecticides.

Honey bees and other pollinators, including wild bees, bats, and birds, play an essential role in crop production.[27] Pollinators are critical to both small local farms and large national farming operations, and to the production of food consumed by people as well as livestock, domestic pets, and wild animals. The U.S. Department of Agriculture ("USDA") reports that a quarter of the American diet depends on honey bee pollination.[28] Honey bee pollination contributes more than fifteen billion dollars in value to U.S. agricultural crops each year.[29]

Alarmingly, the critically important ecological services provided by pollinators are in jeopardy due to significant pollinator declines in recent years. Between April 2014 and April 2015, U.S. beekeepers lost approximately 42 percent of honey bee colonies, with summer losses exceeding winter losses for the first time.[30] From 2007 to 2011, commercial beekeepers in the United States reported a 28- to 33-percent overwinter hive loss, and in 2012, a 22-percent

---

a cancellation or reclassification proceeding "whenever there is a substantial question about the safety of a registered pesticide." (quoting *Envtl. Defense Fund, Inc. v. Ruckelshaus,* 439 F.2d 584, 594 (D.C. Cir. 1971)).

[24] 40 C.F.R. § 155.50(a).

[25] *Id.* § 155.50(b).

[26] *See id.* § 155.58(c).

[27] *See generally* L.A. Garibaldi et al., *Wild Pollinators Enhance Fruit Set of Crops Regardless of Honey Bee Abundance*, 339 SCIENCE 1608 (2013); NATURAL RESOURCES DEFENSE COUNCIL, BUSY AS A BEE: POLLINATORS PUT FOOD ON THE TABLE (2015), *available at* https://www.nrdc.org/sites/default/files/bee-deaths-FS.pdf.

[28] *See* Michael Wines, *Mystery Malady Kills More Bees, Heightening Worry on Farms*, N.Y. TIMES, Mar. 28, 2013.

[29] *See* Presidential Memorandum – Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators (June 20, 2014), *available at* https://obamawhitehouse.archives.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b.

[30] Kim Kaplan, *Bee Survey: Lower Winter Losses, Higher Summer Losses, Increased Total Annual Losses*, U.S. DEP'T OF AGRIC. (May 13, 2015), https://www.ars.usda.gov/news-events/news/research-news/2015/bee-survey-lower-winter-losses-higher-summer-losses-increased-total-annual-losses/.

overwinter hive loss.[31] Those losses, according to the USDA, "far exceed the historical rate . . . and represent a threat to both beekeepers and to those agriculture crops that rely upon pollination as a production input."[32] These bee loses have a significant economic impact, as well, translating to billions of dollars of costs borne by beekeepers.[33]

Recent catastrophic pollinator declines coincide with dramatically increased use of neonicotinoid insecticides (*see, e.g.*, Figure 1 below).[34] Neonicotinoid insecticides are a class of systemic pesticides: water-soluable pesticides that are absorbed by the treated plant or animal, and circulate within its tissues. Neonicotinoid insecticides were first registered for use in the United States in the mid-1990s, and are now abundant in the environment across most of the country. EPA has approved hundreds of neonicotinoid-containing products and authorized broad use of these products in residential and commercial settings, including agricultural use on nearly all major U.S. crops. It is estimated that more than four million pounds of neonicotinoid insecticides are applied to U.S. cropland annually to protect against sap-sucking insects and plant-feeding insects, and application is only projected to grow (*see, e.g.*, Figure 2 below).[35] Much of the use of neonicotinoid insecticides in agriculture is prophylactic, meaning the toxic insecticide is applied prior to any experienced pest problem (for example, as a seed coating).[36] Neonicotinoid insecticides are also approved for a wide variety of non-agricultural uses, including use on lawns and gardens, in building materials, and in treatments for domestic pets.

---

[31] *See* U.S. Dep't of Agric., *Report on the National Stakeholders Conference on Honey Bee Health*, National Honey Bee Health Stakeholder Conference Steering Committee, at 1 (2012) [hereinafter USDA Report]. *See also* Angela M. Spleen et al., *A National Survey of Managed Honey Bee 2011-2012 Winter Colony Losses in the United States: Results from the Bee Informed Partnership*, 52(2) J. APICULTURAL RESEARCH 44 (2013); Wines, *supra* note 28, (reporting even higher 2012 commercial beekeeper hive losses at 40 to 50 percent).

[32] USDA Report, *supra* note 31, at 1.

[33] *See id.* at 1–2.

[34] *See* Margaret R. Douglas & John F. Tooker, *Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides and Preemptive Pest Management in U.S. Field Crops*, 49 ENVTL. SCI. & TECH. 5088 (2015).

[35] *Id.*

[36] *Cf.* Brad Haire, *Are Seed Treatments Worth the Investment?*, SOUTHEAST FARM PRESS (Jan. 9, 2014), http://www.southeastfarmpress.com/soybeans/are-seed-treatments-worth-investment (reporting that sale of insecticide-treated seeds in the United States has tripled over the last decade).

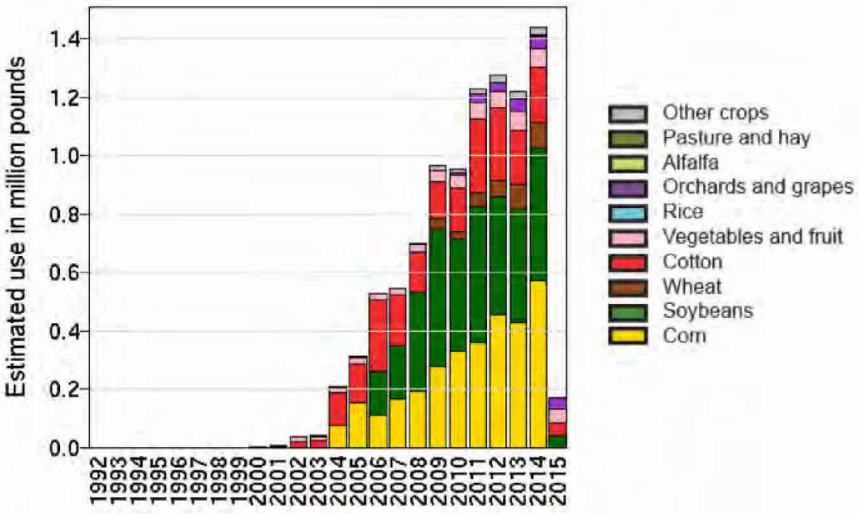

Figure 1. Estimated Thiamethoxam Use by Year and by Crop[37]

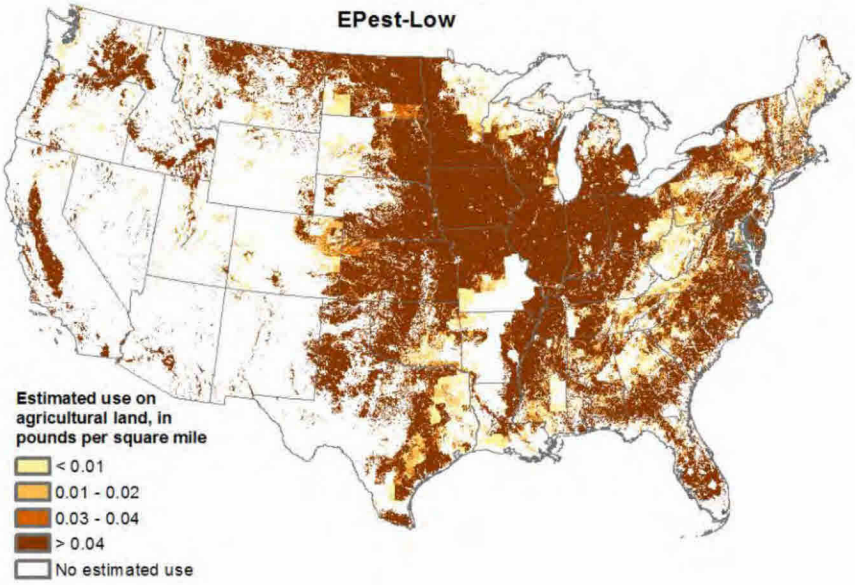

Figure 2. Lower-Bound Estimate of Agricultural Use of Imidacloprid in 2014[38]

---

[37] *Estimated Annual Agricultural Pesticide Use – Pesticide Use Maps – Thiamethoxam*, U.S. GEOLOGICAL SURVEY (2017), https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2014&map=THIAMETHOXAM&hilo=L&disp=Thiamethoxam.

[38] *Estimated Annual Agricultural Pesticide Use – Pesticide Use Maps – Imidacloprid*, U.S. GEOLOGICAL SURVEY (2017), https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2014&map=IMIDACLOPRID&hilo=L

Manufacturers promoted neonicotinoid insecticides as a safer alternative for wildlife because these insecticides were thought to be less toxic to birds and mammals than older classes of chemicals. However, the environmental risks of neonicotinoid insecticides are now a significant global concern, prompting calls for neonicotinoid insecticide bans, and state and international action to limit neonicotinoid insecticide use.[39] Studies have found increasing evidence that neonicotinoid insecticides are harmful not only to pollinators but also to a broad range of terrestrial and aquatic wildlife, threatening the health and functioning of our natural ecosystems.[40] In addition, though there is little research on the human-health risks of chronic exposure to neonicotinoid insecticides, studies raise concerns about significant impacts such as nervous system disorders and developmental impacts to infants and children.[41]

As described below, each of our states has a significant interest in ensuring that in the course of the Registration Reviews, EPA fulfills its responsibilities under FIFRA and takes appropriate action to protect our state's resources, residents, wildlife, and agricultural economy from the risks posed by the Subject Neonicotinoid Insecticides.

Massachusetts

Pollinators play a critical role in supporting Massachusetts' economy and the health and welfare of Massachusetts residents. For centuries, Massachusetts' agricultural economy, which includes more than 7,750 farms and 523,000 acres of farmland, has been a vital source of job opportunities, land preservation, and valuable commodities such as our native cranberry.[42] Nearly half of our state's agricultural production relies on our rich diversity of pollinator species. Massachusetts is home to an estimated 380 wild bee species and 120 butterfly species, including some protected species,[43] as well as numerous managed pollinator species.[44]

In recent years, Massachusetts has experienced declines in pollinator populations that threaten the economic and environmental health of our state. In the 2015/2016 season, Massachusetts beekeepers reported an annual loss of 55.75 percent of honey bee colonies—which is the highest level of bee loss in New England and among the top 10 percent of losses

---

(depicting a lower-bound estimate of agricultural use of imidacloprid in 2014).

[39] *See infra* at pp. 18–23.

[40] *See infra* at pp. 11–17.

[41] *See infra* at pp. 17–18.

[42] *See* APIARY PROG. WORKING GROUP, DIV. OF CROP & PEST SERV., MASS. DEP'T OF AGRIC. RES., MASSACHUSETTS POLLINATOR PROTECTION PLAN 3 (2017), *available at* https://www.mass.gov/files/documents/2017/06/zw/pollinator-plan.pdf [hereinafter MA Pollinator Plan].

[43] The Massachusetts Division of Fisheries and Wildlife and the Natural Heritage and Endangered Species Program have listed seven species of wild bees and nineteen species of butterflies and moths as "of concern," endangered, or threatened. The Natural Heritage and Endangered Species Program has identified pesticides as a key threat to the state's imperiled pollinators. *See id.* at 6–8.

[44] Managed species include, *e.g.*, honey bees, bumble bees, leafcutting bees, and orchard bees. *See id.* at 5.

across the nation.[45] State surveys indicate that on average, beekeepers lost 30 percent of their honey bee colonies that season, with some counties reporting losses as high as 41 percent.[46]

Following guidance from the federal government, the Massachusetts Department of Agricultural Resources ("MDAR"),[47] with input from stakeholder groups, finalized a *Massachusetts Pollinator Protection Plan* ("MA Pollinator Plan") in 2017. The MA Pollinator Plan is designed to improve the health of pollinators by promoting best management practices and facilitating collaboration on solutions to protect Massachusetts' critical pollinator populations.[48] The MA Pollinator Plan links recent alarming colony losses to pesticide use (which the plan notes is one of "the major threats facing pollinators"),[49] and sets forth wide-ranging guidelines for beekeepers, pesticide applicators, land managers and farmers, nurseries and landscapers, and homeowners and gardeners.[50]

The Massachusetts Attorney General's Office has also responded to the risks posed by pesticides. In 2016, Attorney General Maura Healey pursued enforcement action against Bayer CropScience LP for unfair or deceptive practices in marketing the company's lawn and garden products containing imidacloprid and clothianidin. The Attorney General alleged that Bayer CropScience LP violated the state's Consumer Protection Act[51] by failing to disclose harms to bees and making misleading claims regarding its neonicotinoid insecticide products, including that the products were "environmentally friendly" and using them was akin to "taking a daily vitamin." In settlement, Bayer CropScience LP agreed to pay $75,000 and reform its advertising and branding practices for neonicotinoid products in Massachusetts.[52] The Attorney General also initiated an investigation of Scotts Miracle-Gro for similar allegations. Scotts Miracle-Gro announced in 2016 that it was phasing out neonicotinoid insecticides from its lawn and garden product line.

The Massachusetts state legislature has also recognized the grave risks posed by neonicotinoids and developed pioneering legislation that would impose strict state-level controls on the application of bee-toxic pesticides. House bill 4041[53] would limit neonicotinoid use, mandate the disclosure of information regarding risks and alternatives. and require the state to identity opportunities to plant pollinator-attracting vegetation near certain state-owned solar energy projects. House bill 4041 is currently moving swiftly through the legislative process with

---

[45] *See id.* at 6–7.

[46] *See id.* at 7.

[47] MDAR's Pesticide Enforcement Program is responsible for enforcement of FIFRA and the Massachusetts Pesticide Control Act. *See* MASS. GEN. LAWS ch. 132B; 333 MASS. CODE REGS. 1–14.

[48] MA Pollinator Plan, *supra* note 42, at 3.

[49] *See id.* at 7.

[50] *Id.* at 13–24.

[51] MASS. GEN. LAWS ch. 93A.

[52] *See* Assurance of Discontinuance, *Commonwealth of Massachusetts v. Bayer CropScience LP*, Civil Action No. 16-3269G (Suffolk Cty. Super. Crt. Oct. 26, 2016).

[53] *Available at* https://malegislature.gov/Bills/190/H4041.

broad support, and was favorably reported out of a joint committee in November 2017.

District of Columbia

The District of Columbia ("District") is vitally interested in ensuring that EPA performs the Registration Reviews for the Subject Neonicotinoid Insecticides appropriately and considers the results from recent scientific studies and assessments that demonstrate adverse impacts of the Subject Neonicotinoid Insecticides. The District is primarily an urban environment, but within that environment, the District has expansive parks, an impressive tree canopy, miles of shore, numerous buildings with green roofs, open space, and many avid gardeners. The District is home to approximately 130 native bee species. Four of these species are designated as Species of Greatest Conservation Need in the 2015 District of Columbia Wildlife Action Plan,[54] and these species and their critical habitats are managed by the District's Department of Energy & Environment ("DOEE"). In addition, one of them, the rusty patched bumble bee, is an endangered species.

In 2016 the District had the distinction of being proclaimed a Bee City USA in part due to the efforts of the DOEE to promote pollinators through pollinator seed giveaways, native meadow creation, and educational outreach. Although the District has no commercial agriculture or commercial beekeeping for pollination services or honey production, the DOEE has created a Pollinator Protection Plan that focuses not only on the protection of managed pollinators but also on the protection of all pollinators in the District. The goal of this Plan is to engage non-profit organizations, government agencies, businesses, pesticide applicators, beekeepers, educational institutions, and the general public in the promotion and protection of pollinators by helping people understand pollinators' importance and how there can be a home for them in the District's urban environment.

In further promoting the District's interest in the health of pollinators and the potential impacts to human health and the environment, the DOEE is in the process of publishing a proposed rulemaking that will add the Subject Neonicotinoid Insecticides and other pesticides to the list of District Restricted-Use Pesticides ("DRUP"). A pesticide that is on the DRUP list is subject to a number of use restrictions, including purchase and use only by a DOEE-licensed applicator. The DOEE started this rulemaking effort in part due to the extensive scientific and toxicological assessments and corresponding legislation adopted by the State of Maryland and the European Union.[55]

Maryland

Maryland, which has experienced precipitous declines in bee populations, sharply

---

[54] DEP'T OF ENERGY & ENV'T, DISTRICT OF COLUMBIA, 2015 DISTRICT OF COLUMBIA WILDLIFE ACTION PLAN (2015), *available at* https://doee.dc.gov/service/2015-district-columbia-wildlife-action-plan.

[55] *See, e.g.,* MD. DEP'T OF LEGIS. SERVS., POLLINATOR HEALTH AND THE USE OF NEONICOTINOIDS IN MARYLAND (2015), *available at* http://mgaleg.maryland.gov/pubs/legislegal/2015-pollinator-health.pdf; *Pesticides and Bees*, EUR. COMM'N, https://ec.europa.eu/food/animals/live_animals/bees/pesticides_en; Commission Implementing Regulation 485/2013, 2013 O.J. (L 139) 12, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:139:0012:0026:EN:PDF.

restricts the sale and use of neonicotinoid insecticides. Neonicotinoid insecticides can be sold at retail only by entities that sell restricted use pesticides.[56] The use of neonicotinoids is tightly circumscribed, moreover: these pesticides can be used only by certified applicators (or persons working under their supervision); by farmers (or persons working under their supervision) for agricultural purposes; or by veterinarians.[57] Additionally, Maryland's Department of Agriculture is directed, by statute, to "incorporate pollinator habitat expansion and enhancement practices" into the Managed Pollinator Protection Plan that the state develops in coordination with EPA.[58]

Maryland law also directs certain state agencies to create and implement pollinator habitat plans. Subject to certain exceptions, those plans may not permit the use of neonicotinoids, or seeds or plants treated with neonicotinoids, in designated pollinator habitat areas.[59] Consistent with that directive, Maryland's State Highway Administration, Department of Natural Resources, and Environmental Service have issued such plans for land they manage.

III. Analysis

A. The Subject Neonicotinoid Insecticides Pose Severe, Unacceptable Risks to the Environment and Must Be Canceled or Restricted.

Because the neonicotinoid insecticides imidacloprid, clothianidin, thiamethoxam, and dinotefuran pose unreasonable risks to pollinators, other wildlife, human health, and state agricultural economies, EPA must severely restrict or cancel uses of these insecticides under FIFRA.

As described below, a robust body of research demonstrates that neonicotinoid insecticides are toxic to bees, causing a variety of adverse sublethal effects that reduce the survival of colonies and the survival of wild bees.[60] Moreover, neonicotinoid insecticides also pose risks to other wildlife, including fish, amphibians, birds, aquatic invertebrates, and bats. There is a dearth of studies that assess the human health effects of chronic exposure to neonicotinoid insecticides, but what data do exist indicate a risk of potentially serious harms. These significant risks outweigh the benefits of at least many, if not most, uses of neonicotinoid

---

[56] MD. CODE ANN., AGRIC. § 5-2A-02(a).

[57] *Id.* § 5-2A-02(b). The state's restrictions on the use and sale of neonicotinoid pesticides do not apply to certain pet care products, personal care products, and indoor pest control products. *Id.* § 5-2A-02(a)(1).

[58] *Id.* § 5-2A-03.

[59] *Id.* § 2-1801.

[60] *See, e.g.*, A. Decourtye & J. Devillers, *Ecotoxicity of Neonicotinoid Insecticides to Bees*, 683 ADV. EXP. MED. BIOL. 85 (2010); Richard J. Gill et al., *Combined Pesticide Exposure Severely Affects Individual- and Colony-Level Traits in Bees*, 491 NATURE 105 (2012); P.R. Whitehorn et al., *Neonicotinoid Pesticide Reduces Bumble Bee Colony Growth and Queen Production*, 336 SCIENCE 351 (2012). *See also* Press Release, EPA, EPA Releases the First of Four Preliminary Risk Assessments for Insecticides Potentially Harmful to Bees (Jan. 6, 2016), *available at* https://archive.epa.gov/epa/newsreleases/epa-releases-first-four-preliminary-risk-assessments-insecticides-potentially-harmful.html (summarizing EPA's preliminary finding that "imidacloprid potentially poses risk to hives" and exposure to imidacloprid at a common level has likely adverse effects, "includ[ing] decreases in pollinators as well as less honey produced").

insecticides. Accordingly, EPA cannot support a finding under FIFRA that continued extensive use of the Subject Neonicotinoid Insecticides "will not generally cause unreasonable adverse effects on the environment."[61]

1. Neonicotinoid Insecticides Are Ubiquitous in the Environment, Posing a Chronic Threat to Wildlife and Humans.

As a consequence of their chemical characteristics and common application practices, neonicotinoid insecticides are pervasive in the environment, posing a chronic threat to pollinators and other animals.

Neonicotinoid insecticides are the most extensively applied insecticides in the United States by land area.[62] Neonicotinoid product application typically involves spraying or injecting a plant, inundating soil, or coating plant seeds. Because of the systemic nature of neonicotinoid insecticides, a treated plant absorbs the poison into its tissues and vascular systems, rendering its pollen, nectar, roots, leaves, stem, and fruit toxic to insects.

Neonicotinoid insecticides remain in the environment long after they are applied, and can be found in pollen, dust, sediment, water, soils, and untreated vegetation.[63] On average, 95 percent of the active ingredient in neonicotinoid insecticides remains in the environment after application. When sprayed, neonicotinoid-containing products drift via air to nearby soils, water, and other plants. Neonicotinoid insecticides also dissolve in water and therefore move and spread easily throughout the environment via groundwater and surface waters. The U.S. Geological Survey's recent national-scale study of U.S. streams found at least one neonicotinoid present in 63 percent of surveyed streams, in both urban and agricultural areas; and the top four most commonly detected neonicotinoid insecticides were the four chemicals currently under EPA review.[64] The drift and persistence of neonicotinoid insecticides in the environment is especially concerning considering that several neonicotinoid-containing products approved by EPA for homeowner use in gardens and lawns, and on ornamental trees have manufacturer-recommended application rates that are sometimes 120 times higher than rates approved for use on agricultural crops. In general, neonicotinoid insecticides are applied to plants in greenhouses and nurseries and trees in urban areas at much higher rates than field crops.[65]

---

[61] *See* 7 U.S.C. § 136a(c)(5).

[62] *See* CTR. FOR FOOD SAFETY, NET LOSS: ECONOMIC EFFICACY AND COSTS OF NEONICOTINOID INSECTICIDES USED AS SEED COATINGS: UPDATES FROM THE UNITED STATES AND EUROPE 1 (2016) [hereinafter NET LOSS REPORT].

[63] For example, recent research has documented high levels of neonicotinoid contamination in vegetation in rural areas near fields treated with neonicotinoid insecticides. *See, e.g.*, C. Botias et al., *Neonicotinoid Residues in Wildflowers, a Potential Route of Chronic Exposure for Bees*, 49 ENVTL. SCI. TECH. 12731 (2016); Arthur David et al., *Widespread Contamination of Wildflower and Bee-Collected Pollen with Complex Mixtures of Neonicotinoids and Fungicides Commonly Applied to Crops*, 88 ENV'T INT'L 169 (2016).

[64] Michelle L. Hladik & Dana W. Kolpin, *First National-Scale Reconnaissance of Neonicotinoid Insecticides in Streams Across the USA*, 13 ENVTL. CHEMISTRY 12 (2015) (detecting neonicotinoid insecticides in surveyed U.S. streams, including imidacloprid (detected 37 percent of the time), clothianidin (24 percent), thiamethoxam (21 percent), and dinotefuran (13 percent)).

[65] L. Pisa et al., *An update of the Worldwide Integrated Assessment (WIA) on systemic insecticides, Part 2: Impacts on organisms and ecosystems*, ENVTL. SCI. & POLLUTION RESEARCH (July 25, 2017),

There is no escape from these toxic chemicals for imperiled pollinators. Pollinators are chronically exposed to neonicotinoid insecticides via a number of pathways, including direct ingestion of neonicotinoid-laced pollen and nectar from commercial crops (largely via the use of neonicotinoid-treated seeds) and from backyard gardens and plantings where neonicotinoid-containing gardening and lawn-care products have been used.[66] Research shows that bees are drawn to food containing neonicotinoid insecticides such as imidacloprid and thiamethoxam, and cannot limit their exposure to these chemicals.[67] Research also shows that "set-aside" strips of untreated pollinator-friendly vegetation near treated fields fail to provide pollinators relief from neonicotinoid exposures.[68]

Moreover, humans are chronically exposed to neonicotinoid insecticides in the natural environment; in the built environment, where neonicotinoid-containing products are used; and in the water and food supplies.[69] Notably, because of the systemic nature of neonicotinoid insecticides, the insecticides cannot be washed off the surface of foods prior to consumption. The most recent pesticide monitoring study by the U.S. Food and Drug Administration found neonicotinoid residues in a variety of different foods found in the human diet. Imidacloprid was the second most frequently occurring pesticide residue in the study, found in approximately 30 percent of samples. Thiamethoxam and clothianidin were also present in approximately 11 percent of samples.[70] In addition, a recent worldwide survey of neonicotinoids in honey found at least one of five tested neonicotinoid insecticides (acetamiprid, clothianidin, imidacloprid, thiacloprid, and thiamethoxam) in 75 percent of honey samples, with 10 percent of samples containing four or five of the compounds.[71] Neonicotinoid-containing products are also approved for a variety of residential uses and other uses that result in exposures of vulnerable populations such as children and pregnant women. For instance, imidacloprid is permitted for

---

https://link.springer.com/article/10.1007%2Fs11356-017-0341-3.

[66] Other pathways include exposure to treated seed fragments during planting. At least one researcher believes high fructose corn syrup made from corn treated with neonicotinoid insecticides (which is commonly fed to bees by commercial beekeepers) may contain small concentrations of neonicotinoid insecticides and constitute another exposure route. *See* Chensheng Lu, Kenneth M. Warchol, & Richard A. Callahan, In situ *Replication of Honey Bee Colony Collapse Disorder*, 65 BULLETIN OF INSECTOLOGY 99 (2012).

[67] Sebastien C. Kessler et al., *Bees Prefer Foods Containing Neonicotinoid Pesticides*, 521 NATURE 74 (2015).

[68] *See* Christina L. Mogren & Jonathan G. Lundgren, *Neonicotinoid-Contaminated Pollinator Strips Adjacent to Cropland Reduce Honey Bee Nutritional Status*, 6 SCIENTIFIC REPORTS 1 (2016).

[69] In addition, some pesticide handlers and agricultural workers experience occupational exposure. *See* Memorandum from Jennifer R. Tyler et al., Off. of Pesticide Programs, EPA, to Russell Wasem & Susan Lewis, Special Review & Reregistration Div., EPA, at 6 (Dec. 3, 2008), Doc. ID. EPA-HQ-OPP-2008-0844-0004 [hereinafter Imidacloprid Human Health Assessment Scoping Document].

[70] U.S. FOOD & DRUG ADMIN., PESTICIDE RESIDUE MONITORING PROGRAM FISCAL YEAR 2015 PESTICIDE REPORT 27 (2017), *available at* https://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm2006797.htm. *See also* AM. BIRD CONSERVANCY, NEONICOTINOID INSECTICIDES HARMFUL TO BIRDS AND BEES FOUND IN CONGRESSIONAL CAFETERIA FOOD (2015), *available at* https://abcbirds.org/wp-content/uploads/2017/02/Congressional-report_Pesticides_FINAL_7-30.pdf (finding that more than 90 percent of food samples taken from Congressional cafeterias contain neonicotinoid insecticides).

[71] E.A.D. Mitchell et al., *A Worldwide Survey of Neonicotinoids in Honey*, 358 SCIENCE 109 (2017).

use on lawns, golf courses, and ornamental plantings; as a wood preservative and termiticide in dwellings, fence posts, decks, utility poles, and other structures; and in domestic pet treatments.[72]

2. *Neonicotinoid Insecticides Are Highly Toxic to Pollinators and Impair Bee Colony Success.*

There is no question that neonicotinoid insecticides are highly toxic to bees. By their nature, neonicotinoid insecticides are poisons designed to kill insects and invertebrates. Even at tiny doses, neonicotinoid insecticides cause bees to experience convulsions, paralysis, and death. Research shows that bees exposed to neonicotinoid insecticides (including in field-realistic conditions and doses) experience increased mortalities and a number of sublethal adverse effects that impair colony success and increase biodiversity loss.[73] Sublethal adverse effects include:

- neuromuscular impairments;
- disorientation and difficulties navigating back to the hive;
- reduced foraging efficiency;
- increased worker mortality;
- impaired memory, learning, and ability to communicate properly with other bees in the colony;
- reduction in breeding success and colony growth;
- reductions in queen production and survivorship;
- decrease in metabolic efficiency;
- immune suppression; and
- increased susceptibility to disease and parasites.[74]

---

[72] *See* Imidacloprid Human Health Assessment Scoping Document, *supra* note 69, at 1, 4–5.

[73] *See, e.g.*, Ben A. Woodstock et al., *Impacts of Neonicotinoid Use on Long-Term Population Changes in Wild Bees in England*, 7 NATURE COMMUNICATIONS (2016); JENNIFER HOPWOOD ET AL., XERCES SOC'Y, HOW NEONICOTINOIDS CAN KILL BEES: THE SCIENCE BEHIND THE ROLE THESE INSECTICIDES PLAY IN HARMING BEES (2d ed. 2016).

[74] *See, e.g.*, Gill et al., *supra* note 60; Whitehorn et al., *supra* note 60; Pisa et al., *supra* note 65; Annely Brandt et al., *Immunosuppression in Honeybee Queens by the Neonicotinoids Thiacloprid and Clothianidin*, 7 SCIENTIFIC REPORTS (2017); Javier Hernandez Lopez et al., *Sublethal Pesticide Doses Negatively Affect Survival and the Cellular Responses in American Foulbrood-Infected Honeybee Larvae*, 7 SCIENTIFIC REPORTS (2017); N. Tsvetkov et al., *Chronic Exposure to Neonicotinoids Reduces Honey Bee Health Near Corn Crops*, 356 SCIENCE 1395 (2017); B.A. Woodcock et al., *Country-Specific Effects of Neonicotinoid Pesticides on Honey Bees and Wild Bees*, 356 SCIENCE 1393 (2017); Claudia Dussaubat et al., *Combined Neonicotinoid Pesticide and Parasite Stress Alter Honeybee Queens' Physiology and Survival*, 6 SCIENTIFIC REPORTS (2016); Lars Straub et al., *Neonicotinoid Insecticides Can Serve as Inadvertent Insect Contraceptives*, 283 PROCEEDINGS OF THE ROYAL SOC'Y B (2016); Judy Wu-Smart & Maria Spivak, *Sub-Lethal Effects of Dietary Neonicotinoid Insecticide Exposure on Honey Bee Queen Fecundity and Colony Development*, 6 SCIENTIFIC REPORTS (2016); Mohamed Alburaki et al., *Neonicotinoid-Coated Zea mays Seeds Indirectly Affect Honeybee Performance and Pathogen Susceptibility in Field Trials*, 10 PLOS ONE (2015); Maj Rundlof et al., *Seed Coating with a Neonicotinoid Insecticide Negatively Affects Wild Bees*, 521 NATURE 77 (2015); Daren M. Eiri & James C. Nieh, *A Nicotinic Acetylcholine Receptor Agonist Affects Honey Bee Sucrose Responsiveness and Decreases Waggle Dancing*, 215 J. EXPERIMENTAL BIOLOGY 2022 (2012); Erik Stokstad, *Field Research on Bees Raises Concern about Low-Dose Pesticides*, News & Analysis, 335 SCIENCE 1555 (2012).

A growing body of research also links neonicotinoid use to butterfly declines.[75] These threats to pollinators are not at all theoretical. In 2017, the U.S. Fish and Wildlife Service listed a bumblebee species, the rusty patched bumblebee (*Bombus affinis*), as endangered for the first time. The population of this once-common bumblebee has declined nearly 90 percent since the 1990s and is now on the brink of extinction.[76]

The Directorate-General for Internal Policies of the European Parliament issued a report in 2012 concluding that "there is no safe level of exposure [of neonicotinoid insecticides], as even tiny amounts of systemic insecticides can have negative effects in the long term . . . the damage neonicotinoids cause to the central nervous system of insects is both irreversible and cumulative."[77] Moreover, the combined effect of neonicotinoid insecticides and other stressors, which commonly occurs in agricultural areas, can amplify threats to pollinators.[78] Research strongly indicates that exposure to neonicotinoid insecticides is a factor in overall pollinator decline because it impairs the resilience and survival of colonies, and renders pollinators more susceptible to other threats.[79] Exposure to neonicotinoid insecticides may also play a contributing role in the sudden and total collapse of hives known as Colony Collapse Disorder.[80] Furthermore, the demonstrated adverse synergistic and cumulative effects of insecticides in the environment suggest that research and risk assessments to date may have underestimated the real-world adverse effects of neonicotinoid insecticides.[81]

3. Neonicotinoid Insecticides Have Other Adverse Ecological Effects and Risks that Underscore the Need for Stricter Federal Limits.

The risks posed by neonicotinoid insecticides extend well beyond pollinating insects. The scientific literature connects neonicotinoid exposure in terrestrial and aquatic environments to mortality and sublethal effects, such as feeding inhibition, impaired movement, reduced

---

[75] *See, e.g.*, NET LOSS REPORT, *supra* note 62, at 16–17; Pisa et al., *supra* note 65 (reviewing studies concluding that the use of studied neonicotinoid insecticides "cause[s] negative effects on the most common butterfly families, such as reduced survival rate, feeding interruption, and alteration of oviposition behavior"); M.L. Forister et al., *Increasing Neonicotinoid Use and the Declining Butterfly Fauna of Lowland California*, 12 BIOLOGY LETTERS (2016); J.R. Pecanka & J.G. Lundgren, *Non-target Effects of Clothianidin on Monarch Butterflies*, 102 THE SCI. OF NATURE 1 (2015).

[76] *See* Michael Greshko, *First U.S. Bumblebee Officially Listed as Endangered*, NAT'L GEOGRAPHIC, Mar. 22, 2017, *available at* https://news.nationalgeographic.com/2017/03/bumblebees-endangered-extinction-united-states/.

[77] EUR. PARL., DIRECTORATE-GENERAL FOR INTERNAL POLICIES, EXISTING SCIENTIFIC EVIDENCE OF THE EFFECTS OF NEONICOTINOID PESTICIDES ON BEES 15 (2012), *available at* http://www.europarl.europa.eu/RegData/etudes/note/join/2012/492465/IPOL-ENVI_NT(2012)492465_EN.pdf.

[78] Simone Tosi et al., *Neonicotinoid Pesticides and Nutritional Stress Synergistically Reduce Survival in Honey Bees*, 284 PROCEEDINGS OF THE ROYAL SOCIETY B: BIOLOGICAL SCI. (2017).

[79] *See* Francisco Sanchez-Bayo et al., *Are Bee Diseases Linked to Pesticides? – A Brief Review*, 89–90 ENV'T INT'L 7 (2016).

[80] *See* Lu, Warchol, & Callahan, *supra* note 66.

[81] *See* CTR. FOR BIOLOGICAL DIVERSITY, TOXIC CONCOCTIONS: HOW THE EPA IGNORES THE DANGERS OF PESTICIDE COCKTAILS (2016) (arguing that EPA has failed to adequately analyze the risks associated with the synergistic effects of chemical mixtures in the environment, including neonicotinoid products); Tsvetkov et al., *supra* note 74.

fecundity, body size reductions, and immune suppression, in a host of species, including fish, amphibians, birds, bats, and aquatic invertebrates such as insects and crabs.[82] Also concerning are the potential indirect effects of neonicotinoid-induced decline of invertebrate species in both terrestrial and aquatic environments. Such decline can reduce the decomposition capacity of ecosystems and also disrupt the food chain, leading to losses of birds, amphibians, and bats that feed on those invertebrates.[83] In general, there is increasingly strong evidence that neonicotinoid insecticides disrupt important ecosystem functioning and services such as pollination, nutrient cycling, fish productivity, and pest and weed control, as well as ecosystem resilience.[84]

Neonicotinoid impacts to aquatic ecosystems are particularly troubling. Monitoring studies have documented "world-wide contamination of creeks, rivers and lakes" by neonicotinoid insecticides.[85] Although initial studies suggested that neonicotinoid insecticides would not have major impacts on aquatic environments, later studies have since found that aquatic organisms are "much more sensitive" to neonicotinoid insecticides than standard test species.[86] Furthermore, "[d]iscrepancies between the acute and chronic sensitivity of species can lead to water quality benchmarks that are under-protective, especially for low-level chronic

---

[82] *See, e.g.*, CTR. FOR FOOD SAFETY, WATER HAZARD – AQUATIC CONTAMINATION BY NEONICOTINOID INSECTICIDES IN THE UNITED STATES (2015); Pisa et al., *supra* note 65; Francisco Sanchez-Bayo et al., *Contamination of the Aquatic Environment with Neonicotinoids and is Implications for Ecosystems*, 4 FRONTIERS IN ENVTL. SCI. 1, art. 71 (2016); Francisco Sanchez-Bayo, *The Trouble with Neonicotinoids*, 346 SCIENCE 806 (2014); Rosemary Mason et al., *Immune Suppression by Neonicotinoid Insecticides at the Root of Global Wildlife Declines*, 1 J. ENVTL. IMMUNOLOGY & TOXICOLOGY 3 (2013). *See also* Order, *Ellis v. Housenger*, Case No. 13-cv-01266-MMC, Doc. 269 (N.D. Cal. May 8, 2017) (holding, in response to claims from beekeepers, environmental groups, food safety advocates, and consumer advocates that EPA failed to protect wildlife from pesticides containing clothianidin or thiamethoxam, that EPA unlawfully issued registrations for fifty-nine pesticides without consulting with the U.S. Fish and Wildlife Service as required by the Endangered Species Act); Compl., *Natural Resources Defense Council v. Pruitt*, Case No. 17-cv-2034 (D.D.C. Oct. 2, 2017) (alleging that EPA failed to properly evaluate the impacts of hundreds of neonicotinoid products on threatened and endangered species, including pollinator species, and seeking to vacate the registrations of insecticide products containing acetamiprid, dinotefuran, and imidacloprid).

[83] *See* DR. PIERRE MINEAU & CYNTHIA PALMER, AMERICAN BIRD CONSERVANCY, THE IMPACT OF THE NATION'S MOST WIDELY USED INSECTICIDES ON BIRDS (Mar. 2013), *available at* https://abcbirds.org/wp-content/uploads/2015/05/Neonic_FINAL.pdf; Sanchez-Bayo et al., *supra* note 82. *See also* Pisa et al., *supra* note 65 ("The consequences of losing the invertebrate fauna due to continuous exposure to ubiquitous residues of neonicotinoids and fipronil are . . . far reaching and cannot be ignored any longer."); Agence France-Presse, '*Catastrophe' as France's Bird Population Collapses Due to Pesticides*, GUARDIAN, Mar. 20, 2018, *available at* https://www.theguardian.com/world/2018/mar/21/catastrophe-as-frances-bird-population-collapses-due-to-pesticides (describing two recent studies by France's National Museum of Natural History and National Centre for Scientific Research documenting significant declines in bird populations across France, in some cases by more than two-thirds, which researchers speculate are connected to neonicotinoid insecticide use).

[84] *See* Pisa et al., *supra* note 65; SARAH HOYLE & AIMEE CODE, XERCES SOC'Y, NEONICOTINOIDS IN CALIFORNIA'S SURFACE WATERS: A PRELIMINARY REVIEW OF POTENTIAL RISK TO AQUATIC INVERTEBRATES (2016), *available at* https://xerces.org/neonicotinoids-and-surface-waters/; J.L. Pestana et al., *Structural and Functional Responses of Benthic Invertebrates to Imidacloprid in Outdoor Stream Mesocosms*, 157 ENVTL. POLLUTION 2328 (2009).

[85] Sanchez-Bayo et al., *supra* note 82.

[86] *See id.* *See also* HOYLE & CODE, *supra* note 84, at 12 (concluding that "[i]n the case of imidacloprid, there is strong evidence that the EPA aquatic life benchmarks are under-protective of invertebrates."); Pisa et al., *supra* note 65.

exposures."[87] According to Sanchez-Bayo et al. (2016),

> [o]ne particular aspect of neonicotinoids became apparent only after years of testing: median toxicity values varied significantly depending on the time of exposure. . . . Neonicotinoids bind irreversibly to the nicotinic acetylcholine receptors (nAChR) embedded in the synaptic membranes of neurons, and their activation elicits a continuous electric impulse that eventually leads to the death of the neuron. The neuronal death toll accumulates as more and more chemical molecules bind to other nAChRs until the organism cannot cope with the damage and dies . . . . Aquatic organisms are constantly being exposed to residues of chemicals present in water, a medium from which they cannot escape. The time to reach the organism's death threshold depends on the internal concentration of insecticide, which in turn depends on its external concentration and the kinetics and detoxification ability of each species . . . .[88]

Sanchez-Bayo et al. (2016) concludes that "[t]he decline of many populations of invertebrates, due mostly to the widespread presence of waterborne residues and the extreme chronic toxicity of neonicotinoids, is affecting the structure and function of aquatic ecosystems."[89]

Another recent review of neonicotinoid insecticides in surface waters finds "[s]trong evidence exists that water-borne neonicotinoid exposures are frequent, long-term, and at levels . . . which commonly exceed several existing water quality guidelines" and "neonicotinoids in surface waters worldwide are well within the range where both short- and long-term impacts on aquatic invertebrate species are possible . . . ."[90] The toxicological risk to aquatic systems and birds has led the American Bird Conservancy to call for an outright ban on neonicotinoid insecticides.[91]

4. Evidence of Potential Serious Risks to Human Health Should Lead EPA to Take a Precautionary Approach and Restrict Neonicotinoid Insecticide Use.

As noted above, neonicotinoid insecticides are ubiquitous in the environment, including in our groundwater, our surface waters, and the food we eat. Yet, there is very little research on the human-health risks of chronic exposure to these chemicals. What limited data do exist are alarming; neonicotinoid insecticides have been shown to disrupt mammalian nerve cell activity,

---

[87] HOYLE & CODE, *supra* note 84, at 12

[88] Sanchez-Bayo et al., *supra* note 82.

[89] *Id. See also generally* HOYLE & CODE, *supra* note 84.

[90] Christy A. Morrissey et al., *Neonicotinoid Contamination of Global Surface Waters and Associated Risk to Aquatic Invertebrates: A Review*, 74 ENV'T INT'L 291 (2015).

[91] MINEAU & PALMER, *supra* note 83.

raising concerns about significant human-health impacts such as nervous system disorders and developmental impacts to infants and children.

According to a recent review of the risks of neonicotinoid exposure to human health, Cimino et al. (2017),[92] neonicotinoid insecticides have been linked to adverse effects in vertebrates, and recent studies show adverse effects on mammals even at sublethal doses. For instance, neonicotinoid insecticides have similar effects to nicotine, affecting human brain receptors that are critically important to development, memory, cognition, and behavior. Similar nerve cell effects play a role in central nervous system disorders such as Alzheimer's disease, Parkinson's disease, schizophrenia, and depression. Other studies have shown adverse reproductive and developmental effects such as reduced sperm production, reduced pregnancy rates, stillbirth, premature birth, and reduced offspring weight. Overall, Cimino et al. (2017) concludes that "there remains a paucity of data on neonic exposure and human health. Given the widespread use of neonics in agriculture and household products and its increasing detection in U.S. food and water, more studies on the human health effects of chronic (non-acute) neonic exposure are needed."[93]

In light of the dearth of studies about the impacts of neonicotinoid insecticides on human health—and acknowledging the critical need for additional studies regarding chronic neonicotinoid insecticide exposure, in particular—EPA should restrict product use pending research that demonstrates a lack of significant adverse human health effects. FIFRA requires EPA to base its risk evaluation on sufficient data, and any determination by EPA that the Subject Neonicotinoid Insecticides pose reasonable risks to human health would not be supported by substantial evidence.[94] As in *Pollinator Stewardship Council v. EPA*, "[t]he limitations of the underlying data in this case mean that no such conclusion can be reached."[95]

B. Stricter Federal Controls Are Needed to Fulfill Federal Policy Goals, Protect States from the Unreasonable Risks of Neonicotinoid Insecticides, and Buttress State Action to Protect Pollinators.

Since 2014, it has been the express policy of the federal government to promote the health of pollinators, including by avoiding pesticide uses that would aggravate already severe pollinator losses, and to support state efforts to develop and implement their own pollinator protection plans.[96] Given that states and EPA have invested considerable resources to advance the federal policy of protecting pollinators from the damaging effects of pesticides, it would be

---

[92] *See* Andria M. Cimino et al., *Effects of Neonicotinoid Pesticide Exposure on Human Health: A Systematic Review*, 125 ENVTL. HEALTH PERSPECTIVES 155 (2017).

[93] *Id.* at 160.

[94] *See Pollinator Stewardship Council*, 806 F.3d at 532 ("Without sufficient data, the EPA has no real idea whether [a pesticide] will cause unreasonable adverse effects . . . as prohibited by FIFRA.").

[95] *Id.* at 531.

[96] *See* Presidential Memorandum – Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators (June 20, 2014), *available at* https://obamawhitehouse.archives.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b [hereinafter Federal Pollinator Memorandum].

wholly unreasonable for EPA now to undermine this policy by reregistering the continued extensive use of the Subject Neonicotinoid Insecticides, which poses grave risks to pollinators in our states.

In 2014, President Obama issued a memorandum entitled *Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators*[97] ("Federal Pollinator Memorandum"), which recognized recent severe pollinator losses and established an interagency Pollinator Health Task Force. The Pollinator Health Task Force was charged with developing a National Pollinator Health Strategy ("Federal Pollinator Strategy") that sets forth plans for research, public education, and public-private partnerships.[98] The Federal Pollinator Memorandum further required the Pollinator Health Task Force member agencies, including EPA, to develop and implement plans to enhance pollinator habitat and incorporate consideration of pollinator health into certain agency decision-making processes. Additionally, the Federal Pollinator Memorandum required all executive departments and agencies to take appropriate action to protect pollinators, including "avoiding the use of pesticides in sensitive pollinator habitats."[99]

The Federal Pollinator Strategy finalized by the Pollinator Health Task Force in 2015 states that:

> **[m]itigating the effects of pesticides on bees is a priority for the Federal government**, as both bee pollination and insect control are essential to the success of agriculture. . . . [T]he Federal government seeks to create physical and temporal space between the use of pesticides and those areas and times when pollinators are present.[100]

The Federal Pollinator Strategy further details actions that EPA will take by 2020 to protect pollinators as directed by the Federal Pollinator Memorandum. Among other actions, the Federal Pollinator Strategy states that EPA will "[r]estrict the use of pesticides that are acutely toxic to bees," including by potentially restricting uses of pesticides that pose a particular risk to pollinators, such as foliar (leaf) application during bloom periods.[101] Notably, the Federal Pollinator Memorandum specifically required EPA to "assess the effect of pesticides, including neonicotinoids, on bee and other pollinator health,"[102] and the Federal Pollinator Strategy cites

---

[97] *Id.*

[98] *See* POLLINATOR HEALTH TASK FORCE, NATIONAL STRATEGY TO PROMOTE THE HEALTH OF HONEY BEES AND OTHER POLLINATORS (2015), *available at* https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf.

[99] Federal Pollinator Memorandum, *supra* note 96.

[100] POLLINATOR HEALTH TASK FORCE, *supra* note 98, at 47 (emphasis added).

[101] *Id.* at 49.

[102] Federal Pollinator Memorandum, *supra* note 96.

the Registration Reviews as a key implementation action.[103]

The Federal Pollinator Memorandum also specifically required EPA to "engage" states and tribes "in the development of State and tribal pollinator protection plans[.]"[104] As described in these comments, many of our states and other jurisdictions across the country have developed such plans and are taking other action to strictly control bee-toxic chemicals and promote pollinator health.[105] For instance, at least six states have enacted policies to protect their valuable pollinators from neonicotinoid insecticides (*see* Table 1 below).[106]

Table 1. Examples of State Policies Regarding Neonicotinoid Insecticides

California	**Assembly Bill 1789 (2014)**[107] requires the Department of Pesticide Regulation to reevaluate neonicotinoid insecticides by July 1, 2018 and thereafter "adopt any control measures necessary to protect pollinator health."
Connecticut	**Senate Bill No. 231 (2016)**:[108] • prohibits applying neonicotinoid insecticides to certain plants; • requires the Department of Energy and Environmental Protection to classify certain neonicotinoid insecticides as "restricted use" pesticides; • requires the Department of Agriculture to develop best practices for minimizing the release of dust from neonicotinoid-treated seeds; and • encourages protection and restoration of pollinator habitat.
Maryland	**Senate Bill 198 (2016)**:[109] • limits the sale of neonicotinoid insecticides to establishments that sell restricted use pesticides; • generally restricts neonicotinoid use to certified applicators, farm employees, or veterinarians; and • upon completion of EPA's Registration Reviews, requires the Department of Agriculture to review the state's pesticide laws and regulations and recommend changes to protect pollinators.

[103] POLLINATOR HEALTH TASK FORCE, *supra* note 98, at 47, 48–49, 52.

[104] Federal Pollinator Memorandum, *supra* note 96.

[105] *See generally Pollinator Health*, NAT'L CONFERENCE OF STATE LEGISLATURES (2016), http://www.ncsl.org/research/environment-and-natural-resources/pollinator-health.aspx (listing state legislation supporting research on issues related to pollinator health, protecting pollinators from pesticides, protecting and restoring pollinator habitat, educating the public about the role of pollinators, or supporting local beekeepers). *See also supra* pt. II.

[106] In addition, in 2007, New York State denied applications for registration of four new pesticide products containing clothianidin based on concerns regarding impacts to non-target aquatic species and non-target pollinators. *See* Letter from N.Y. Dep't of Envtl. Conservation to Arysta Life Science North America Corp. (July 17, 2007).

[107] *Codified at* CAL. FOOD & AGRIC. CODE § 12838.

[108] 2016 CONN. PUB. ACTS 16-17.

[109] *Codified at* MD. CODE ANN., AGRIC. §§ 5-2A-01 *et seq.*

Massachusetts	**House Bill 4041 (*pending*):**[110] • would establish licensing requirements for neonicotinoid insecticide applicators; • would limit the use of neonicotinoid insecticides during the blooming season; • would mandate the disclosure of information regarding risks and alternatives prior to use; and • would require the state to identity opportunities to plant pollinator-attracting vegetation near certain state-owned solar energy projects. House Bill 4041 was favorably reported out of the Joint Committee on Environment, Natural Resources and Agriculture in November 2017.
Minnesota	**Executive Order 16-07 (Aug. 25, 2016)**:[111] • directs the Department of Agriculture to require a "verification of need" prior to the use of neonicotinoid insecticides, where appropriate, and to implement restrictions on pesticide product labels to protect pollinators; • requires the Department of Natural Resources to develop an integrated pest management strategy for public lands; and • encourages protection and restoration of pollinator habitat.
Oregon	**House Bill 4139 (2014)**[112] requires Oregon State University, in consultation with the State Department of Agriculture, to develop educational materials detailing measures that pesticide applicators can take to protect pollinator health, which shall be included as part of the education required for the pesticide applicator licensing examination. **Administrative Rule No. 603-057-0388 (2015)** prohibits the use of any product containing clothianidin, dinotefuran, imidacloprid, or thiamethoxam on *Tilia* species (*e.g.*, linden trees), which are highly attractive to bees.
Vermont	**House Bill 869 (2014)**[113] requires the Secretary of Agriculture Food, and Markets to evaluate whether neonicotinoid insecticides are safe and not harmful to human health or the health of Vermont's pollinators.

State-level actions to mitigate the threats of neonicotinoid insecticides evidence a growing, widespread consensus that these chemicals pose unreasonable risks and should be strictly curtailed. However, only EPA has the power to limit the use of neonicotinoid insecticides throughout the United States. Given how neonicotinoid insecticides can and do adversely affect pollinating insects, other species, and ecosystems in ways that have serious consequences without respect to state borders, unless EPA takes appropriate action to strictly control them, neonicotinoid insecticide use will continue to undermine state initiatives—as well as federal policy goals—to protect our pollinators, other natural resources, and economies from adverse environmental effects.

---

[110] *Available at* https://malegislature.gov/Bills/190/H4041.

[111] *Available at* https://mn.gov/governor/assets/2016_08_25_EO_16-07_tcm1055-253931.pdf.

[112] OR. REV. STAT. § 634.045.

[113] 2014 Vt. Legis. Serv. 159.

C. Actions by Other Governments and Major Retailers Evidence a Watershed Consensus That the Risks of Neonicotinoid Insecticides Outweigh Benefits.

Science-based state actions by other governments to limit neonicotinoid insecticide use—and the net benefits associated with those limits—provide further evidence that extensive use of neonicotinoid insecticides poses unreasonable environmental risks.

Since 2013, the European Union has prohibited the use of clothianidin, imidacloprid, and thiamethoxam on flowering crops. Despite industry claims that this moratorium would be disastrous for agricultural productivity and the economy, there is no evidence of production declines; in fact, on average, production of major crops rose following the imposition of the moratorium.[114] Following an assessment of more than 1,500 studies of the effects of clothianidin, imidacloprid, and thiamethoxam, the European Food Safety Authority recently concluded that most uses of neonicotinoid insecticides pose a risk to wild bees and honeybees.[115] European Union member states are now considering proposals by the European Commission to expand restrictions on these neonicotinoid insecticides.

The European moratorium experience generally accords with independent analyses of the relative economic costs and benefits of neonicotinoid insecticide use.[116] In a recent review, the Center for Food Safety concludes regarding seed coatings that

> [t]he lack of economic justification for the prophylactic use of neonicotinoid-coated seeds for soybeans (the second most extensively planted U.S. crop after corn), is virtually uncontested based on the overwhelming weight of independent reviews. . . . On the 'loss' side, a further array of new U.S., Canadian and U.K. scientific studies solidly document harms occurring from the overuse of neonicotinoid seed coatings. . . . **In sum, the net costs of this technology to society outweigh the industry-claimed benefits**.[117]

Notably, Canada's Pest Management Regulatory Agency ("PMRA") is also reevaluating its registrations of imidacloprid, clothianidin, and thiamethoxam, and developing measures to protect pollinators and aquatic life from risks. Following pollinator risk assessments conducted in collaboration with EPA and the California Department of Pesticide Regulation, PMRA recently proposed to phase out some uses of clothianidin and thiamethoxam, and to impose precautionary restrictions on other uses of these insecticides where acceptable risk to bees and

---

[114] *See generally* NET LOSS REPORT, *supra* note 62.

[115] See Press Release, European Food Safety Authority, Neonicotinoids: Risks to Bees Confirmed (Feb. 28, 2018), *available at* https://www.efsa.europa.eu/en/press/news/180228.

[116] *See generally* NET LOSS REPORT, *supra* note 62; C.H. Krupke et al., *Planting of Neonicotinoid-Treated Maize Poses Risks for Honey Bees and Other Non-Target Organisms Over a Wide Area Without Consistent Crop Yield Benefit*, 54 J. APPLIED ECOLOGY 1449 (2017).

[117] NET LOSS REPORT, *supra* note 62, at 1–2 (emphasis added).

other pollinators cannot be demonstrated.[118] PMRA will propose measures to protect aquatic life from clothianidin and thiamethoxam in July 2018. PMRA has already assessed the environmental risks of imidacloprid and has concluded that "imidacloprid is being measured at levels that are harmful to aquatic insects."[119] Consequently, PMRA has proposed to phase out the majority of outdoor uses of imidacloprid, including agricultural uses.[120] PMRA intends to make a final decision on measures to protect aquatic life and pollinators from imidacloprid in late 2018.[121] Moreover, Quebec and Ontario have already imposed restrictions on neonicotinoid insecticides, and Montreal banned all uses of neonicotinoid insecticides within city limits in 2015.

Governments are not the only entities responding to calls from the public for action against neonicotinoid insecticides. More than 110 major garden retailers, including Home Depot, Lowe's, Walmart, and True Value, have committed voluntarily to phase out the sale of plants and other products containing neonicotinoid insecticides in recognition of the environmental risks they pose.[122] In addition, at least five large garden center chains in Europe (operating 78 garden stores in the United Kingdom) have agreed voluntarily to remove products containing neonicotinoid insecticides from their shelves.

EPA should follow Europe's lead in recognizing that risks to pollinators necessitate swift federal action to severely curtail the use of neonicotinoid insecticides. And like Canada's PMRA—which is relying on some of the same assessment data as EPA—EPA should propose to restrict severely or cancel uses of the Subject Neonicotinoid Insecticides, including unnecessary uses and other uses that pose particular risk to pollinators and aquatic environments.

CONCLUSION

As EPA continues to evaluate the environmental effects of imidacloprid, clothianidin, thiamethoxam, and dinotefuran, we urge EPA to thoroughly consider the severe risks that these pesticides pose to our states' economies, food supplies, public health, and natural resources. EPA should take heed of the information presented herein, including actions by our states and other jurisdictions here and abroad to protect pollinators, ecosystems, and public health from the unreasonable adverse effects of neonicotinoid insecticides. In light of the compelling evidence linking neonicotinoid insecticides to environmental harm and health risks, we are confident that EPA's evaluation of the costs and benefits of the Subject Neonicotinoid Insecticides will lead EPA to conclude that uses of each of the Subject Neonicotinoid Insecticides should be cancelled or severely restricted for the reasons detailed above.

---

[118] HEALTH CANADA, UPDATE ON THE NEONICOTINOID PESTICIDES 1–2 (Dec.19, 2017), *available at* https://www.canada.ca/content/dam/hc-sc/documents/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/update-neonicotinoid-pesticides/update-neonicotinoids-eng.pdf.

[119] *Id.* at 2.

[120] *Id.*

[121] *Id.* at 3.

[122] *See* Press Release, Friends of the Earth, Walmart and True Value to Phase Out Bee-Killing Pesticides While Ace Hardware Lags Behind (May 3, 2017).

We would be pleased to work with you as EPA continues its Registration Reviews. Please do not hesitate to contact us if you wish to engage us further in this important effort.

Sincerely,

Melissa Hoffer
Chief, Energy & Environment Bureau
MASSACHUSETTS OFFICE OF THE ATTORNEY GENERAL
One Ashburton Place, 18th Floor
Boston, Massachusetts 02108
(617) 727-2200

Wade H. Hargrove III
Deputy Attorney General
Health and Human Services Division
HAWAII DEPARTMENT OF THE ATTORNEY GENERAL
465 South King Street, Room 200
Honolulu, Hawaii 96813
(808) 586-4070

Leah J. Tulin
Assistant Attorney General
MARYLAND OFFICE OF THE ATTORNEY GENERAL
200 Saint Paul Place
Baltimore, Maryland 21202
(410) 576-6962

Catherine Jackson
Chief, Public Integrity Section
Public Advocacy Division
OFFICE OF THE ATTORNEY GENERAL
FOR THE DISTRICT OF COLUMBIA
441 Fourth Street, N.W.,
Suite 630 South
Washington, D.C. 20001
(202) 442-9864

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

Writer's Direct No.
(212) 416-8132

ERIC T. SCHNEIDERMAN
Attorney General

DIVISION OF SOCIAL JUSTICE
Environmental Protection Bureau
REBECCA FROMER
Assistant Attorney General

July 31, 2017

SUBMITTED VIA ELECTRONIC MAIL

Mr. Richard Dumas
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001
Phone: (703) 308-8015
dumas.richard@epa.gov

Re: *Comments of the Attorney General of the State of New York on EPA's Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam* (82 Fed. Reg. 24,113)

Clothianidin Docket ID Number EPA-HQ-OPP-2011-0865
Thiamethoxam Docket ID Number EPA-HQ-OPP-2011-0581

Dear Mr. Dumas:

Pursuant to our July 24, 2017, telephone conversation, the Attorney General of the State of New York ("NYAG") submits these comments on the United States Environmental Protection Agency's ("EPA") January 5, 2017, Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam, 82 Fed. Reg. 24,113 (May 25, 2017).

I. Introduction

For the reasons discussed below, the Preliminary Risk Assessment has material deficiencies and in its present form cannot support a finding that clothianidin and thiamethoxam "will not generally cause unreasonable adverse effects on the environment" under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). 7 U.S.C. § 136a(c)(5). First, the assessment fails to examine risks to pollinators from exposure to treated seed dust created during the planting of treated seeds, despite EPA's acknowledgement that dust from treated seeds "has been associated with numerous incidents of honey bee mortality." (pp. 42.) Second, to justify the failure to address dust-off created during the planting of treated seeds, the assessment seeks to rely on mitigation measures that the agency has not identified. EPA, however, cannot establish the effectiveness of mitigation measures without first assessing the risks from dust-off and then identifying the appropriate measures necessary to mitigate risks. Third, the assessment fails to assess cumulative, synergistic, and aggregate risks of exposure to clothianidin and thiamethoxam.

Accordingly, NYAG urges EPA to consider the additional information provided here and thoroughly assess the risks to bees and other pollinators posed by the continued use of clothianidin and thiamethoxam before re-registering these pesticides and approving uses that pose substantial risks to bees and other pollinators.

II. New York's Interest

Since 2006, honey bee colony loss in the United States has been severe and the urgency to stop precipitous losses cannot be overstated. Indeed, between 2012 and 2017 total annual colony losses nationally ranged from 33.2% to 45.2%.[1] In New York State alone,[2] beekeepers experienced a 43.78% total annual colony loss in 2016-2017,[3] while colony losses of commercial migratory bees based in the State have exceeded 70%.[4] In 2015, the U.S. Department of Agriculture and EPA declared the national honey bee colony losses unacceptable and set a ten-

---

[1] Steinhauer, N.A., et al. (2014). A national survey of managed honey bee 2012–2013 annual colony losses in the USA: results from the Bee Informed Partnership 2012–2013. *Journal of Apicultural Research, 53*(1), 1–18 DOI: 10.3896/IBRA.1.53.1.01; Lee, K.V., et al. (2015). A national survey of managed honey bee 2013–2014 annual colony losses in the USA. *Apidologie, 46*:292-305 DOI: 10.1007/s13592-015-0356-z; Seitz, N., et al. (2016). A national survey of managed honey bee 2014–2015 annual colony losses in the USA. *Journal of Apicultural Research, 54*:4 DOI:10.1080/00218839.2016.1153294; Steinhauer N., et al. "Colony Loss 2015-2016: Preliminary Results" (May 4, 2016). Available at: https://beeinformed.org/results/colony-loss-2015-2016-preliminary-results/; Steinhauer, N., et al. "Honey Bee Colony Losses 2016-2017: Preliminary Results" (May 25, 2017). Available at: https://beeinformed.org/2017/05/25/2016-2017-loss-results-thank-you-to-all-survey-participants/

[2] New York has not registered clothianidin for any agricultural use, based in part on its finding that the pesticide is "highly toxic to bees on an acute oral and contact basis." New York State Department of Environmental Conservation, *November 16, 2005 Letter Re: Withdrawal of Application for Registration of the New Product Poncho 600 (EPA Reg. No. 264-789-7501) Which Contains the New Active Ingredient Clothianidin.*

[3] Preliminary: 2016-2017 State Total and Average Losses. (May 26, 2017). Available at: https://beeinformed.org/2017/05/26/preliminary-2016-2017-state-total-and-average-losses/.

[4] New York State Department of Environmental Conservation and Department of Agriculture and Markets. *New York State Pollinator Protection Plan* (June 24, 2016), p. 4. Available at: http://www.dec.ny.gov/docs/administration_pdf/nyspollinatorplan.pdf

year goal to reduce losses during winter to no more than 15%.[5] To address these losses in New York, in 2016 the New York State Departments of Environmental Conservation and Agriculture and Markets developed the "New York State Pollinator Protection Plan," which aims "to promote the health and recovery of pollinator populations in New York State in order to sustain the state's robust agricultural economy and unparalleled natural resources."[6]

Indeed, in the United States, honey bees, wild bees, and other insect pollinators provide ecological services critical to maintaining agricultural crop values of over fifteen billion dollars.[7] Many of New York's seven million acres of agricultural crops, including apples, cabbage, berries, and pumpkins, rely on insect pollination, either from approximately 80,000 managed pollinator colonies in the State, or from New York's 450 wild pollinator species.[8] Pollinator loss threatens agricultural production and natural plant communities across New York, the United States, and the world.

III. Background

A. *FIFRA's Standard for Pesticide Registration*

Under FIFRA, all pesticides must be registered before their sale, distribution, or use in the United States. 7 U.S.C. § 136a(a). The EPA Administrator may only register a pesticide if it will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). 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 . . ." 7 U.S.C. § 136(bb) (emphasis added). This "unreasonable adverse effects" language thus creates a "risk-benefit" standard wherein EPA must compare the risks presented by a pesticide's use with the benefits to society from that use. If a pesticide causes unreasonable adverse effects on the environment, it cannot be registered for use. 7 U.S.C. § 136d(b). EPA is required to review again each registered pesticide by October 1, 2022, or "the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered," whichever date is later. 7 U.S.C. §§ 136a(g)(1)(A)(i), 136a(g)(1)(A)(iii).

EPA conditionally registered thiamethoxam in 1999 and clothianidin in 2003 based upon minimal data and information from the registrant regarding ecological impacts.[9]

---

[5] U.S. Department of Agriculture and U.S. Environmental Protection Agency. Pollinator Health Task Force's *National Strategy to Promote the Health of Honey Bees and Other Pollinators* (May 19, 2015). Available at: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf; Bee Informed reports total colony loss in the winters ranging from 22% to 36% between 2006-2016. See: Steinhauer N., et al. "Colony Loss 2015-2016: Preliminary Results" (May 4, 2016). Available at: https://beeinformed.org/results/colony-loss-2015-2016-preliminary-results/.

[6] *New York State Pollinator Protection Plan*, p. 1, *supra* note 4.

[7] Calderone, N. W. (2012). Insect Pollinated Crops, Insect Pollinators and US Agriculture: Trend Analysis of Aggregate Data for the Period 1992–2009. PLoS ONE 7:5, e37235.

[8] *New York State Pollinator Protection Plan,* pp. 5-6, *supra* note 4.

[9] U.S. Environmental Protection Agency, Thiamethoxam Final Work Plan; Registration Review Case No. 7641 (June 2011). Available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0581-0024; U.S. Environmental Protection Agency, Clothianidin Conditional Registration (May 30, 2003). Available at: https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-044309_30-May-03.pdf.

B. *Use and Impacts of Seeds Treated with Clothianidin and Thiamethoxam*

1. *Seed Treatment is the Predominant Use of Clothianidin and Thiamethoxam in the United States*

Clothianidin and thiamethoxam are neonicotinoid pesticides that affect the central nervous system of insects, resulting in nervous stimulation, paralysis, and death. They are systemic pesticides, meaning that once absorbed by the plant, the neonicotinoid moves throughout the plant's vascular system, exposing insects feeding on the plant to the pesticide. Neonicotinoids are highly toxic to non-target species including critical pollinators such as honey bees and other bee species.

The Preliminary Risk Assessment reveals that seed treatments constitute the most significant agricultural use of clothianidin and thiamethoxam when considering annual pounds of active ingredient. Clothianidin seed treatment usage is estimated at 1,458,000 pounds of active ingredient per year, whereas 25,000-35,500 pounds per year are used in foliar and soil applications. Thiamethoxam seed treatment usage is estimated at 792,000 pounds per year, whereas 121,000-132,500 pounds per year are used in foliar and soil applications. (pp. 34-35, Tables 2.4, 2.5.) Combined clothianidin and thiamethoxam seed treatment annual use is thus at least thirteen times greater than both foliar and soil use combined. Additionally, the assessment shows that the number of acres planted with treated seeds for predominant agricultural commodities is also significant. For example, in 2016, for corn and soybean crops – the two most widely planted crops in the United States – EPA estimated that 66 million acres of treated corn seed were planted out of 94.1 million total acres planted, while 15.1 million acres of treated soybean seed were planted out of 83.7 million total acres planted. (p. 35, Table 2.6.)

Despite the pervasive prophylactic use of treated seeds, according to EPA that use does not improve soybean crop production or crop yields compared to areas planted with non-treated seeds. On October 15, 2014, EPA released an analysis questioning the benefits of soybean treated seeds and concluding that treated soybeans "provide negligible overall benefits to soybean production in most situations . . . in most cases there is no difference in soybean yield when soybean seed was treated with neonicotinoids versus not receiving any insect control treatment."[10] Studies have also shown no crop yield benefit of planting neonicotinoid-treated corn seed.[11]

2. *Dust from Seeds Treated with Clothianidin and Thiamethoxam Causes Adverse Effects on Non-Target Species, Such as Bees*

The Preliminary Risk Assessment itself cites to several studies that reflect the exposure

---

[10] U.S. Environmental Protection Agency. "Benefits of Neonicotinoid Seed Treatments to Soybean Production" (October 15, 2014). Available at: http://www2.epa.gov/sites/production/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf.

[11] Krupke, C.H., Holland, J. D., Long, E. Y., and Eitzer, B. D. (2017). Planting of neonicotinoid-treated maize poses risks for honey bees and other non-target organisms over a wide area without consistent crop yield benefit. *Journal of Applied Ecology* doi: 10.1111/1365-2664.12924.

impacts from seed coatings.[12] Additional field studies not included in the assessment also demonstrate that neonicotinoid exposure causes significant harm to pollinator health:

- Tsvetkov et al. (2017) shows that despite the mandated use of dust-reducing seed lubricants during planting, honey bee colonies located near corn fields planted with neonicotinoid-treated seeds are chronically exposed to the neonicotinoids not just during dust-off, but for months. Exposure to neonicotinoids decreased survival of bees and fitness of colonies, and of additional serious concern, both clothianidin and thiamethoxam show synergistic effects and become nearly twice as toxic to bees when the bees are also exposed to a commonly used fungicide, boscalid.[13]

- Woodcock et al. (2017), a large real-world experiment on exposure from commercially available treated seeds planted in fields across three European countries, shows exposure to clothianidin or thiamethoxam via seed treatment reduces overwintering success and colony reproduction in nearby bee colonies.[14]

- Marzaro et al. (2011) and Girolami et al (2012) documented that contact with abraded seed dust during planting of neonicotinoid-treated corn seeds was fatal to bees, especially in high humidity environments.[15] Another Italian study showed that abraded seed dust migrated off the agricultural field, and grass and flowers from surrounding fields tested positive for neonicotinoid contamination, even when a seed coating was used to reduce abrasion and dust-off.[16]

IV. The Assessment Fails to Examine the Risks to Bees and other Pollinators, Including Threatened and Endangered Species, from Exposure to Treated Seed Dust

The Preliminary Risk Assessment is "intended to account for the major routes of pesticide exposure that are relevant to bees (i.e. through diet and contact)." (p. 48.) Nonetheless, although seed treatments are the predominant application method of clothianidin and thiamethoxam, and the assessment (pp. 7, 42) identifies abraded seed coat dust as an "important

[12] Forster, R. (2009). Bee poisoning caused by insecticidal seed treatment of maize in Germany in 2008. Pages 126 – 131 *in* P. A. Oomen and H. M. Thompson (editors) Hazards of Pesticides to Bees, 10th International Symposium of the ICP-BR Bee Protection Group, Bucharest (Romania), October 8 – 10, 2008. Julius Kühn Arch 423; Krupke, C. H., Hunt, G.J., Eitzer, B.D., Andino, G., and Given, K. (2012). Multiple routes of pesticide exposure for honey bees living near agricultural fields. PLoS ONE 7(1): e29268. Doi:10.1371/journal.pone.0029268; Tapparo, A. D., et al. (2012). Assessment of the environmental exposure of honey bees to particulate matter containing neonicotinoid insecticides coming from corn-coated seeds. *Environmental Science and Technology 46*: 2592 - 2599.

[13] Tsvetkov N., et al. (2017). Chronic exposure to neonicotinoids reduces honey bee health near corn crops. *Science 356*, 1395–1397.

[14] Woodcock B.A., et al. (2017). Country-specific effects of neonicotinoid pesticides on honey bees and wild bees. *Science 356*, 1393–1395.

[15] Marzaro, M., et al. (2011). Lethal aerial powdering of honey bees with neonicotinoids from fragments of maize seed coat. *Environ Sci Technol 46*:2592-2599; Girolami, V., et al. (2012). Fatal powdering of bees in flight with particulates of neonicotinoids seed coating and humidity implication. *J. Appl Entomol 136*:17-26.

[16] Greatti M., Barbattinni R., Stravisi A., Sabatini A.G., and Rossi S. (2006). Presence of the a.i. imidacloprid on vegetation near corn fields sown with Gaucho dressed seeds. *Bulletin of Insectology 59*(2):99-103.

route of exposure" and "a route of concern," the assessment fails to examine the risks associated with contact with, and off-site movement of, seed coat dust and residue.

Rather, EPA "assumed that bees are not present until after planting; therefore, contact exposures would not reasonably be expected to occur" and "exposure through consumption of residues in nectar and pollen [is] expected to be the dominant route." (pp. 347, 48.) These assumptions are contrary to academic analyses that demonstrate, e.g., that "the influence of planting neonicotinoid treated maize seeds is likely to be pervasive ... [and] the overwhelming majority of honey bee foragers in our study area are likely to come in contact with neonicotinoid residues from planter dust."[17] In the assessment, EPA adopts these assumptions as fact by stating "[r]elatively speaking, exposures from foliar and soil applications are greater compared to those from seed treatments." (p. 365.)

EPA is mandated to assess the potential risks of all recognized exposure routes. Clearly, an exposure route that is, according to EPA itself, the predominant application method of clothianidin and thiamethoxam by volume of active ingredient, should be included in the assessment. To be sure, the recent substantial increase in neonicotinoid use is a reflection of the growing use of large-scale prophylactic seed treatment application on field crops,[18] and must be evaluated.

In addition to bees, the assessment also fails to assess the risks of clothianidin and thiamethoxam exposure to non-bee pollinators including hover flies and bee flies (Bombyliidae family).[19] Those species are demonstrated crop pollinators in agricultural settings. Researchers have also found that non-target species are exposed to neonicotinoids from contaminated plants growing adjacent to agricultural fields, including monarch butterflies exposed to clothianidin-contaminated milkweed.[20] Likewise, the assessment fails to consider impacts to pollinators that are federal endangered and threatened species, such as the recently listed Rusty Patched Bumble bee (Bombus affinis, listed March 21, 2017). Indeed, the Federal Register Notice announced the availability of the assessment by calling it the "Combined Preliminary *Pollinator* Risk Assessment for Clothianidin and Thiamethoxam,"[21] while EPA's "Schedule for Review of Neonicotinoid Pesticides" discusses the potential issuance of the "Preliminary *Pollinator*-Only Risk Assessment" as well as "Potential Early *Pollinator* Mitigation in 2017."[22] (Emphasis

---

[17] Krupke, C.H., Holland, J.D., Long, E.Y., and Eitzer, B.D. (2017). Planting of neonicotinoid-treated maize poses risks for honey bees and other non-target organisms over a wide area without consistent crop yield benefit. *Journal of Applied Ecology* doi: 10.1111/1365-2664.12924.

[18] Douglas, M.R. and Tooker, J.F. (2015). Large-scale deployment of seed treatments has driven rapid increase in use of neonicotinoid insecticides and preemptive pest management in U.S. field crops. *Environ. Sci. Technol. 49*, 5088−5097.

[19] Klein, A., Brittain, C., Hendrix, S.D., Thorp, R., Williams, N., and Kremen, C. (2012). Wild pollination services to California almond rely on semi-natural habitat. *Journal of Applied Ecology, 49*:723-732; Orford, K.A., Vaughan, I.P., and Memmott, J. (2015). The forgotten flies: the importance of non-syrphid Diptera as pollinators. *Proc. R. Soc. B 282*:20142934.

[20] Pecenka, J.R. and Lundgren, J.G. (2015). Non-target effects of clothianidin on monarch butterflies. *Sci. Nat.* 102:19. DOI 10.1007/s00114-015-1270-y.

[21] 82 Fed. Reg. 24,113.

[22] EPA's Schedule for Review of Neonicotinoid Pesticides, last updated May 23, 2017. Available at: https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides on 7/21/2017. NYAG notes

added.) The scope of the assessment should include the risks from clothianidin and thiamethoxam, to all affected pollinators, not just bees.

V. The Assessment Relies on Unidentified Mitigation Measures that May Be Ineffective Absent a Complete Assessment of Risks from Treated Seeds

In the Preliminary Risk Assessment, EPA justifies its exclusion of seed treatment as an exposure pathway by positing that EPA may require mitigation measures. But those measures are not identified in the assessment. After conceding in the assessment that: "[e]xposure of bees to clothianidin and thiamethoxam via drift of abraded seed coat dust, is considered a route of concern given that bee kill incidents have been associated with planting of clothianidin- or thiamethoxam-treated corn," EPA continues:

> *However, the Agency is working with different stakeholders to identify best management practices and to promote technology-based solutions that reduce this potential route of exposure. As such, this exposure route was not quantitatively considered in this assessment.* (Emphasis added.)

Logically, however, without having assessed the *risk* to bees from their contact with clothianidin and thiamethoxam through dust-off during planting, it is impossible for EPA to determine whether mitigation will reduce risk associated with exposure to treated seeds below levels of concern.

Importantly, EPA's mitigation approach in this assessment was rejected by the Ninth Circuit Court of Appeals in *Pollinator Stewardship Council v. United States EPA*, No. 13-72346, 2015 U.S. App. LEXIS 19945, at *17-21 (9th Cir. Nov. 12, 2015). In that case, the court vacated EPA's registration of another pesticide, sulfoxaflor, in part because EPA had improperly relied on un-assessed mitigation measures to justify its registration of sulfoxaflor, which EPA had previously classified as "very highly toxic to bees." The court found that EPA's decision to register sulfoxaflor was not supported by substantial evidence on the record. Specifically, the court held that the "lack of any meaningful study of the effects of the mitigation measures" warranted remand to the agency. *Id.* at *23. The court found that "*[w]ithout sufficient data, the EPA has no real idea whether sulfoxaflor will cause unreasonable adverse effects on bees, as prohibited by FIFRA.*" *Id.* at *25. (Emphasis added.) The Ninth Circuit's reasoning in that case applies with equal force here. Measures relied on to reduce risks must be preceded by an examination of the actual risks to be mitigated.

Moreover, peer-reviewed studies raise concerns that mitigation measures envisioned by EPA may not be effective in reducing the risk of exposure. Tapparo et al. (2012) states:

> [A]nalytical results regarding factor emissions, air concentration of insecticide around the drilling machine and consequent bee contamination, reveal that all kinds of the tested seed coatings (also those more recently proposed) do not prevent the dispersion of large amounts of micrometric particles containing the insecticide, producing lethal exposure of

---

that the document entitled "Potential Early Pollinator Mitigation in 2017" implies that EPA intends for a proposed mitigation plan to be forthcoming, but no such document has yet been issued.

[sic] flying bees. Moreover, the modifications of the air outlet of drilling machines so far adopted seem to have a limited effect on both the factor emission and the effective bee contamination.

More recently, Tsvetkov et al. (2017) confirmed that in Canadian cornfields, the use of dust-reducing seed lubricants during planting did not prevent exposure to a toxicologically significant level of neonicotinoids.[23]

While mitigation should certainly be part of the solution for reducing risks from pesticide use,[24] without a full assessment of the risks the mitigation measures aim to alleviate, reliance on mitigation cannot support re-registration. Indeed, under FIFRA's risk/benefit standard for determining whether a pesticide poses unreasonable adverse effects, the risks to pollinators alone that are associated with neonicotinoid use as a seed treatment may outweigh any benefit when used on seeds – which can only be determined if EPA actually assesses the risk associated with dust-off from treated seeds.

VI. The Assessment Fails to Assess Cumulative, Synergistic, and Aggregate Risks of Exposure to Neonicotinoids

The Preliminary Risk Assessment also fails to evaluate the cumulative and synergistic risks of simultaneous exposure to multiple neonicotinoids and to other insecticides, herbicides, fungicides, or other chemicals used in agricultural production.[25] As noted above, Tsvetkov et al. (2017) shows that both clothianidin and thiamethoxam become nearly twice as toxic to bees when the bees are also exposed in the field to a commonly used fungicide. The U.S. Geological Survey has established, through in-field studies, that nearly 50% of native bees tested have been exposed to at least two or more pesticides.[26] Without question, bees are exposed to more than one pesticide. Indeed, a GAO report charges the EPA to identify the most common mixtures of pesticides used on crops, enabling EPA to assess cumulative or synergistic effects of commonly-used pesticide mixtures.[27]

Further, the assessment fails to evaluate the risk of other combinations of exposure, including: 1) the aggregate risk of exposure to one neonicotinoid caused by multiple routes of exposure, e.g., the risk to bees exposed to clothianidin during treated seed planting, and also exposed to foliar spray; and 2) the cumulative risk of exposure to more than one neonicotinoid, which evaluation EPA simply states it is not undertaking (p. 5) – despite these combinations

---

[23] Tsvetkov N., et al., (2017). Chronic exposure to neonicotinoids reduces honey bee health near corn crops. *Science 356*, 1395–1397.

[24] For instance, in 2016 the Province of Ontario, Canada, included mitigation within their action plan for clothianidin, thiamethoxam, and imidacloprid. NYAG specifically notes that Ontario's plan aims to reduce the use of neonicotinoid-treated corn and soybean seeds by 80%. Ministry of Agriculture, Food, and Rural Affairs (2016). *Ontario's Pollinator Health Action Plan.* Available at: http://www.omafra.gov.on.ca/english/pollinator/action_plan.htm.

[25] Tsvetkov N., et al. (2017), *supra* note 23.

[26] Hladik, M.L., Vandever, M., Smalling, K.L. (2016). Exposure of Native Bees Foraging in an Agricultural Landscape to Current-Use Pesticides. *Science of the Total Environment 542(A):* 469-477.

[27] United States Government Accountability Office. *Bee Health: USDA and EPA Should Take Additional Actions to Address Threats to Bee Populations.* February 2016. GAO-16-220.

posing real risks to pollinators. The assessment provides no rationale for EPA's failure to address these combinations of exposure.

VII. Conclusion

FIFRA requires the EPA Administrator to determine, before re-registering any pesticide, that the pesticide, when used in its commonly recognized method, can perform its intended function without unreasonable adverse effects on the environment. NYAG requests that EPA undertake a full review of the risks and adverse effects of clothianidin and thiamethoxam on bees and other vitally important pollinators. If, after a full assessment, those adverse effects and risks from seed treatment outweigh the crop yield benefits, EPA must take appropriate regulatory action in this re-registration process.

Very truly yours,

Rebecca Fromer
Assistant Attorney General
Environmental Protection Bureau
(212) 416-8132

/S/ Maureen Leary
Maureen Leary
Assistant Attorney General
Environmental Protection Bureau
(518) 776-2411

/S/ Jennifer Nalbone
Jennifer Nalbone
Environmental Scientist
Environmental Protection Bureau
(716) 853-8417