May 4, 2020

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

RE: Comments on the Proposed Interim Registration Review Decisions for the Neonicotinoid Insecticide Class

The following comments are submitted on behalf of the Natural Resources Defense Council (NRDC), Sierra Club, Pesticide Action Network North America (PANNA), and our millions of members and activists nationwide (hereafter, "Environmental Groups"). The Environmental Groups oppose the Environmental Protection Agency's (EPA) proposed interim registration review decisions, which would permit continued widespread use of neonicotinoid pesticides. These comments are submitted to the following dockets:

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

The Environmental Groups incorporate by reference, in full, all studies cited in these comments. The Groups also incorporate by reference their previous comments on preliminary risk assessments, benefits assessments, and other documents published by EPA. Each document is attached:

Comments from NRDC on the Ecological Non-Pollinator Risk Assessments (Apr. 19, 2018) (Attachment A)

Comments from NRDC on the EPA Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid (Apr. 14, 2016) (Attachment B)

Comments from NRDC on the Preliminary Aquatic Risk Assessment (Dec. 2016) to Support the Registration Review of Imidacloprid (Jul. 24, 2017) (Attachment C)

Comments from NRDC on the Imidacloprid Human Health Draft Risk Assessment for Registration Review (Nov. 13, 2017) (Attachment D)

Comments from NRDC on the Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam (Jul. 24, 2017) (Attachment E)

Comments from NRDC On the Draft Assessment of the Potential Effects of Dinotefuran on Bees (July 24, 2017) (Attachment F)

Supplemental Comment Letter from NRDC to the Office of Pesticide Programs (Apr. 1, 2019) (Attachment G)

I. BACKGROUND AND SUMMARY

Neonicotinoid pesticides ("neonics") were first introduced in the mid-1990s and today are the most commonly used insecticides nationwide. For years, neonics have been identified as a leading cause of mass honey bee colony losses,[1] which began in the mid-2000s, just as neonic use dramatically increased worldwide.[2] More recently, neonics have been implicated in the broader biodiversity crisis, linked to vast insect losses[3]—sometimes dubbed the "insect apocalypse"[4]— as well as losses of birds, fish, and aquatic invertebrates that support whole ecosystems. Water sampling across the nation routinely finds these neurotoxic insecticides in surface water, groundwater, and even tap water.[5] Finding unacceptable risks to bees and other wildlife, the European Union has banned outdoor uses of four of the most common neonics;[6] Canada has moved to impose similar restrictions.[7]

Against this backdrop, EPA has been conducting its registration review of neonics under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136a(g), for the last decade. EPA has released numerous assessments of the risks that neonics pose to terrestrial

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[1] *See, e.g.*, Lennard Pisa et al., *An Update of the Worldwide Integrated Assessment (WIA) on Systemic Insecticides. Part 2: Impacts on Organisms and Ecosystems*, Env. Sci. and Pollution Research Int'l (Nov. 9, 2017), https://bit.ly/2XIZpbC; Thomas Wood & Dave Goulson, *The Environmental Risks of Neonicotinoid Pesticides*, 24(21) Envtl. Sci. Pollution Research Int'l 17285 (Jun. 7, 2017), https://bit.ly/2Hpn8T5; Ben A. Woodcock et al., *Country-specific Effects of Neonicotinoid Pesticides on Honeybees and Wild Bees*, 356 Science 6345, 1393-1395 (Jun. 30, 2017), https://politi.co/2HrEnDl; Ben A. Woodcock et al., *Impacts of neonicotinoid use on long-term population changes in wild bees in England*, 7 Nature Communications 12459 (Aug. 16, 2016), https://go.nature.com/2EU6Xho.

[2] *See* U.S. Geological Survey, *Estimated Annual Agricultural Pesticide Use - Imidacloprid*, https://on.doi.gov/2J7pF6K (last visited March 23, 2020) (showing steadily increasing use of imidacloprid throughout the 1990s, increasing rapidly starting around 2007); Congressional Research Service, *Bee Health: Background and Issues for Congress*, 10 (Jan. 20, 2015), https://fas.org/sgp/crs/misc/R43191.pdf (bee losses started in 2005 and jumped dramatically around 2010).

[3] Michael DiBartolomeis et al., *An Assesement of Acute Insect Toxicity Loading (AITL) of Chemical Pesticides Used on Agricultural Land in the United States*, PLoS ONE (Aug. 6, 2019), https://bit.ly/35oo6M7 (neonics principally responsible for increase in pesticide toxicity loading, likely contributing to insect and insectivorous bird losses).

[4] Brooke Jarvis, The Insect Apocalypse is Here, *The New York Times Magazine* (Nov. 27, 2018), https://nyti.ms/2MD0GMB.

[5] *See, e.g.*, Katherine Klarich et al., *Occurrence of Neonicotinoid Insecticides in Finished Drinking Water and Fate during Drinking Water Treatment*, 4 (5) Envtl. Sci. & Technology Letters (Apr. 5, 2017), https://bit.ly/2KIYSPc; Michelle Hladik et al., *Widespread Occurrence of Neonicotinoid Insecticides in Streams in a High Corn and Soybean Producing Region, USA*, 193 Envtl. Pollution 189-96 (Oct. 2014), https://bit.ly/3aPhQxW.

[6] European Commission, Neonicotinoids, https://bit.ly/3dqEhvW (last visited Mar. 23, 2020).

[7] CBC Radio, Canada Bans Neonic Pesticides Implicated in Bee Declines (Aug. 17, 2018), https://bit.ly/2JaWgIU.

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invertebrates, aquatic life, and human beings, finding substantial costs of neonic use. These findings largely mirror those found to justify broad neonic bans in Europe and Canada.

On February 3, 2020, EPA released its "Proposed Interim Registration Review Decisions" (PID) for the five registered neonics. Pesticide Registration Review: Proposed Interim Registration Decisions for Several Neonicotinoid Pesticides, 85 Fed. Reg. 5,953 (Feb. 3, 2020). In stark contrast with its international counterparts, EPA proposes to approve continued, widespread use of neonics throughout the nation, with only very limited mitigation.

As detailed in the comments that follow, EPA's decision is based on a flawed cost-benefit analysis that props up even the most problematic neonic uses. EPA underestimates costs of neonic use and overestimates their benefits, biasing EPA's review toward continued approval of uses that cause "unreasonable adverse effects on the environment," in violation of FIFRA. Moreover, EPA has failed to undertake an analysis of the effects of neonic registration on endangered and threatened species, as required by the Endangered Species Act, 16 U.S.C. § 1536.

EPA also fails to explain how its proposed mitigation will eliminate or offset the unacceptable risks and costs identified. Indeed, most of EPA's proposed mitigation will have a negligible effect. As a result, EPA's proposed interim decisions violate the standard for pesticide registration established by FIFRA.

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II. LEGAL BACKGROUND

a. FIFRA and FDCA

Two statutes govern the use and sale of pesticides: FIFRA, 7 U.S.C. § 136 et seq., and the Federal Food, Drug, and Cosmetic Act ("Food Act" or FDCA), 21 U.S.C. § 346a. No pesticide may be sold or used unless it is registered with EPA under FIFRA. 7 U.S.C. § 136a(a). Before registering a pesticide, EPA must determine that it will "perform its intended function without unreasonable adverse effects on the environment" ("FIFRA standard"). *Id.* § 136a(c)(5)(C). The term "unreasonable adverse effects on the environment" means (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 pesticide," or (2) "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under [the FDCA, 21 U.S.C. § 346a]." 7 U.S.C. § 136(bb).

Under the FDCA, EPA must establish tolerances for pesticide residues on food. Tolerances are maximum amounts of a pesticide that can be found on a particular food, subject to EPA's determination that the amount is "safe." 21 U.S.C. § 346a(b)(2)(A)(i). This means "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." *Id.* § 346a(b)(2)(A)(ii). In addition to the cost-benefit analysis described in FIFRA, the FIFRA standard requires EPA to assess a pesticide product's compliance with this safety standard, which is purely health-protective. 7 U.S.C. § 136(bb).

During registration review, EPA prepares risk and benefit assessments to assess "any changes that may have occurred since the Agency's last registration decision" and determine whether those changes affect the registration's compliance with the FIFRA standard. 40 C.F.R. § 155.53(a). Based on those assessments, EPA ultimately issues a registration review decision, which is "the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA." *Id.* § 155.57. As it has for neonics, EPA may also issue an interim registration review decision before its final decision to "require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review." *Id.* § 155.56. An interim registration review decision is itself final agency action.

b. The Food Quality Protection Act

In 1996, Congress passed the Food Quality Protection Act (FQPA), which amended the Food Act to protect sensitive populations, such as pregnant mothers, fetuses, and young children, from dangerous chemicals in food and the environment. To this end, the FQPA requires EPA to take three steps when establishing tolerances for pesticide residues under the Food Act. First, it requires EPA to consider "aggregate exposure" of consumers to pesticide residues from all dietary and other non-occupational exposure sources. 21 U.S.C. § 346a(b)(2)(D)(vi). Second, EPA must consider "cumulative effects of such residues and other substances that have a

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common mechanism of toxicity." *Id.* § 346a(b)(2)(D)(v). Third, the FQPA requires EPA to apply an "additional tenfold margin of safety . . . to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." *Id.* § 346a(b)(2)(C)(ii)(II). EPA may use a different safety factor if it finds, "on the basis of reliable data, such margin will be safe for infants and children." *Id.*

c. The Endangered Species Act

The Endangered Species Act (ESA), 16 U.S.C. § 1531 et seq., was enacted by Congress in 1973 "to halt and reverse the trend towards species extinction, whatever the cost." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 184 (1978). Interagency consultation under Section 7, 16 U.S.C. § 1536, designed to ensure actions by the federal government do not imperil listed species, is the "heart" of the ESA. *Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009). That section directs that all federal agencies "shall" consult with the Fish and Wildlife Service or National Marine Fisheries Service to "insure that any action authorized, funded, or carried out" by the agency "is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of" their critical habitat. 16 U.S.C. § 1536(a)(2).

Federal agencies must consult "at the earliest possible time" on any action that "may affect" listed species. 50 C.F.R. § 402.14(a). This is a low bar. "Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement." 51 Fed. Reg. at 19,949-50. For actions that may affect listed species, agencies may determine, with the written concurrence of the expert agency, that the action is "not likely to adversely affect" listed species, ending the consultation process. 50 C.F.R. § 402.14(b)(1). But where an agency determines an action is "likely to adversely affect" listed species or their critical habitat, formal consultation resulting in a full biological opinion is required. If, based on the biological opinion, the expert agency determines that the action will jeopardize the continued existence of a listed species or destroy or adversely modify critical habitat, the action cannot move forward as proposed. 16 U.S.C. § 1536(b)(4), (b)(3)(A).

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III. COMMENTS

a. The Federal Insecticide, Fungicide, and Rodenticide Act

EPA's PIDs are predicated on a balancing of the harms caused by neonic use and the benefits associated with those uses. Where EPA determines that the harm of a use outweighs its benefit, EPA must at a minimum require effective mitigation to ensure that such use does not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C). In its review of neonic insecticides, EPA makes three critical errors in performing this analysis. Namely, the PIDs: (1) underestimate harms caused by neonic use; (2) overestimate benefits of their use; and (3) propose mitigation that will fail to eliminate unreasonable adverse effects on the environment. Properly analyzed, these factors demand that EPA initiate cancellation proceedings for considerably more neonic uses.

i. EPA's Risk Assessments Underestimate the Environmental Harms of Neonic Use

The PIDs reflect fundamental errors that underestimate the risks of neonic use to all taxa, particularly for terrestrial invertebrates, birds, and aquatic invertebrates. EPA ignores major costs of neonic use and fails to explain fundamental assumptions underlying its analyses, rendering the PIDs arbitrary and unsupported by substantial evidence. By ignoring, underestimating, or failing to give appropriate weight to the risks of neonic use, EPA fails to identify neonic uses that cause "unreasonable adverse effects on the environment," requiring mitigation under FIFRA.

A. Terrestrial Invertebrates

1. EPA concludes neonics' "off-field risks may be overestimated," but ignores important modes of off-field neonic transport. EPA finds that because "spray drift" is not associated with soil treatment or treated seed neonic uses, the risk of off-field movement of neonics will be low to nonexistent. *See* EPA, Imidacloprid Proposed Interim Registration Review Decision 25 (Jan. 2020); ("Imid. PID") ("[s]oil applications are assumed to have low off-field risk because of low potential to drift."); EPA, Clothianidin and Thiamethoxam Proposed Interim Registration Review Decision 36 (Jan. 2020) ("C&T PID"); EPA, Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam 78 (Jan. 14, 2020) ("C&T Final Bee RA") ("As spray drift would not be present from these use patterns, there would be no off-field exposure expected."). This assumption, however, ignores substantial evidence showing that neonics migrate off treated areas via runoff and, in the case of treated seed, through abraded seed dust. Indeed, runoff of neonics from treated fields via these routes is virtually inevitable.

Open literature studies demonstrate that there is substantial risk of off-field contamination with neonics, especially from soil treatments and treated seed. These include studies showing off-field transport of neonics from these application modes.[8] They also include

[8] *See, e.g.*, Michelle Hladik et al. (2014), https://bit.ly/3aPhQxW; Felix Wettstein et al., *Leaching of the Neonicotinoids Thiamethoxam and Imidacloprid from Sugar Beet Seed Dressings to Subsurface Tile Drains*, 64(33) J. of Ag. and Food Chem. 6407-15 (Aug. 16, 2016), https://bit.ly/3bSkCUO; Anders Huseth & Russell Groves,

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studies that document neonic contamination of off-field wildflowers, exposing pollinators to contaminated pollen and nectar.[9]

Even EPA acknowledges that:

> Depending on the timing of rainfall events, there is some potential for exposure via clothianidin and thiamethoxam runoff to areas immediately adjacent to the treated field where residues could be taken up by pollinator-attractive plants.

C&T Final Bee RA at 56. Consistent with the open literature, EPA's risk analyses suggest there is more than "some potential" for runoff. Initially, neonics are highly water soluble. *See, e.g.*, EPA, Clothianidin – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review 24 (Nov. 27, 2017) ("Cloth. Non-Pollinator RA") (clothianidin has solubility of 327 mg/L (at 20°C)); Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid 28 (Dec. 22, 2016) ("Imid. Aquatic RA") (imidacloprid has solubility of 580-610mg/L (at 20°C)). They are also persistent, with half-lives commonly exceeding a year. *See, e.g.*, Imid. Aquatic RA at 28 (aerobic soil half-life is 608 days). And runoff is a major source of aquatic contamination. *See, e.g.*, *id.* at 27 ("major routes transporting imidacloprid from treatment sites to aquatic habitats include runoff and spray drift"). EPA's comparative aquatic assessment even acknowledges that aquatic contamination is expected as a result of runoff from treated seeds and soil applications. EPA, Comparative Analysis of Aquatic Invertebrate Risk Quotients 17, 21 (Jan. 7, 2020) ("Comparative Aquatic RA"). If neonics can be transported via runoff to aquatic environments, they can be transported via irrigation water or precipitation to adjacent terrestrial environments, too. Thus, acknowledged

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Environmental Fate of Soil Applied Neonicotinoid Insecticides in an Irrigated Potato Agroecosystem, 9(5) PLoS ONE e97081 (May 13, 2014), https://bit.ly/2ShtXha; Jesse Radolinski et al., *Plants Mediate Precipitation-driven Transport of a Neonicotinoid Pesticide*, 222 Chemosphere 445-52 (May 2019), https://bit.ly/35iKpC1 ("neonicotinoids can be transported from seed coatings both above and through the soil profile, which may enable migration into surrounding ecosystems.").

[9] *See, e.g.*, Cristina Botias et al., *Contamination of Wild Plants Near Neonicotinoid Seed-Treated Crops, and Implications for Non-target Species*, 566-567 Science of the Total Environment 269-278 (Oct. 1, 2016), https://bit.ly/2EdJG9i; Cristina Botias et al., *Neonicotinoid Residues in Wildflowers, a Potential Route of Chronic Exposure for Bees*, 49(21) Environ. Sci. Technol. 12731-40 (Oct. 6, 2015) ("exposure [of bees to neonics] is likely to be higher and more prolonged than currently recognized because of widespread contamination of wild plants growing near treated crops."), https://bit.ly/2RNAHDU; Christina Mogren & Jonathan Lundgren, *Neonicotinoid-contaminated Pollinator Strips Adjacent to Cropland Reduce Honey Bee Nutritional Status*, 6 Scientific Reports (Jul. 14, 2016) (finding negative impacts on bees resulting from "unintended accumulation of clothianidin [in flowering plants] from adjacent treated corn fields."), https://go.nature.com/2LM1fBA; Bonmantin et al., *Environmental Fate and Exposure; Neonicotinoids and Fipronil*, 22 Env. Sci. and Pollution Research 35-67 (Aug. 7, 2014), https://bit.ly/35iN3HX; Anson Main et al., *Reduced Species Richness of Native Bees in Field Margins Associated with Neonicotinoid Concentrations in Non-target Soils*, 287 Ag., Ecosystems & Environ. (Jan. 1, 2020), http://bit.ly/2OhMB6W (Neonics detected in soils adjacent to both fields with historic neonic seed treatment use and those without historic neonic use; higher soil concentrations were correlated with lower native bee species richness.).

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contamination of aquatic ecosystems is seemingly at odds with EPA's assumption that runoff from these application modes cannot contaminate adjacent terrestrial habitats.

EPA also fails to account for planter dust from seed treatments as a route of exposure. The agency explains that planter dust is "noted as a potential route of concern" for terrestrial invertebrates, Imid. PID at 25; C&T PID at 36. Initially, planter dust is more than a "potential" route of concern; it is "pervasive" during the planting season, and researchers predict that honey bee foragers could encounter a lethal contact dose during this period.[10] U.S. Department of Agriculture (USDA) Cooperative Extension Resources even warn beekeepers about risk of exposure to neonics during corn planting season.[11] Nonetheless, EPA appears not to factor this exposure route into its risk analysis for treated seeds. In its bee RAs, EPA claims that planter dust will be "addressed through separate ongoing development of best management practices." *See, e.g.*, EPA, Final Bee Risk Assessment to Support the Registration Review of Imidacloprid 29 (Jan. 22, 2020) ("Imid. Final Bee RA"). But these management practices are mentioned nowhere in the PIDs.

By failing to address both planter dust and runoff from seed treatments and soil applications, EPA fails to assess the off-field harms to terrestrial invertebrates from field crops that are ubiquitous in certain areas of the country. For example, in 2019, U.S. farmers planted 91.7 million acres of corn, making it "America's Largest Crop."[12] At least 80% of corn acres are treated with neonics.[13] The next largest crop, by acreage, was soybeans,[14] over half of which were treated with neonics between 2012-2014.[15] EPA itself reports that on average, over 1.4 million pounds of clothianidin and 800 thousand pounds of thiamethoxam were used on field crops annually between 2005 and 2014. C&T PID at 17-18.

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[10] Christian 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 (5) J. of Applied Ecology 1449-58 (Oct. 2017), http://bit.ly/2rmvkjU.

[11] eXtension, Protecting Honey Bees During Corn and Soybean Planting Season (Aug. 20, 2019), https://bit.ly/2yDawZ4.

[12] U.S. Department of Agriculture, Corn is America's Largest Crop in 2019 (Aug. 1, 2019), http://bit.ly/32pzru5.

[13] Margaret Douglas & John 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(8) Envtl. Sci. & Technol. 5088-97 (Mar. 20, 2015), https://bit.ly/3bNaXyM; Adam Alford & Christian Krupke, *Translocation of the Neonicotinoid Seed Treatment Clothianidin in Maize*, 12(3) PLoS ONE e0173836 (Mar. 10, 2017), https://bit.ly/2YjHYyy ("Neonicotinoid seed treatments, typically clothianidin or thiamethoxam, are routinely applied to >80% of maize (corn) seed grown in North America").

[14] *See* Tom Capehart & Susan Proper, *Corn is America's Largest Crop in 2019*, USDA (Aug. 1, 2019), http://bit.ly/32pzru5.

[15] Sara LaJeunesse, Pesticide Seed Coatings are Widespread but Underreported, *Penn State News* (Mar. 17, 2020), https://bit.ly/2JbYJmB ("76% of soybean acres were grown with treated seeds. Of the insecticides applied to seeds, neonicotinoids accounted for roughly 80%").

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Despite the prevalence of these uses, EPA dismisses off-field impacts of seed treatments and soil applications. This contradicts substantial evidence showing that seed treatments are contributing to environmental contamination. Ignoring runoff and planter dust from seed treatments—the number one agricultural use of neonics—disregards millions of pounds of neonics that enter the environment each year. C&T PID at 17, 18. In its PIDs, EPA must fully account for and address risks to terrestrial invertebrates and other wildlife resulting from off-field transport via runoff and seed dust from neonic-treated seeds. It is arbitrary and unlawful for EPA not to do so.

2. EPA's analysis of off-field risk from spray drift is incomplete. EPA uses the AGDRIFT computer model to estimate the extent of neonic spray drift from treated agricultural fields. The model is inadequate because while it characterizes the extent of spray drift up to 1000 feet from the edge of a treated field, it routinely finds that risks from spray drift extend beyond this limit. Imid. PID at 25; C&T PID at 36. Accordingly, while EPA concludes that "off-field dietary risks . . . extend greater than 1000 feet" beyond field boundaries, it has no way of knowing the magnitude or significance of those risks.

More than a few neonic use patterns result in high risk quotients (RQ) more than 1000 feet beyond field boundaries; examples include: aerial and airblast applications to citrus and pome fruit, ground applications to globe artichoke, aerial applications to stone fruit and tree nuts, and aerial applications to tuberous and corm vegetables. Imid. Final Bee RA at 213-17. EPA must either improve its modeling to better understand the extent of spray drift, or it should implement conservative estimates and mitigation to ensure potential spray drift risks do not exceed the limits of the AGDRIFT model.

Moreover, it appears that EPA analyzed only oral exposure from off-field spray drift. *See* Imid. PID at 25; C&T PID at 36; EPA, Final Bee Risk Assessment to Support the Registration Review of Dinotefuran 13 (Jan. 14, 2020) ("Dino. Final Bee RA"). EPA does not explain why contact exposure is not likewise problematic for off-field pollinators. Further still, EPA wholly failed to analyze off-field exposure of terrestrial invertebrates to acetamiprid. *See generally* EPA, Registration Review: Preliminary Environmental Fate and Ecological Risk Assessment for Acetamiprid (Dec. 22, 2017) ("Acet. Ecological RA"). EPA cannot finalize its risk assessments without considering these possible sources of off-field risk to terrestrial invertebrates; doing so would be arbitrary and unsupported.

3. EPA's analysis of oral exposure is inadequate because it analyzes only consumption of contaminated pollen and nectar. EPA explains that it "lacks information" to quantify invertebrate exposure from "contaminated surface water, plant guttation fluids, honey dew, soil (for ground-nesting bees), and leaves" and therefore ignores them in its risk analysis. Imid. Final Bee RA at 27. There is considerable evidence, however, showing that these routes of exposure are significant for pollinators.

Open literature studies show that, at minimum, exposure to neonics via guttation fluid raises concerns. For example, *Girolami et al.* find that plants grown from seeds treated with imidacloprid, thiamethoxam, and clothianidin produce substantial neonic residues in guttation

fluid, up to an average of 47 mg/L for imidacloprid.[16] These results were found in corn—the number one crop in the U.S.[17] Research conducted by Syngenta scientists confirms that "maize is considered as the worst case crop in terms of frequency, duration and intensity of guttation and of residue level of compounds found in guttation fluid."[18] EPA must analyze guttation fluid and other routes of exposure before publishing an interim or final registration review decision.

4. EPA arbitrarily ignores exposure risks from non-pollinator attractive crops. Because EPA ignores routes of exposure other than contaminated pollen and nectar, the agency assumes that seed treatments or soil applications of imidacloprid, thiamethoxam, and clothianidin on crops that are "not attractive to honey bees" or "harvested prior to bloom" present a low on-field risk to terrestrial invertebrates. Imid. Final Bee RA at 222; C&T Final Bee RA at 115. On this basis, it forgoes higher-tier risk assessments of these crops. But bees and other insects could routinely be exposed to neonics applied to crops even if they are not foraging. The non-floral alternative exposure routes —such as guttation fluid, planter dust, or others enumerated above—are relevant regardless of whether the plant is bee-attractive or harvested prior to bloom. EPA's failure to examine these alternate exposure routes for crops not attractive to honey bees or harvested prior to bloom is arbitrary and unsupported by substantial evidence.

4. EPA fails to account for harm to ground-dwelling terrestrial invertebrates, including ground-nesting bees. Neonics are highly water soluble and readily move through soil, and there is strong evidence that soils in and around areas of neonic use—particularly treated seed use—experience persistent neonic contamination.[19] EPA, however, at no point attempts to analyze, let alone quantify, the impacts of soil contamination on terrestrial invertebrates, including ground-nesting bees, which comprise about 70% of all bee species.[20] Research demonstrates that contamination of soil with neonics presents risks to ground-nesting bees[21] as

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[16] V. Girolami, *Translocation of Neonicotinoid Insecticides from Coated Seeds to Seedling Guttation Drops: A Novel Way of Intoxication for Bees*, 102(5) J. Econ. Entomol. 1808-15 (Oct. 2009), https://bit.ly/35sbnZ7.

[17] *See* USDA (2019), http://bit.ly/32pzru5.

[18] Jens Pistorius et al., *Assessment of Risks to Honey Bees Posed by Guttation*, ICP-BR, Bee Protection Group, 11th International Symposium, Wageningen, The Netherlands (Jan. 2012), https://bit.ly/2zJk05F.

[19] *See* Wood & Goulson (2017), https://bit.ly/3aXhXIV; J.M. Bonmatin et al., *Environmental Fate and Exposure; Neonicotinoids and Fipronil*, Envtl. Sci. & Pollution Research (Aug. 7, 2014), https://bit.ly/3c17PyI.

[20] Cornell University, College of Agriculture and Life Sciences, Department of Entomology, *Ground Nesting Bees in Your Backyard*, http://bit.ly/2uyGRP6 (last visited Feb. 25, 2020).

[21] *See, e.g.*, D. Susan Willis Chan et al., *Assessment of Risk to Hoary Squash Bees and Other Ground-Nesting Bees from Systemic Insecticides in Agricultural Soil*, 9 Scientific Reports 11870 (Aug. 14, 2019), https://go.nature.com/35f9ApU; Nicholas Anderson et al., *Chronic Contact with Realistic Soil Concentrations of Imidacloprid Affects the Mass, Immature Development Speed, and Adult Longevity of Solitary Bees*, 9 Sci. Reports 3724 (Mar. 6, 2019), https://go.nature.com/2V9WA04; L.W. Pisa et al., *Effects of Neonicotinoids and Fipronil on Non-target Invertebrates*, 22 Envtl. Sci. & Pollution Research 68-102 (2015), https://bit.ly/2y1UqII ("ground-

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well as other terrestrial invertebrate species.[22] EPA's failure to account for these studies is arbitrary and the PIDs lack substantial evidence that neonic uses do not pose unreasonable adverse effects on ground-nesting bees.

5. EPA ignores the synergistic effects of neonic exposure with other chemicals, such as fungicides, and risk factors, such as parasitic mites and disease. While direct harms from neonics are concerning for bees and other wildlife, neonics' adverse impacts may be significantly elevated when combined with other stressors. For example, recent research shows that low levels of clothianidin and thiamethoxam exposure may also decrease the ability of honey bees to combat parasitic varroa mite and increase incidence of deformed wing virus.[23] Other research shows that neonics' toxicity to bees and other insects may increase up to 8-fold when paired with fungicides commonly used alongside neonics.[24] Heightened risks from synergistic effects, like these, stem directly from neonic use and environmental contamination. EPA must, therefore, incorporate the environmental risks of neonics' synergistic effects with other chemicals and risk factors into its risk analyses for bees and other wildlife.

6. EPA arbitrarily selects the honey bee as a proxy for all bees. EPA largely uses the honey bee as a surrogate to assess risks to all bees. *See, e.g.*, Imid. Bee RA at 26. The honey bee, however, is a poor proxy for the incredibly diverse array of native bees found in this country. The U.S. is home to over 4,000 native bee species—all of which are pollinators, but almost none of which form colonies or make honey.[25] The vast majority of the country's bees are solitary and do not enjoy the protections inherent in honey bee hives, where overall colony health is often insulated from an individual's fatal exposures to pesticides.[26] EPA fails to mitigate Tier-1 risks

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nesting species may face additional exposure risks (i.e. pesticide-contaminated soil) that are not encountered by honeybees, but which remain to be evaluated").

[22] *See* Pisa et al. (2014), https://bit.ly/39WCFY3.

[23] Nuria Morfin et al., *Effects of Sublethal Doses of Clothianidin and/or V. Destructor on Honey Bee (Apis Mellifera) Self-Grooming Behavior and Associated Gene Expression*, 9 Scientific Reports 5196 (Apr. 22, 2019), https://go.nature.com/2Y3nfLU; Lars Straub et al., *Neonicotinoids and Ectoparasitic Mites Synergistically Impact Honeybees*, 9 Scientific Reports 8159 (Jun. 4, 2019), https://go.nature.com/2WTIjU8 ("Our data clearly show a significant negative synergistic effect of neonicotinoids and *V. destructor* mites on *A. mellifera* honeybee body mass and longevity").

[24] Helen Thompson et al., *Potential Impacts of Synergism in Honeybees (Apis Mellifera) of Exposure to Neonicotinoids and Sprayed Fungicides in Crops*, 45 (5) Apidologie 545-553 (2014), https://bit.ly/2Wax2k4; *see also* Fabio Sgolastra et al., *Synergistic Mortality Between a Neonicotinoid Insecticide and an Ergosterol-Biosynthesis-Inhibiting Fungicide in Three Bee Species*, 73(6) Pesticide Management Science 1236-43 (Jun. 2017), https://bit.ly/2WcdNH1.

[25] Beatriz Moisset & Stephen Buchmann, *Bee Basics: An Introduction to Our Native Bees*, U.S. Forest Service & Pollinator Partnership Publication (Mar. 2011), https://bit.ly/2RLFkh8.

[26] *See* Andi M. Kopit & Theresa L. Pitts-Singer, *Routes of Pesticide Exposure in Solitary, Cavity-Nesting Bees*, Environmental Entomology (Apr. 4, 2018), https://bit.ly/2nnXdWY.

ED_006569J_00033604-00011

to these solitary species. *See infra*, Argument 35. Moreover, 70% of bee species are ground-nesting,[27] and EPA does not take into account this distinguishing factor when using honey bees as a proxy. *See supra*, Argument 4. Accordingly, EPA's selection of the honey bee as the sole surrogate for all bees is arbitrary.

7. EPA must attempt to characterize risks of neonics to non-bee pollinators, like bats and butterflies. EPA's bee risk assessment explains that honey bees are used as a proxy for other non-apis bees. *See, e.g.*, Imid. Final Bee RA at 26. However, EPA never explains how or whether bees—or any other organism—are considered appropriate surrogates for bats or butterflies and other invertebrate pollinators. Non-bee pollinators are fundamentally dissimilar to honey bees, yet these species also suffer from neonic exposures. In particular, other native pollinator species may differ greatly from honey bees in: (1) their sensitivity to neonics; (2) their preferences for particular flowers; (3) pollen and nectar consumption rates; (4) how they provision for their young; and (5) their relative susceptibility to neonic risks from exposure routes other than those evaluated by EPA, including contact with contaminated soil and water, guttation fluid, and non-target pollen and nectar.

Indeed, there is a growing body of evidence that neonics impact these non-bee pollinators. For example, recent research links increasing neonic use rates in lowland California with decreases in butterfly populations, even controlling for climatic and land use changes.[28] EPA's pollinator incident reports also include evidence that neonics adversely affect butterflies. *See, e.g.*, Imid. Final Bee RA at 200. Moreover, open literature studies show that neonics may have adverse direct and indirect effects on bats.[29] EPA, however, does not address impacts of neonics to butterflies, bats, and non-bee insect pollinators generally, or explain how or whether bees might serve as an appropriate surrogate. Its determination that neonics satisfy the FIFRA standard, therefore, is arbitrary and unsupported by substantial evidence.

8. EPA should call in additional studies on the impacts of neonic exposure on bees and other terrestrial invertebrates. One of the main purposes of an interim registration review decision is to "identify data or information required to complete the review." 40 C.F.R. § 155.56. In its PIDs, EPA identifies several areas where it has limited or no data, including:

- Bee exposure via contaminated surface water, plant guttation fluids, honey dew, soil, and leaves, *see, e.g.*, Imid. Final Bee RA at 27;
- Toxicity and exposure for bumble bees, solitary bees, and other non-*apis* species, including colony-level effects data, *see, e.g.*, Imid. Final Bee RA at 25-26;

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[27] Cornell University, College of Agriculture and Life Sciences, Department of Entomology, *Ground Nesting Bees in Your Backyard*, http://bit.ly/2uyGRP6 (last visited Feb. 25, 2020).

[28] Andre S. Gilburn et al., *Are Neonicotioid Insecticides Driving Declines of Widespread Butterflies?*, PeerJ (Nov. 24, 2015), https://bit.ly/1IGvH0y.

[29] *See* Chung-Hsin Wu et al., *Effects of Imidacloprid, A Neonicotinoid Insecticide, on the Echolocation System of Insectivorous Bats*, 163 Pesticide Biochemistry and Physiology 94-101 (Feb. 2020), https://bit.ly/3aAybqx; Pierre Mineau & Carolyn Callaghan, *Neonicotinoid Insecticides and Bats: An Assessment of the Direct and Indirect Risks*, Canadian Wildlife Federation (Dec. 2018), https://bit.ly/2KCJwvH.

ED_006569J_00033604-00012

- Residues of neonics in pollen and nectar as a result of carryover residues in soil, *see, e.g.*, Imid. Final Bee RA at 121;
- Synergistic effects of neonics with other pesticides, Final Imid. Bee RA at 124; and
- Synergistic effects of neonics with other stressors, including climate change, disease, and parasites.

Instead of relying on simplified assumptions that underestimate the impacts of neonic use on bees and other insects, EPA must solicit additional data to improve its analysis. EPA cannot conclude that risks to bees and other insects are tolerable or outweighed by purported benefits without adequately assessing those risks. It is arbitrary for EPA to conclude its assessments without attempting to gather additional information about these crucial data gaps.

9. EPA must take into account the most recent research on the effects of neonics on bees and other wildlife. EPA's RAs must consider recent research regarding neonics' sublethal and time-cumulative exposure effects, which identify critical endpoints and considerations not analyzed in the RAs. These include studies finding:

- Neonic exposure impairs brain growth and adult learning in bumblebees; and[30]
- Neonics impart "time-cumulative toxicity," meaning that the "toxicity of [neonics] increases with exposure time as much as with the dose."[31] The authors specifically note that tests conducted by registrants seeking product approval are insensitive to this obvious dimension of ecotoxicity, depriving regulatory agencies of critical information needed to accurately assess risk. This is especially "apparent in the case of neonicotinoid compounds, for which the current evidence demonstrates their actual environmental impacts on both aquatic and terrestrial ecosystems are larger than previously estimated."[32]

10. EPA should use sublethal endpoints to analyze neonic toxicity to bees and other wildlife. Research indicates that the LD50 is an inadequate endpoint to capture all relevant impacts of acute neonic toxicity on bees and other wildlife. Principally, the time-cumulative toxicity of neonics recently described by *Sanchez-Bayo et al.*,[33] means that even sublethal effects may not be detected in the short window of observation permitted by conventional studies,

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[30] Dylan B. Smith et al., *Insecticide Exposure During Brood or Early-adult Development Reduces Brain Growth and Impairs Adult Learning in Bumblebees*, 287 Proceedings of the Royal Society B (Mar. 4, 2020), http://bit.ly/2TVA0Jx.

[31] Francisco Sanchez-Bayo & Henk A. Tennekes, *Time-Cumulative Toxicity of Neonicotinoids: Experimental Evidence and Implications for Environmental Risk Assessments*, 17(5) Int. J. Environ. Res. Public Health 1629 (Mar. 3, 2020), https://bit.ly/2KAeIvk.

[32] *Id.*

[33] Sanchez-Bayo & Tennekes (2020), https://bit.ly/2KAeIvk.

ED_006569J_00033604-00013

especially registrant-submitted field and semi-field studies.[34] Moreover, sublethal effects more generally—like impaired brain growth and learning,[35] immune response,[36] grooming,[37] and flight dynamics and endurance[38]— may ultimately prove lethal in the long-term. These same effects may have impacts that negatively affect colony or population-level survival. By basing its acute risk assessment solely on the LD50 for bees and other wildlife, EPA arbitrarily ignores sublethal toxicity and its ultimately lethal effects.

B. Birds

11. EPA arbitrarily discounts harm from neonic-treated seeds to small songbirds. EPA finds that "[e]xposures from treated seeds result in the highest acute and chronic risks to terrestrial organisms," particularly for birds eating neonic treated seeds, which it acknowledges many birds do. *See, e.g.*, C&T PID at 32-33. Indeed, given recent research documenting dramatic losses of songbirds in North America,[39] the frequency of ingestion of treated seed,[40] and negative impacts of neonic ingestion on birds' migratory success and ultimate survival,[41] neonic exposure from ingestion of treated seed warrants careful consideration. However, EPA summarily

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[34] *See* J.P. van der Sluijs et al., *Conclusions of the Worldwide Integrated Assessment on the Risks of Neonicotinoids and Fipronil to Biodiversity and Ecosystem Functioning*, 22 Envtl. Sci. & Pollution Research Int'l 148-54 (2015), https://bit.ly/2KXAlGl (explaining that because toxic "effects often occur at concentrations well below those associated with direct mortality," "short-term survival is not a relevant predictor neither of mortality measured over the long term nor of an impairment of ecosystem functions and services performed by the impacted organisms").

[35] Smith (2020), http://bit.ly/2TVA0Jx.

[36] Gennaro Di Prisco et al. *Neonicotinoid Clothianidin Adversely Affects Insect Immunity and Promotes Replication of a Viral Pathogen in Honey Bees*, 110 Proceedings of the Nat'l Academy of Sciences 18466–18471 (Oct. 2013), https://bit.ly/3bK7rVR.

[37] Morfin et al. (2019), https://go.nature.com/2Y3nfLU.

[38] Daniel Kenna et al., *Pesticide Exposure Affects Flight Dynamics and Reduces Flight Endurance in Bumble Bees*, 9 Ecology and Evolution 5637-5650 (Apr. 29, 2019), http://bit.ly/2KSaiAE.

[39] Kenneth Rosenberg et al., *Decline of the North American Avifauna*, 366 (6461) Science 120-24 (Oct. 4, 2019), https://bit.ly/3d4vP4N.

[40] *See, e.g.*, Charlotte Roy et al., *Neonicotinoids on the Landscape: Evaluating Avian Exposure to Treated Seeds in Agricultural Landscapes*, Minnesota Department of Natural Resources & Wildlife Restoration (2017), https://bit.ly/337ENZK (last visited Apr. 29, 2020) (documenting exposed neonic-treated seed in 25 percent of 48 fields sampled, and reporting that ring-necked pheasants, Canada geese, American crows, various species of sparrows, and blackbirds, as well as white-tailed deer, rodents, rabbits, and raccoons, were all observed eating the seeds); Ana Lopez-Antia et al., *Risk Assessment of Pesticide Seed Treatment for Farmland Birds Using Refined Field Data*, 53 J. of Applied Ecology 1373-1381 (Oct. 2016), https://bit.ly/2m0Z5Ef.

[41] Margaret Eng et al., *A Neonicotinoid Insecticide Reduces Fueling and Delays Migration in Songbirds*, 365 (6458) Science 1177-1180 (Sept. 13, 2019), http://bit.ly/2XSIp0E.

ED_006569J_00033604-00014

dismisses this risk to smaller birds, finding that "the larger size of [corn and soybean] seeds prevents smaller birds and mammals from consuming them." C&T PID at 29.

This conclusion rests on a series of faulty assumptions. EPA's guidance on treated seed risk assessments explains: "If this median seed size is greater than maximum seed size the bird species could potentially consume . . . , then that species would be assumed to not feed on the treated seed."[42] By definition, half the seeds will be smaller than the median sized seed. That means that EPA is ignoring the mathematical fact that half the neonic-coated seeds may be within the size range that is consumable for the birds. In other words, even if a bird species were shown to be capable of consuming the smallest 49% of seeds of a particular type where the median seed size was deemed too large, EPA would assume the species cannot consume that seed type at all. This is an inaccurate and arbitrary assumption that underestimates risk to birds from ingestion of treated seeds.

Additionally, EPA's assumption that species are not able to consume seeds of a certain size is based on a single, thirty-year-old study[43] that does not support the proposition. Initially, the study draws no conclusions about the capacity of the studied birds to consume seeds above a specific size; it analyzes the efficiency of different species when consuming different-size seeds. Moreover, the study compares several species of finches and sparrows, finding that "[s]parrows consume seeds that are approximately an order of magnitude smaller in size that those consumed by finches *of similar body mass*."[44] In other words, different species of approximately the same mass ate different seed sizes; this undermines EPA's assumption that body mass is a good predictor of the seeds a bird is capable of eating. Finally, the sample size of the study is insufficient to support EPA's crucial assumption; data were gathered for only four individuals of just six species.[45]

More recent studies have documented sparrows and other songbirds eating corn and soybean seeds presumed by EPA to be too large to ingest.[46] The agency also does not analyze the possibility that birds might encounter fragments of treated larger seeds that are small enough to eat. EPA's reliance on oversimplified assumptions to discount risks from treated seeds is arbitrary and cannot support continued registration of seed treatments.

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[42] EPA, *Refinements for Risk Assessment of Pesticide Treated Seeds – Interim Guidance* (Mar. 31, 2016), http://bit.ly/2VApLLZ (emphasis added).

[43] *Id.* at 7.

[44] Craig W. Benkman & H. Ronald Pulliam, *Comparative Feeding Ecology of North American Sparrows and Finches*, 69 (4) Ecology 1195-1199 (Aug. 1, 1988), https://bit.ly/3btVKCd.

[45] *Id.* at 1-2.

[46] *See, e.g.*, Roy et al. (2017), https://bit.ly/337ENZK (simulating spills with treated corn and soybean seeds and finding ring-necked pheasants, Canada geese, American crows, various species of sparrows, and blackbirds, all observed eating the seeds).

ED_006569J_00033604-00015

12. EPA ignores the impacts of neonic seed ingestion on migrating birds. *Margaret Eng et al.* recently reported that ingestion of small amounts of imidacloprid results in weight loss, reduced fueling, and delayed migration in white-crowned sparrows.[47] Ultimately, delayed migration could result in failure to match migration patterns to food sources and favorable weather patterns and result in death or reduced reproductive success. This finding is particularly concerning given EPA's prediction of "high-intensity exposure" to neonics during migration. Cloth. Non-Pollinator RA at 91. Neither the PIDs nor the associated risk assessments address the impacts of neonic ingestion on successful migration. EPA's failure to consider the impacts of neonic seed ingestion on migratory success is arbitrary and unlawful.

13. EPA ignores indirect impacts of prey reduction on birds and other wildlife. EPA's PIDs identify risks of concern that suggest the potential that widespread neonic use may decrease populations of aquatic and terrestrial invertebrates. *See, e.g.*, Imid. PID at 24 (finding strong evidence of "colony-level risks" to bees); C&T PID at 37 (same), 40 ("risks of concern were identified for all four neonicotinoid insecticides . . . to freshwater invertebrates on both an acute and chronic basis."). The PIDs, however, fail to analyze the effects of prey reduction on (i.e., loss of food sources for) birds, reptiles, and other insectivorous wildlife—only briefly referencing indirect effects on fish and aquatic-phase amphibians. *See, e.g.*, Imid. Aquatic RA at 14, 99, 119; Cloth. Non-Pollinator RA at 15; Acet. Ecological RA at 5, 15, 72, 73; EPA, Preliminary Ecological Risk Assessment (Excluding Terrestrial Invertebrates) for the Registration Review of Dinotefuran 13, 65 (Nov. 28, 2017) ("Dino. Ecological RA"). This omission is particularly glaring in light of recent independent scientific research linking the prey reduction effects of neonic use to considerable declines in bird and fish populations.[48] Indeed, a recent comprehensive assessment of neonics' ecological impacts of neonics notes that "indirect effects [of neonic use] may be as important as direct toxic effects on vertebrates and possibly more important."[49] Nothing in FIFRA, EPA's regulations, or guidance permits such a narrow analysis of the environmental effects of pesticides. *See* 63 Fed. Reg. 26846, 26,859, 26,895 (May 14, 1998) (describing the importance of "secondary" impacts, such as loss of prey species, in ecological risk assessments).

C. Aquatic Ecosystems

14. EPA must publish revised aquatic risk assessments for neonics. Before issuing the PIDs, EPA published several aquatic risk assessments, totaling hundreds of pages in length. As noted by commenters, including NRDC and the California Department of Pesticide Regulation,

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[47] Eng et al. (2019), http://bit.ly/2XSIp0E.

[48] *See, e.g.*, Casper Hallman et al., *Declines in Insectivorous Birds Are Associated with High Neonic Concentrations*, 511 (7509) Nature 341-43 (Jul. 17, 2014), https://bit.ly/3f3gKCi; Yamamuro et al., *Neonicotinoids Disrupt Aquatic Food Webs and Decrease Fishery Yields*, 366 (6465) Science 620-23 (Nov. 1, 2019), https://bit.ly/3cYlB5H; David Gibbons et al., *A Review of the Direct and Indirect Effects of Neonicotinoids and Fipronil on Vertebrate Wildlife*, 22 Envtl. Sci. Pollution Research Int'l 103-18 (Jun. 18, 2014), https://bit.ly/2YeJORn (reviewing literature on indirect effects of prey reduction).

[49] Pisa et al. (2017), https://bit.ly/2XIZpbC.

ED_006569J_00033604-00016

these risk assessments contained serious errors that underestimate the impacts of neonic use. For example, in its preliminary assessments, EPA assumed that treated seeds planted 2 cm below the soil surface had no impact on water quality. *See, e.g.*, Imid. Aquatic RA at 36 ("The model estimates no exposure (*i.e.* EECs= zeros) for seeds planted at depths >2 cm.").

In response to these and other comments, EPA explains that it has revised some of its modeling of surface water effects, *see, e.g.*, Imid. PID at 13; C&T PID at 15-16, and that this revised modeling factors into its Comparative analysis of Aquatic Invertebrate Risk Quotients. But that document applies modeling changes without sufficiently explaining EPA's reasoning and methodology, making it impossible for the public to comment on EPA's final conclusions regarding aquatic risks.

Only by releasing full, revised risk assessments can the public assess the adequacy of the reasoning supporting the PIDs. Indeed, EPA's regulations state that after taking comments on a draft risk assessment, EPA "*will* publish a notice in the Federal Register *announcing the availability of a revised risk assessment*, an explanation of any changes to the proposed document, and its response to comments." 40 C.F.R. § 155.53(c) (emphasis added). In accordance with these regulations, EPA must publish final, revised aquatic RAs that support its determinations in the PIDs.

15. EPA fails to characterize indirect effects on fish, amphibians, and other insectivorous wildlife. Direct impacts of neonics on invertebrate populations are likely to have indirect effects on species that feed on invertebrates. EPA's RAs make clear that widespread neonic use is likely to impact populations of aquatic invertebrates. C&T PID at 40 ("risks of concern were identified for all four neonicotinoid insecticides . . . to freshwater invertebrates on both an acute and chronic basis."). But EPA fails to account for the impacts of these losses on the many species that prey on aquatic invertebrates.

In several places, EPA makes general statements about indirect impacts of prey reduction on fish and aquatic-phase amphibians. *See, e.g.*, Imid. Aquatic RA at 14, 99, 119; Cloth. Aquatic RA at 15; Acet. Ecological RA at 5, 15, 72, 73; Dino. Ecological RA at 13, 65. Yet, neither the RAs nor PIDs indicate that EPA has attempted to characterize, qualitatively or quantitatively, the extent of these indirect impacts. Peer-reviewed open literature studies have linked dramatic losses of bird and fish populations with the presence of exceptionally small amounts of neonics in surface water, likely due to these indirect prey reduction impacts.[50] Because the neonic water concentrations observed in these studies match those commonly seen in surface waters across the country,[51] it is likely that these indirect neonic impacts cause significant and destructive effects to wildlife populations nationwide. Accordingly, EPA cannot make informed registration decisions as to whether neonic uses meet the FIFRA standard without quantifying or characterizing these indirect impacts. *See* 63 Fed. Reg. 26846 at 26,895 (describing the importance of "secondary" impacts, such as loss of prey species, in ecological risk assessments). Its failure to do so is arbitrary, and without this analysis, EPA fails to support its PIDs with substantial evidence.

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[50] *See* Hallman et al. (2014), https://bit.ly/3f3gKCi; Yamamuro et al. (2019), https://bit.ly/3cYIB5H. .

[51] Hladik et al. (2014), https://bit.ly/3aPhQxW.

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ii. EPA Overestimates Benefits of Neonicotinoid Use.

Where EPA identifies risks of concern for a neonic use, it must analyze whether the benefits of that use justify the risks. EPA's benefits assessments presume or overstate the benefits of numerous uses, often without a credible rationale or any factual support, and often contrary to the considerable weight of independent scientific research. The agency cannot rely on these assessments to determine that those uses satisfy the FIFRA standard.

16. EPA compares neonics only to the highest cost alternatives, artificially inflating benefits of continued registration. Where EPA conducted a quantitative assessment of the benefits of neonics compared to alternative pesticides, EPA considered "the highest cost alternative [to neonics] . . . to estimate the greatest potential impact to grower net revenue." EPA, Usage, Pest Management Benefits, and Possible Impacts of Potential Mitigation of the Use of the Four Nitroguanidine Neonicotinoids in Pome Fruits (Apple, Pear), 12, 13 (Dec. 11, 2019) ("Pome Benefits Assessment"). While considering this "worst-case scenario" may have some relevance to EPA's benefits analysis, EPA fails to explain why an applicator would ever choose the highest cost alternative in the absence of neonics. The agency ignores a more likely scenario, that applicators would select the *lowest* cost alternative. Indeed, elsewhere, EPA explains that it "assumes that growers make rational decisions and are profit maximizers when choosing which alternative is the most cost-effective pest control available." Pome Benefits Assessment at 10. EPA's failure to analyze applicators' most likely response to a neonic ban—substituting neonics for the least cost alternative—is arbitrary, making its benefits calculation likewise arbitrary and unsupported by substantial evidence.

17. EPA arbitrarily equates greater use of neonics with greater benefit. Many of EPA's benefits analyses rely on usage data as the sole metric for measuring the benefits of a given use. *See, e.g.*, EPA, Benefits of Neonicotinoid Use and Impacts of Potential Risk Mitigation in Vegetables, Legumes, Tree Nuts, Herbs, and Tropical and Subtropical Fruit Crops (Dec. 20, 2019); Pome Benefits Assessment. Moreover, EPA relies on arbitrary and unsupported assumptions to justify usage data as a metric of neonics' benefits. EPA's assessment of neonic tree nut uses provides a good illustration of how it conflates use with benefit. In it, EPA states that:

> In most cases, if the label rate were set below the rate an individual grower would choose, he or she would likely expect a decrease in performance at the lower rate. This would result in greater pest damage and/or an increase in the likelihood of disease transmission implying lower expected yields and revenue. Resistance management programs may also be compromised.

EPA, Benefits of Neonicotinoid Use and Impacts of Potential Risk Mitigation in Vegetables, Legumes, Tree Nuts, Herbs, and Tropical and Subtropical Fruit Crops, 9 (Dec. 20, 2019) ("Catch-All Benefits Assessment"). Here, EPA assumes that: 1) lowering approved use rates below present rates of use will result in reduced pest control; 2) decreased pest control will increase pest damage and/or disease transmission; and 3) increased pest damage will result in lower yields and revenue. An evidence-based analysis of these causal relationships should form the crux of EPA's benefits analysis, yet EPA provides no factual support for these assumptions.

ED_006569J_00033604-00018

This cannot be considered an assessment of benefits since EPA has failed to provide any verifiable information that can be assessed.

In the PIDs, EPA likewise relies on these assumptions to equate greater neonic use with greater benefits. *See, e.g.*, Dino. PID at 36 ("Benefits are considered to be high for this use of dinotefuran as data showed that an average of 139,000 lbs. are applied annually."); Imid. PID at 48 ("Benefits were considered high for this use for imidacloprid, as it accounts for 75% of turf treated with neonicotinoids."). EPA's reliance on these unsubstantiated assumptions is arbitrary and unsupported by substantial evidence.

Indeed, for neonic treatments on corn and soybean seeds—perhaps the two largest single uses of neonics nationwide[52]—open literature studies and EPA's own analyses contradict the assumption that greater or more widespread use of a neonic application correlates with efficacy, benefit, or need. In 2014, EPA found that neonic soybean seed treatments "provide negligible overall benefits to soybean production in most situations." EPA, Benefits of Neonicotinoid Seed Treatments to Soybean Production 1-2 (Oct. 15, 2014)[53] ("Treated Soybean Assessment"). Subsequent research and publications by several leading agricultural extensions support the conclusion that soybean seed treatments provide "little to zero net benefit [to growers] in most cases."[54] Similarly for corn, recent research finds "no statistical differences in stand count, root ratings, or yield between treated and untreated seed"[55] and no statistically significant difference in yield in clothianidin-treated corn,[56] likely because of rapid loss of the neonic from treated seeds following sowing. At least one study has even found that seed treatments may *decrease* yields in some circumstances by decreasing populations of invertebrates that prey on pest species.[57] Accordingly, it appears that two of the largest neonic uses in the nation provide little to no benefit at all.

This situation may be partly explained by the fact that farmers frequently do not know that the seeds they are using are treated with neonics[58] or are unable to purchase seeds without

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[52] Douglas & Tooker (2015), https://bit.ly/3aJYTwM.

[53] EPA appears to have removed this document from the docket. It is available at https://bit.ly/3exwblL.

[54] Sypridon Mourtzinis et al. *Neonicotinoid Seed Treatments of Soybean Provide Negligible Benefits to U.S. Farmers*, 9 Scientific Reports (Sept. 9, 2019), https://go.nature.com/2kylh8v; USDA Agricultural Extension, *The Effectiveness of Neonicotinoid Seed Treatments in Soybean* (2015), https://bit.ly/2Kfgj9S.

[55] *See, e.g.*, Alford & Krupke(2017), http://bit.ly/38gpv7j.

[56] Krupke et al., 54 (5) J. of Applied Ecology 1449-58 (Oct. 2017), http://bit.ly/2rmvkjU.

[57] *See, e.g.,* Dara A. Stanley et al., *Neonicotinoid Pesticide Exposure Impairs Crop Pollination Services Provided by Bumblebees*, Nature (Nov. 18, 2015), https://bit.ly/2qnhWLW; Margaret Douglas et al., *Neonicotinoid Insecticide Travels Through a Soil Food Chain, Disrupting Biological Control of Non-Target Pests and Decreasing Soya Bean Yield*, 52(1) J. of Applied Ecology 250-260 (Feb. 2015), https://bit.ly/2IRr4MF; Purdue University, *Don't Just Spray – Survey*, https://on.nrdc.org/2m0a9Bt.

[58] *See* LaJeunesse (2020), https://bit.ly/2JbYJmB.

ED_006569J_00033604-00019

neonic coatings. Corn seed, in particular, is frequently only available with neonic seed treatments.[59] This means that purchasing and application decisions for a considerable amount of neonic use bear no relation to the pesticides' purported or actual benefits.

EPA's reliance on usage data to characterize neonic benefits is particularly inapt because they are frequently used to address problems originally *created* by overuse—*e.g.*, poor soil health, decimation of predatory invertebrates, birds, and other species that prey on crop pests, and pest resistance. Also, farmers' and landscapers' purported reliance on neonics is fueled by registrants' ability to corner the pesticide market and give these users little option but to use their product, as in the case of treated corn seed. This cannot justify continued, largely unmitigated use of neonics. The Environmental Groups recognize that the pain inflicted on growers by crop damage is real. However, while initially the use of neonics may seem like a solution, it is only treating the visible symptoms, while the underlying causes are compounded by the treatment. NRDC is working in myriad ways to support farmers with effective, affordable, long-term solutions.[60]

Finally, EPA's analysis leads to the absurd result that the more a pesticide is used—regardless of its real-world impacts on yield or farmer revenue—the less likely it is that EPA will mitigate its impacts. At minimum, widespread use should *also* factor into the harms associated with an insecticide—the release of millions of pounds of a pesticide into the environment is more likely to cause harm than dumping one pound. But this type of analysis is absent from EPA's risk assessments. EPA's imbalanced consideration of high usage rates as an indication of benefit, and not harm, is arbitrary and invariably biases its analysis toward promoting pesticide use instead of protecting the environment.

18. EPA arbitrarily ignores its own previous benefits assessment for neonic-treated soybean seeds. The original benefits assessment for treated soybean seed, published in 2014, concluded that these treatments frequently have zero or negligible benefits for farmers; but EPA ignores this conclusion in its PIDs. EPA's analysis of seed treatments is crucial. These applications—especially on corn and soy—account for the vast majority of agricultural neonic use in the U.S.[61] EPA's 2014 assessment explains:

> BEAD concludes that these seed treatments provide negligible overall benefits to soybean production in most situations. . . . In comparison to the next best alternative pest control measures,

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[59] N. Simon-Delso, *Systemic Insecticides (Neonics and Fipronil): Trends, Uses, Mode of Action and Metabolites*, 22 Envtl. Sci. & Pollution Research 5-34 (Sept. 19, 2014), https://bit.ly/2RJoPSu ("[I]n many of the most important crops grown in North America (notably maize), there are no non-neonicotinoid seed alternatives readily available to producers in the marketplace.").

[60] *See, e.g.*, Allison Johnson, Lara Bryant, & David Wallinga, MD, *Fund Our Farmers So They Continue to Feed Us* (Apr. 9, 2020), https://www.nrdc.org/experts/allison-johnson/fund-our-farmers-they-continue-feed-us

[61] Douglas & Tooker (2015), https://bit.ly/2zDpIWt.

ED_006569J_00033604-00020

> neonicotinoid seed treatments likely provide $0 in benefits to growers and at most $6 per acre in benefits (i.e., a 0%-1.7% difference in net operating revenue).

Treated Soybean Assessment at 1-2. EPA's conclusions—that neonic seed treatments are used prophylactically and that yield benefits are minimal—are consistent with open literature studies that analyze seed treatment benefits in soybean.[62]

In 2017, EPA issued its response to public comments on its 2014 assessment. EPA, Biological and Economic Analysis Division's (BEAD) Response to Comments on the Preliminary Risk Assessments and Benefit Assessments for Citrus, Cotton, Soybean Seed Treatment, and Other Crops Not Assessed for Neonicotinoid Insecticides (Dec. 23, 2019) ("Seed Treatment Response"). Despite EPA's best efforts to backtrack from its earlier conclusions, the crux of its analysis remained the same: neonic seed treatments are routinely used in situations with no pest threat and therefore provide no benefit. And yet that conclusion does not factor at all into EPA's PIDs for clothianidin and thiamethoxam. *See* C&T PID at 48-49. In fact, the original Treated Soybean Assessment does not appear in the neonic dockets. EPA lists only BEAD's response to comments in its "Summary of Clothianidin and Thiamethoxam Registration Review," but not the original analysis. C&T PID at 5-9. The agency also fails to reference either document in its "List of Documents Supporting the Neonicotinoid Registration Review" in the Pesticide Re-evaluation Division's response to comments. EPA, Response from the Pesticide Re-evaluation Division to Comments on the Draft Risk Assessments and Benefits Assessments Supporting the Registration Review of the Nitroguanidine-substituted Neonicotinoid Insecticides 8-10 (Jan. 16, 2020). EPA's proposal to permit continued, nationwide registration of neonic seed treatments is arbitrary and unsupported if its analysis fails to incorporate or consider the central findings of its 2014 and 2017 assessments or, at minimum, explain why those findings are no longer relevant.

19. EPA ignores availability of non-chemical means of pest control. Throughout its benefits assessments, EPA compares the cost of neonics with alternative means of controlling pests. EPA has said that benefits of a pesticide "depend[] on the availability of alternative pest control measures, whether chemical, *biological or cultural*." Pesticides; Procedural Regulations for Registration Review, 71 Fed. Reg. 45,720, 45,725(Aug. 9, 2006) (emphasis added).

In the PIDs, however, EPA compares the benefits of neonics with only those of other available conventional insecticides, such as organophosphates, diamides, carbamates, and pyrethroids. *See, e.g.*, Imid. PID at 33 (comparing cost of producing cotton using imidacloprid with costs using organophosphates and pyrethroids). This ignores effective methods used by organic producers throughout the country, such as cultural methods like cover-cropping, crop rotation, and trap cropping, that can provide effective control while preserving biodiversity. In fact, a study from France, where all outdoor uses of neonics have been banned, found that 78%

[62] *See* Mourtzinis et al. (2019), https://go.nature.com/2kylh8v.

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of neonic uses are replaceable by non-chemical pest control methods.[63] Where chemicals are needed, biopesticides, designated minimum risk pesticides, and organic pesticides are available to address pest threats. Nowhere throughout EPA's benefits assessments does EPA consider whether these alternative modes of pest control might be as effective, less risky, and/or less expensive than neonics. EPA's benefits assessments are unsupported by substantial evidence so long as EPA ignores these alternative modes of pest control.

20. EPA must conduct a benefits assessment for corn seed treatments. The agency has explained that it conducts benefits assessments based on risks of concern identified in its RAs. *See, e.g.*, Catch-All Benefits Assessment at 5. For corn seed treatments, EPA's comparative aquatic risk analysis found that several RQs exceed the chronic LOC for aquatic invertebrates. *See* Comparative Aquatic RA at 21. EPA also finds risks of concern in its Tier 1 pollinator assessment for clothianidin, used by EPA to approximate risks to solitary bees. *See supra*, Argument 35. These identified risks are considerable given their massive scale. At least 80% of corn acres in the U.S.—representing tens of millions of acres—are treated with neonic seed treatments,[64] making corn seed treatments likely the single largest agricultural use of neonics in the country. EPA should, therefore, conduct a benefit assessment for corn seed treatments to determine whether their benefits justify such widespread use and substantial risk to aquatic ecosystems, solitary bees, and other wildlife.

In conducting such an assessment, it is especially crucial that EPA not rely on usage data as an indicator of benefit. Researchers at Penn State recently found that only 65% of corn growers could provide the name of the seed treatment they use on their corn.[65] Widespread usage, therefore, often does not reflect a conscious choice by farmers to use neonics. In fact, untreated seeds, especially for most varieties of conventional corn, are unavailable.[66] Given the evidence that farmers have little option but to use corn seed treatments, widespread usage is not an indication of the benefits of neonic seed treatments in corn.

21. EPA arbitrarily ignores open literature studies demonstrating negligible or non-existent benefits of corn seed treatments. Neonic-treated corn seed dominates agricultural landscapes across the U.S., especially the Midwest, where it causes widespread contamination of surface water[67] and likely causes or contributes to extensive pollution of drinking water.[68] For

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[63] Herve Jactel et al., *Alternatives to Neonicotinoids*, 129 Environ. International 423-29 (Aug. 2019), available at https://bit.ly/2zBloHg.

[64] Douglas and Tooker (2015), https://bit.ly/2yep5Cp.

[65] LaJeunesse (2020), https://bit.ly/2JbYJmB.

[66] Simon-Delso (2014), https://bit.ly/2RJoPSu ("[I]n many of the most important crops grown in North America (notably maize), there are no non-neonicotinoid seed alternatives readily available to producers in the marketplace.").

[67] *See, e.g.* Hladik et al. (2014), https://bit.ly/3aPhQxW.

[68] *See, e.g.*, Klarich et al. (2017), https://bit.ly/2KIYSPc (neonics "ubiquitously detected" in Iowa City drinking water).

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this reason, it is imperative that EPA, at minimum, impose restrictions to mitigate this environmental contamination. EPA must also determine whether benefits of such uses justify their continued registration. Open literature studies demonstrate that they do not. Alford and Krupke (2017) found in a field experiment that seed treatments on corn did not have a significant effect on root rating, stand count, or yield in either of the two years studied.[69] In another study, Krupke et al. "documented no benefit, in terms of crop yields, of planting neonicotinoid-treated maize over three cropping seasons."[70] As this evidence is uncontroverted in the PID dockets, EPA's decision to permit continued, unmitigated use of seed treatments in corn is arbitrary and unsupported by substantial evidence.

22. EPA cannot rely on AgInfomatics' registrant-funded study of neonic benefits in ornamentals. In 2014, Bayer CropScience, Mitsui, Syngenta, and Valent—registrants of neonic pesticides—commissioned a series of reports by AgInfomatics, LLC to analyze the value of neonics uses in turf and ornamentals. *See* EPA, Review of "The Value of Neonicotinoids in Turf and Ornamentals" prepared by AgInfomatics, LLC for Bayer CropScience, Mitsui, Syngenta, and Valent (Dec. 11, 2019) ("AgInfomatics Review"). EPA's assessments of the benefits of neonic in turf and ornamentals, as explained in the PIDs, appear to rely solely on its review of these reports. *See* Imid. PID at 38-39; C&T PID at 49-50; Dino. PID 31-32. However, the reports are—as EPA partly acknowledges—pervasively biased in favor of neonics. EPA's explanation that it "agrees" with the reports' conclusions, despite these pervasive problems, is arbitrary and unsupported by substantial evidence. Four shortcomings of the reports stand out.

First, the consumer choice survey is replete with evidence that suggests bias in favor of neonics. Most notably, EPA acknowledges that the study's data does not support its conclusion that "neonicotinoids best fit" the preferences of homeowners. AgInfomatics Review at 12. Instead, the results show that neonicotinoids were the preferred insecticidal class for *only one of three* uses (flowers and shrubs). *Id.* at 8, 10, 11. The study authors, therefore, misrepresent the study results, overstating the value of neonics.

Second, in the AgInfomatics reports, the study authors determine which pesticides have the attributes that the consumers report preferring. In other words, a surveyed consumer may say that they value a pesticide that has "very high effectiveness of control," but it is the authors who decide which pesticides have "very high" effectiveness and which do not. In this way, the study authors define which pesticides its survey participants prefer—and, perhaps unsurprisingly, often find that consumers prefer neonics. This highly subjective, un-scientific, and self-interested assessment cannot form the basis for EPA's analysis of the benefits of neonics to ornamentals.

Third, the study questions are skewed to hide attributes that do not favor neonics. For instance, in the consumer choice survey, one of the attributes surveyed was "safety to humans, pets, and wildlife." *Id.* at 7. The only three possible responses were excellent, very good, and good. *Id.* The question pre-supposes that the safety of all pesticides to wildlife is at least "good."

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[69] Alford and Krupke (2017), http://bit.ly/38gpv7j.

[70] Krupke et al. (2017), http://bit.ly/2rmvkjU.

To the contrary, available evidence suggests that neonics devastate wildlife populations across the spectrum,[71] and are far more dangerous to wildlife than organic and minimum risk alternatives. But the study questions provide no opportunity to express a strong preference *against* pesticides that have known, widespread environmental effects—and therefore do not have "good" safety to wildlife. Thus, these questions failed to give consumers a meaningful choice about the pesticide attributes available.

Fourth, the reports contain information that is wholly irrelevant to EPA's determination of the benefits of neonic use under FIFRA. In the PIDs, EPA notes that "the turf and ornamentals industries in the U.S. account for over 400,000 businesses, millions of jobs, and billions in annual revenues." Imid. PID at 38. To the extent this information factors into EPA's benefits assessment, neither AgInfomatics nor EPA provides any evidence that loss of neonics will result in the loss of these businesses, jobs, and revenues. Moreover, EPA references general, unsupported statements about the contribution of turf and ornamentals to home values. Even if true—and EPA provides no evidence that it is—the value of turf and ornamentals generally says nothing about the efficacy or value of using neonics. To the extent EPA is relying on these general economic statements to support a finding of neonics' benefits, that reliance is arbitrary and unsupported by substantial evidence.

On the whole, the AgInformatics reports grossly overrepresent the value of neonics on ornamentals. EPA itself acknowledges "there were areas for improvement" in virtually every element of the reports—namely, their "methodology, results, and general conclusions." Imid. PID at 39. Nevertheless, EPA "agrees with AgInfomatics that neonicotinoids are a useful tool and often a top choice for pest control in the turf and ornamental industries." *Id.* EPA provides no basis for its "agreement" with the deeply flawed reports. Because EPA arbitrarily relies on this information to determine whether ornamental neonic applications satisfy the FIFRA standard, those decisions are arbitrary and unsupported by substantial evidence.

iii. EPA's Proposed Mitigation Is Inadequate to Protect People, Pollinators, Birds, Aquatic Ecosystems, and Other Wildlife from the Harms of Neonic Use.

23. The proposed mitigation fails to protect sensitive human populations. EPA determined in its risk assessments that several neonic uses present unacceptable risk of harm to people. *See, e.g.*, Imid. PID at 41. In some situations, EPA has taken appropriate action by proposing to prohibit those uses. For example, EPA has proposed banning spray application of imidacloprid on residential turf and on-farm application of imidacloprid to canola, millet, and wheat. *Id.* However, for many harmful uses, EPA only proposes to require added personal protective equipment. *See, e.g.*, *Id.* at 42 (requiring double layer clothing and gloves for on-farm imidacloprid seed treatment use for barley and cotton and requiring gloves for liquid/foliar handgun application to citrus); C&T PID at 53 (requiring gloves and a respirator for clothianidin seed treatment uses and liquid application of clothianidin to buildings). These types of mitigation measures are widely regarded as the least effective way to prevent occupational exposure.

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[71] *See, e.g.*, Dave Goulson, *REVIEW: An Overview of the Environmental Risks Posed by Neonicotinoid Insecticides*, 50 Applied Ecology 977-87 (Jun. 13, 2013), https://bit.ly/2xUe35r; Wood and Goulson (2017), https://bit.ly/3aXhXIV.

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EPA's proposal to require double-layer clothing and gloves will not reduce the unreasonable risks to health from seed treatments and handgun applications of imidacloprid, and EPA's proposal to adopt this mitigation is not supported by substantial evidence demonstrating that it will be effective. The National Institutes for Occupational Safety and Health (NIOSH) aptly summarizes concerns with relying on personal protective equipment (PPE): "Administrative controls and PPE programs may be relatively inexpensive to establish but, over the long term, can be very costly to sustain. These methods for protecting workers have also proven to be less effective than other measures, requiring significant effort by the affected workers."[72]

EPA's proposed PPE-based mitigation relies on a number of questionable assumptions. For example, gloves are only effective at reducing risk if new, formulation-specific, gloves are provided for each application. The PIDs specify that the gloves must be chemical-resistant gloves. *See id.* at 61. The proposal assumes, among other things, that: farmworkers are able to access and/or pay for product-appropriate chemical-resistant gloves; farmworkers will wash and maintain non-disposable gloves and other equipment; and disposable gloves will be replaced regularly. EPA cannot simply assume that appropriate PPE will be available or that it alone will protect farmworkers from chemicals EPA has determined are harmful to their heath.

Even where PPE is available, barriers to adoption exist. For example, studies looking at the use of eyeglasses to prevent eye injuries among Florida citrus harvest crews found many factors inhibited adoption, such as humid weather causing the glasses to fog up, making it impossible to timely complete work tasks. After several years of study, the authors concluded that adoption required consistent intervention, found only at large companies that could provide consistent support.[73] Even though the study involved very simple PPE (eye glasses), adoption was still only 28-37% at the end of two full harvesting seasons of implementation of the education and training program; without, the program regular use of eye protection was less than 2%.[74] EPA proposes to require more cumbersome PPE, such as respirators and chemical-resistant gloves, but envisions no field worker program for adoption of PPE, likely ensuring that its requirements will not be followed in practice by the vast majority of users.

EPA's proposed mitigation regarding respirators is especially problematic. *See, e.g.* C&T PID at 55. EPA briefly acknowledges that "[i]f the respirator does not fit properly, use of clothianidin and thiamethoxam may cause unreasonable adverse effects on the pesticide handler." *Id.* Yet EPA dismisses this concern, explaining that the RAs "assume [NIOSH] protection factors (i.e., respirators are used according to OSHA's standards)." C&T PID at 55. This baseless assumption runs counter to likely real-world conditions as well as EPA's previous statements about the many reasons respirator use may be impossible or infeasible:

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[72] NIOSH, Center for Disease Control and Prevention, *Hierarchy of Controls*, https://bit.ly/3bTmjB5 (last visited Mar. 3, 2020).

[73] J. Antonio Tovar-Aguilar et al., *Improving Eye Safety in Citrus Harvest Crews Through the Acceptance of Personal Protective Equipment, Community Based Participatory Research, Social Marketing, and Community Health Workers*, 19(2) J. of Agromedicine 107-116 (2014), https://bit.ly/2YoIgUP.

[74] P.F. Monaghan et al., *Adoption of Safety Eyewear Among Citrus Harvesters in Rural Florida*, 14(3) J. of Immigration Minor Health 460-6 (Jun. 14, 2012), https://bit.ly/2WaMixy.

ED_006569J_00033604-00025

> Individuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for tight fitting full-face piece respirators to provide the required protection. Individuals with facial hair, like beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998). According to OSHA, "improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health.

Proposed Rule for Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7473-74 (Jan. 19, 2017), https://bit.ly/3f5rz6P. EPA fails to square its assumption that all farmworkers will use respirators properly with its earlier finding that many people are unable to wear respirators. In fact, as the current Covid-19 pandemic demonstrates, respirators may not always be available.[75] Without addressing these real-world barriers to adoption, EPA's current proposal virtually ensures that neonic use will result in unreasonable adverse effects to some farmworkers. EPA must propose protective measures that will actually reduce risk for these populations, or else cancel these neonic uses.

EPA must also account for the fact that many applicators may fail to read, understand, or follow label language requiring PPE. EPA itself has explained:

> consumers and professionals do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; [and] even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings."

82 Fed. Reg. 7473-74. Applicators are even less likely to heed EPA's instruction that applicators wear two layers of clothing. In many areas of the country, farmworkers or other applicators may be applying neonics in excessive heat, making two layers of clothing and gloves extremely uncomfortable. EPA fails to cite any evidence that applicators will follow label language regarding PPE.

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[75] Beyond Pesticides, Farmworkers at High Risk During Coronavirus Pandemic (Apr. 2, 2020), https://bit.ly/2VWxtOP.

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In light of findings by NIOSH, OSHA, and EPA itself regarding the ineffectiveness of PPE, the agency must provide an explanation, supported by substantial evidence, of how PPE will mitigate the harms identified in the neonic RAs. But nowhere in the PIDs or Human Health RAs does the agency explain the basis for its conclusion; it simply concludes, for example, that "[w]ith the addition of single-layer gloves the MOE would be 160 and not of concern." Imid. PID at 42. Relatedly, EPA fails to propose additional mitigation for other occupational risks because "risk estimates were not of concern with current baseline attire or with personal protective equipment." *Id.* Like for newly proposed PPE, EPA fails to offer any evidence or justification for its assumption that PPE is effective at reducing those risks.

24. The proposed residential ornamental advisory will fail to protect pollinators and aquatic ecosystems from unreasonable adverse effects. Application of imidacloprid, clothianidin, and thiamethoxam to ornamental plants presents enormous risks to pollinators, with EPA finding the "strongest evidence" of "colony-level risk" from these applications. Imid. PID at 26; C&T PID at 67; Dino. PID at 37-38. These uses also pose grave risks to aquatic invertebrates that support entire ecosystems. Chronic risk quotients for aquatic invertebrates from residential ornamental uses reach up to 1020 for imidacloprid—over 1000 times the chronic level of concern. Imid. PID at 28.

EPA proposes to mitigate these risks by adding an advisory label on ornamental products containing imidacloprid, clothianidin, thiamethoxam, and dinotefuran: "Intended for use by professional applicators." *Id.* at 66. EPA states that this advisory language is necessary, in part, "to decrease the likelihood of misapplication or overapplication." *Id.* at 50; C&T PID at 68; Dino. PID at 38. However, the risks of concern that EPA identifies for these products result from use in compliance with label instructions, not misapplication. *See* Imid. Final Bee RA at 24, n. 8. Without explaining how the proposed mitigation will address these identified risks, EPA's selection of the mitigation is arbitrary and unsupported by substantial evidence.

Even assuming that all unacceptable risks result from inappropriate application, there is no evidence that EPA's proposed label amendment will mitigate these risks. EPA itself acknowledges that label warnings are often ineffective because consumers fail to read and understand them and generally "base [their] decision to follow label information on previous experience and perceptions of risk." 82 Fed. Reg. at 7473-74. EPA provides no explanation for why its label advisory in this instance will effectively change consumer behavior.

If EPA intends these products to be used by professional applicators, it must explain why it simply does not designate the products as restricted use pesticides. Restricted use designation limits purchase or use to certified applicators, ensuring that homeowners would not misapply or overapply the products. *See* 7 U.S.C. § 136j(a)(2)(F). As this often-used and enforceable designation best serves EPA's stated intentions for the products' use, its decision to opt instead for advisory language likely to have no meaningful effect is arbitrary and unsupported by substantial evidence.

25. EPA provides no evidence that its proposed crop stage restrictions will adequately protect pollinators. EPA proposes to impose new restrictions on use of neonics

during and around bloom for various crops. The agency explains that such restrictions "can limit exposure during critical periods in the growing season when exposures to pollinators are more likely to occur." Imid. PID at 48. However, as discussed below, the RAs themselves suggest pre-bloom restrictions will be inadequate to eliminate unreasonable adverse effects to pollinators. Moreover, many of the proposed restrictions permit use of neonics at some point prior to bloom.

Initially, EPA's pollinator RAs recognize that neonic residues stay in plants for a long period of time. Imidacloprid, for example, was found in parts of treated plants up to 147 days after application for some crops. Imid. Final Bee RA at 79. In fact, EPA detected residues at the maximum time analyzed for all tested crops—whether applied to soil or foliage—indicating neonics applied before bloom often persist in plants, contaminating pollen and nectar throughout the blooming period and presenting an exposure risk to pollinators. *See id.* EPA fails to explain how its proposed mitigation will address these risks or, alternately, why they are not of concern.

EPA's RAs also show that neonics can remain in soil for long periods of time, allowing plants to continue to absorb neonics well after application. For example, EPA's modeling indicates that:

> an **accumulation of [of neonics amounting to] about 5 times the annual rate** is potential [sic] within 10 years of repeated annual applications. This simulation does not take into account important routes of dissipation including leaching, run-off, and **plant up-take of imidacloprid residues** . . . .

Imid. Final Bee RA at 121 (emphasis added). In other words, even with seasonal restrictions in place, neonics are likely to remain in the soil year-to-year, allowing crops to absorb neonics in the soil that were applied the previous year.

On the whole, the RAs indicate that EPA's proposed bloom restrictions will have limited impact on oral exposure of pollinators to neonics and fail to support the agency's conclusion that the restrictions will mitigate identified risks of concern to pollinators. The proposed restrictions, therefore, are arbitrary and not based on substantial evidence.

26. EPA's "Pest Resistance Management" recommendations will encourage greater use of pesticides that cause harm to people and the environment and fail to address the most likely source of pesticide resistance. EPA proposes label language to advise pesticide applicators "to use pesticides with different chemical modes (or mechanisms) of action against the same target pest population" to prevent pesticide resistance. Imid. PID at 56; C&T PID at 73. This recommendation, however, encourages increased pesticide use and ignores the possible synergistic effects of neonics with other pesticides. Current research has identified synergistic effects of neonics and fungicides;[76] similar synergisms may occur with other pesticides or agricultural chemicals, but there is currently insufficient research into these effects.

[76] *See, e.g.*, Sgolastra et al. (2017), https://bit.ly/2WcdNH1; Thompson et al. (2014), https://bit.ly/2Wax2k4.

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To truly combat pesticide resistance and mitigate the effects of neonics on pollinators, aquatic invertebrates, and ecosystems, EPA must address their widespread prophylactic use, such as from seed treatments. Neonics are used in vast quantities even where there is no apparent pest problem, releasing millions of pounds of neonics into the environment and exposing target and non-target insects to low levels of neonics. *See* Treated Soybean Assessment at 1-2. As EPA explains, repeated pesticide use "kills sensitive pest individuals but allows less susceptible ones in the targeted population to survive and reproduce, thus increasing in numbers." Imid. PID at 56. The same applies to overuse of pesticides; pests will more frequently encounter these chemicals in the environment, killing the most sensitive pests and leaving those that are resistant. Widespread prophylactic use allows this selection process to occur at a larger scale without offering direct benefits to farmers. This is similar to concerns about overuse of antibiotics contributing to antibiotic resistance, as explained by the World Health Organization.[77] EPA's recommendation to use of multiple pesticide chemicals fails to address this most-likely source of pest resistance and will likely magnify the already devastating ecological costs of neonic overuse. This proposal, as well as EPA's failure to analyze its implications, is arbitrary and unsupported by substantial evidence.

27. EPA fails to provide evidence that its proposed application rate reductions will mitigate identified unreasonable adverse effects to pollinators and ecosystems. EPA identifies that RQs associated with many neonic uses exceed levels of concern by hundreds or even thousands of times. *See, e.g.*, Imid. Final Bee RA at 209 (screening level chronic RQs are 2336 for fruiting vegetables and 7,301 for citrus and pome fruit). EPA proposes to mitigate these risks by reducing maximum annual application rates for some crops. Most of these proposed reductions, however, represent marginal decreases in maximum application rate. *See, e.g.*, Imid. PID at 43 (Brassica/cole, leafy vegetables, and fruiting vegetables reduced from 0.23 to 0.20 lbs AI/A/yr). Moreover, EPA often explains these reductions will likely have little impact on real-world use. *See, e.g.*, *id.* at 44 (explaining that the average applicator uses imidacloprid at far below the revised maximum rate for blueberries and caneberries).

Presumably, EPA's rate reductions are aimed at eliminating "worst-case scenario" applications at the maximum allowed rate, which would result in high estimated environmental concentrations (EEC) and therefore a higher risk of exposure for pollinators and aquatic wildlife. If this is the case, the PIDs do not make this rationale explicit. Even assuming this is EPA's rationale, the agency provides no explanation of how the reduced application rates would affect the expected EECs or RQs for neonic use, let alone whether those rates would be low enough to prevent unreasonable adverse environmental impacts. This information is vital to EPA's mitigation decision. Without it: (1) EPA cannot support its determination that mitigation reduces or eliminates unreasonable adverse effects on the environment; and (2) commenters cannot assess the adequacy of mitigation. EPA must explain how its proposed application rate reductions will reduce risk to pollinators and aquatic ecosystems. Without such explanation, EPA's proposed application rate reductions are arbitrary and unsupported by substantial evidence.

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[77] *See* World Health Organization, Antibiotic Resistance, https://bit.ly/3f27yxY (last visited Mar. 15, 2020) (explaining "[a]ntibiotic resistance is accelerated by the misuse and overuse of antibiotics" and directing health professionals to "[o]nly prescribe and dispense antibiotics when they are needed").

28. EPA proposes spray drift "mitigation" measures that increase ecological risks. Throughout the neonic RAs, EPA identified spray drift from aerial application as a major contributor to off-field pollinator risk. *See, e.g.*, Imid. Final Bee RA at 213-16; C&T Final Bee RA at 111. This risk extends over 1000 feet beyond field boundaries, the limit of EPA's model, for practically all crops and all endpoints when wind speeds reach 15 mph or greater. *See* Imid. PID at 25; C&T PID at 36. As noted, a model that accounts for risk only up to 1000 feet beyond field boundaries, but shows that risk extends beyond that limit, is inadequate to fully assess the risks of spray drift to pollinators. *See supra*, Argument 2. This shortcoming indicates that EPA should take a conservative approach to estimating off-field risk and take steps to limit spray drift to the maximum extent possible. Instead, in its PIDs for clothianidin, thiamethoxam, acetamiprid, and dinotefuran, EPA proposes label language that the RAs suggest will *increase* the risk of spray drift from aerial applications:

> Proposed changes will *allow applications of thiamethoxam at higher wind speed*, which will provide growers with greater flexibility to make applications in a timely manner. Further, at wind speeds of 10 mph or less, the *boom length for helicopter is increased* to 90 percent of the rotor diameter, which may necessitate fewer passes to complete an application, likely decreasing application costs. The proposed changes will provide clarity to clothianidin users.

C&T PID at 70-71 (emphasis added); *see also* Acet. PID at 21; Dino. PID at 40. EPA provides no explanation for these "mitigation measures" aside from allowing growers "greater flexibility," providing "clarity," and decreasing costs. The RAs identify wind speed as a factor that increases off-field pollinator risk. *See* Imid. Final Bee RA at 212. Though EPA's risk assessments do not assess the impacts of boom length on spray drift, the fact that upper limits exist suggest that longer booms increase spray drift or some other risk. But EPA proposes relaxing limitations on both parameters, almost certainly increasing risk to pollinators.

EPA's decision to increase off-field risk to pollinators to make applications more flexible, clear, and inexpensive for applicators violates FIFRA. The sole purpose of registration review is to review whether continued registration complies with the FIFRA standard, i.e., whether the registration causes unreasonable adverse effects on the environment. 40 C.F.R. § 155.40. EPA has concluded that aerial and spray applications contribute to substantial off-field risk to pollinators, but proposes to increase these risks without reference to the FIFRA standard. This decision is unsupported by EPA's analysis and divorced from the considerations permitted by FIFRA.

The pollinator RAs show that EPA must cancel aerial applications of neonics. If it is unwilling to do that, it must, at a minimum, explain how its proposed mitigation will decrease—not increase—off-field risk to pollinators from aerial spray applications to acceptable levels.

29. EPA's advisory language for disposal of treated seed will fail to mitigate the unreasonable adverse effects of their use on the environment. EPA proposes label language for imidacloprid, thiamethoxam, clothianidin, and acetamiprid seed treatment products, requiring

users to affix "advisory language" to bags of seed after treatment that would encourage farmers to "cover or collect treated seeds spilled" and "dispose of all excess treated seed burying treated seed away from bodies of water." Imid. PID at 67; C&T PID at 67; Acet. PID at 19.[78] This proposal attempts to mitigate identified ingestion risks to birds and mammals from neonic treated seed, Imid. PID at 67; C&T PID at 67; Acet. PID at 19, and, presumably, risks to aquatic species and ecosystems from neonic treated seed runoff. *See, e.g.,* Cloth. Non-Pollinator RA at 82, 85 (identifying acute and chronic risks of concern for rice seed treatments on aquatic invertebrates); C&T PID at 67 ("adding these [advisory] statements to labels is also expected to benefit aquatic organisms by reducing neonicotinoid loading in aquatic systems"). The proposal, however, will fail to accomplish either goal.

Initially, EPA fails to explain how its advisory seed bag language will change farmer behavior. While EPA states that its purpose is to "encourage the adoption of best management practices," Acet. PID at 19, EPA provides no evidence or reasoning as to why farmers would undertake the time and expense of doing so. Typical farm sizes range from several hundred to several thousand acres,[79] which means that finding seed spills, collecting those seeds, and burying them according to EPA's proposed guidance may require considerable additional work. Without any independent financial incentive to do that work, it is most likely that farmers will simply ignore EPA's proposed advisory seed bag labeling. Because the PIDs fail to provide any evidence or reasoning to the contrary, they fail to provide substantial evidence that the advisory language will mitigate identified risks to birds, mammals, and aquatic species.

Even assuming farmers embrace the proposed advisory practices, EPA does not sufficiently explain how those practices will mitigate identified risks. For ingestion risks to birds and mammals, EPA finds the most likely sources of exposure are "accidental spills, excess unplanted seed on the edges of the field, shallow planted seed, and the improper disposal." Imid. PID at 57. Yet, the advisory practices do not address risks from shallow planted seed. Further, unplanted excess seed and spills are generally accidental—farmers are likely often unaware of the locations of these exposed seed piles and may be unable to find or remove them before they are consumed. Even where seeds are buried or planted at depth, considerable risks remain—EPA itself acknowledges that "some mammals are highly capable of burrowing in soil and acquiring buried seeds and may cache them for later consumption." C&T PID at 67. Indeed, burying a large amount of neonic treated seed in one place may increase risks for some burrowing animals.

The proposed advisory language also fails to provide sufficient guidance on the appropriate practices to decrease risk, such as the correct or necessary burial depth, buffer from bodies of water, maximum quantity of seeds to buried in one location, soil type for the burial site, buffer from pollinator-attractive plants, or surface slope. Again, burial of a large amount of treated seed may increase ingestion risks to birds and mammals—particularly where it is buried shallow enough to be accessed or in a site prone to erosion. Without more detailed parameters and a clear explanation of how they will reduce identified risks to mammals, birds, pollinators,

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[78] EPA fails to mention or explain the basis for its imidacloprid advisory in the body of the PID, but only mentions the advisory in the Appendix. Imid. PID at 86.

[79] *See* U.S. Department of Agriculture, *Farms and Land in Farms 2018 Summary*, 7 (Apr. 2019), https://bit.ly/33WvQV6 (average U.S. farm size is over 440 acres).

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aquatic invertebrates, and other wildlife, EPA cannot substantiate how they will effectively mitigate identified risks.

Lastly, EPA's proposed advisory language, if observed, would concentrate excess seed—and their pesticide coatings—in a small area, increasing the risks associated with concentrated neonic loading to adjacent soil and water. While the PIDs appear to acknowledge neonic treated seed burial sites pose a risk of neonic loading, *see, e.g.*, C&T PID at 67 (advising to bury seeds away from water bodies), nothing in EPA's proposed language would prevent an applicator from dumping 10, or 100, or even 1000 pounds of treated seed at a single site. As mentioned, EPA's proposal provides no guidance on the appropriate buffers from water resources, pollinator attractive plants, or other potentially sensitive sites, such as endangered species habitat. EPA cannot encourage disposal of neonics in the environment without addressing the substantial possibility that such disposal could result in increased contamination and risk to wildlife, including threatened and endangered species.

30. EPA's advisory language for disposal of treated seed is at odds with the Resource Conservation and Recovery Act. EPA's proposed advisory language for neonic seed treatment products hearkens back to a time when farmers, industry, and other polluters could simply dispose of excess toxic chemicals by throwing them into ditches or letting them seep, uncontrolled, across the landscape. Indeed, Congress intended to prevent such irresponsible disposal of chemicals—like pesticides—when it passed the Resource Conservation and Recovery Act (RCRA) over 40 years ago. *See* 42 U.S.C. § 6902(3) (listing among the objections of RCRA, "prohibiting future open dumping on the land"). EPA's disposal language would encourage violations of RCRA in several respects.

First, EPA's proposal directs farmers to dispose of excess neonics in a manner that may cause an "imminent and substantial endangerment to health or the environment." 42 U.S.C. § 6972(a)(1)(B). RCRA authorizes citizen suits against any person that has contributed or is contributing to the disposal of solid waste that presents an "imminent and substantial endangerment to health or the environment." 42 U.S.C. § 6972(a)(1)(B). Burying excess neonics is a disposal of solid waste under RCRA. *See Ecological Rights Foundation v. PSEG*, 713 F.3d 502, 515 (9th Cir. 2013) ("The key to whether a manufactured product is a solid waste, then, is whether that product has served its intended purpose and no longer wanted by the consumer." (quotes and alterations omitted)). And depending on the circumstance, it is possible that leaching of neonics from a burial site into adjacent land could present an "imminent and substantial endangerment." At a minimum, it is arbitrary and capricious for EPA to endorse disposal of pesticides in a manner that does or could violate other environmental laws, like RCRA.

Second, the proposal violates RCRA's prohibition on open dumping of solid waste. *See* 42 U.S.C. § 6945(a). An open dump proscribed by RCRA is any "facility for the disposal of solid waste," 40 C.F.R. § 257.2, that "cause[s] or contribute[s] to the taking" of ESA-listed species or creates other health or environmental hazards, *id.* § 257.3. EPA advises pesticide users to dispose of neonics in ways that may violate this standard. As above, it is arbitrary and capricious for EPA to direct pesticide users to violate RCRA.

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EPA proposes to encourage seemingly unlimited, unrestrained disposal of neurotoxic neonics in the environment. EPA cannot finalize this proposed mitigation without explaining how it is consistent other laws that govern storage and disposal of solid waste, including RCRA.

31. EPA fails to propose measures to mitigate the considerable risks posed by the planting of neonic treated seeds—the most common agricultural use of neonics. EPA identifies risks of concern from the use of neonic treated seed for several crops. *See* Comparative Aquatic RA at 17, 21 (finding aquatic RQs exceed the chronic LOC for seed treatment uses for corn, soybean, sugarbeet, rice, and wheat). While EPA attempts to address risks from spilled and excess neonic treated seed, the PIDs contain no application rate reductions or other measures intended to reduce the identified risks associated with normal planting. *See* C&T PID at 57-62; Imid. PID at 43.

These risks are substantial given the incredibly widespread use of neonic treated seeds—covering well over a hundred fifty million acres of U.S. farmland every year and accounting for the single largest use of neonics in agriculture.[80] Moreover, as discussed, EPA's RAs also largely overlook or underestimate the risks posed by neonic seed coatings—including environmental impacts associated with their migration through soils, absorption by non-target plants, and contamination surface and ground water. *See supra*, Arguments 1 & 3. A considerable and growing body of scientific evidence shows that the most widely used seed treatments provide little to no yield benefits to farmers, *see supra*, Arguments 17, 18, 20, 21, and EPA fails to provide proof that the significant risks and harms posed by neonic seed treatments are sufficiently offset by measurable benefits. *See id.* Accordingly, EPA's decision to propose no mitigation for these risks—both risks it identified and those it failed to—is arbitrary, unsupported by substantial evidence, and will allow the normal planting of neonic treated seed to continue to cause unreasonable adverse effects to the environment.

32. EPA must revoke the treated article exemption for neonic treated seed in order to mitigate their unreasonable adverse effects. FIFRA authorizes EPA to exempt from the act's requirements any pesticide that it determines "to be of a character which is unnecessary to be subject to [FIFRA] in order to carry out the purposes of [FIFRA]." 7 U.S.C. § 136w. Pursuant to this provision, EPA has exempted neonic treated seeds from regulation as "treated articles."[81] 40 C.F.R. § 152.25. EPA must revoke this exemption in order to mitigate their unreasonable adverse effects on the environment.

EPA proposes mitigation to decrease risks posed by spilled and excess neonic treated seed. *See* Imid. PID at 67; C&T PID at 67; Acet. PID at 19. Without the ability to regulate use of treated seed directly, however, its proposal is necessarily convoluted—registered seed treatment products will receive new label language requiring applicators to affix advisory labels regarding

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[80] *See* Douglas & Tooker (2015), https://bit.ly/2SmFJGW; Mourtzinis et al. (2019), https://go.nature.com/2kylh8v; *See* USDA (2019), http://bit.ly/32pzru5; LaJeunesse (2020), https://bit.ly/2JbYJmB; USDA Farm Service Agency, Crop Acreage Data, https://bit.ly/39jf0AI (last visited Mar. 27, 2020) (corn, cotton, wheat, and soybean covered about 220 million acres in 2019).

[81] EPA & the Pest Management Regulatory Agency of Canada, *Regulatory Directive: Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States*, § 2.1 (Apr. 11, 2003), https://bit.ly/3alDJ8T.

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best management practices to bags of seeds after treatment. C&T PID at 86. Initially, EPA fails to identify its authority for requiring the labeling of products which are not themselves regulated as "pesticides," or how that authority jibes with that of the U.S. Department of Agriculture under the Federal Seed Act, 7 U.S.C. §§ 1551-1611. Moreover, the advisory labeling will likely have no effect on farmer behavior regarding the use, handling, or disposal of treated seed. *See supra*, Argument 29. To the extent EPA has determined that FIFRA demands better management of excess and spilled neonic treated seeds, it must directly regulate their use to ensure that it happens. The selection of a complicated and ineffective mitigation plan, simply to preserve a regulatory exemption for pesticide treated seed, is arbitrary.[82]

Additionally, the normal planting of neonic treated seeds poses significant and unjustified environmental risks. See Arguments 1, 3, 11, 12. Addressing these risks will require EPA to exercise control over the use of these seeds, something it cannot do while maintaining the regulatory exemption for neonic treated seed. Accordingly, EPA must revoke the treated article exemption for neonic treated seed or find another means of ensuring that the use, handling, or disposal of neonic treated seed does not cause unreasonable adverse impacts to the environment, such as by cancelling all neonic seed treatment products.

33. EPA fails to propose measures to mitigate risks to bees from foliar uses of imidacloprid on citrus. EPA's refined tier I analysis for foliar applications of imidacloprid to citrus identifies substantial risks to pollinators, with RQs ranging up to 86 for chronic risks to adult bees. Imid. Final Bee RA at 221. Moreover, pre-bloom foliar application of imidacloprid on oranges presents the "strongest evidence" of colony-level risk to bees. Imid. PID at 26. But neither the proposed application rate reductions nor the stage-based restrictions for imidacloprid apply to citrus. Imid. PID at 43, 48. EPA must propose mitigation for pre-bloom application to citrus or explain how its cost-benefit analysis supports its decision not to mitigate these substantial risks to pollinators.

34. EPA must, at a minimum, require vegetative buffers for acetamiprid applications. EPA identifies risks to aquatic invertebrates from acetamiprid that are substantially similar to those identified from use of thiamethoxam, clothianidin, dinotefuran, and imidacloprid. *Compare, e.g.,* Acet. PID at 16 *with* Imid. PID at 27-28. The agency, however, does not propose requiring vegetative buffers for use of acetamiprid, as it does for the other four neonics. EPA must require these buffers for acetamiprid or explain why the risks of aquatic contamination with acetamiprid do not justify imposing vegetative buffers.

35. EPA fails to mitigate on-field impacts of seed treatments on solitary bees. EPA explains that "Tier I conclusions for honey bees . . . are . . . also used to represent risks to solitary bees." C&T Final Bee RA at 29. In the agency's refined Tier-1 risk assessments for

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[82] EPA's explanation of this mitigation is misleading, as it contradicts the proposal in the Appendix. The PID states that seed advisories will be located on the products intended for seed treatment, but the Appendix directs that the advisories will located on bags of treated seed. *Compare* C&T PID at 67 ("EPA is proposing that all pesticide products that contain either clothianidin and/or thiamethoxam and are registered for seed treatment uses must include the following advisory statements") *with id.* at 86 ("seed treatments, add to seed bad [sic] tag" and "[a]dd the following statements to tags to clean up spills, dispose of excess seed to avoid contamination of water bodies").

clothianidin, imidacloprid, and thiamethoxam, EPA identifies risks of concern to honey bees from seed treatments. *See, e.g.*, *id.* at 218-219 (seed treatments of clothianidin on corn and soybean present Tier-1 risks to bees), 221 (seed treatments of thiamethoxam on soybean and peanuts present Tier-1 risks to bees). Nevertheless, EPA fails to propose any mitigation for on-field use of seed treatments to address this risk to solitary bees. EPA arbitrarily fails to address or mitigate this risk of concern.

iv. The Proposed Interim Decisions Violate FIFRA.

EPA's proposed interim decisions allowing the continued registration of nearly all neonic pesticide products, as well as much of the analysis that undergirds them, violate FIFRA. FIFRA requires that EPA ensure that registered pesticides do not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5); *see also* 40 C.F.R. § 155.40(a)(1). Accordingly, registration determinations must balance the economic, social, and environmental costs and benefits of a pesticide's use and must be based on substantial evidence. 7 U.S.C. §§ 136(bb), 136n. Registration review is intended to "ensure that each pesticide registration continues to satisfy the FIFRA standard for registration." 40 C.F.R. § 155.40. The PIDs fail to do so because: (1) EPA's determinations that neonic products satisfy the FIFRA standard are unsupported by substantial evidence; (2) the reasoning and conclusions of EPA's risk and benefits analyses are frequently arbitrary, unsupported by substantial evidence, and divorced from the language and purpose of the statute; and (3) EPA's proposed mitigation is unsupported by substantial evidence and divorced from the language and purpose of the statute. Moreover, EPA has failed to provide final assessments that fully explain the risks that informed EPA's PIDs.

36. EPA's cost-benefit analysis fails to support its interim decisions to permit continued registration of neonic products with substantial evidence. The agency's registration review decisions must be supported by "substantial evidence," 7 U.S.C. § 136n, yet none of the PIDs meet this standard. As set out in Sections III(a)(i)-(ii), EPA arbitrarily downplays the costs of neonic use and inflates their benefits. As a result, EPA fails to identify and mitigate "unreasonable adverse effects on the environment" caused by neonic use. Even where EPA identifies risks of concern, it often fails to provide mitigation or proposes mitigation without evidence or reasoning indicating that the measures proposed will actually reduce or eliminate the identified risks. Accordingly, EPA's PIDs permitting continued widespread use of neonic products are arbitrary, insufficiently substantiated, and violate FIFRA.

37. EPA's benefits analysis, which relies on usage data as an indicator of benefit, violates FIFRA. EPA's cost-benefit analysis must analyze the economic, social, and environmental costs and benefits of use. 7 U.S.C. § 136(bb). EPA has explained that:

> Benefits are the advantages that accrue to the pesticide users or society in general, such as increased production, decreased production costs, pest-free homes, or disease-vector control.

71 Fed. Reg. at 45,719. Consistent with the purpose of FIFRA, each of these benefit categories is a tangible benefit of the pest-control effects of pesticide use.

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Widespread use itself is not a "benefit" appropriately considered under EPA's FIFRA-mandated cost-benefit analysis. To the extent use itself has any economic benefit, it accrues to the pesticide manufacturer, but "impacts on pesticide manufacturers are not germane to this type of regulatory decision, in which the risk of the use of a pesticide is compared to the benefit of those uses." Health Risks and Economic Impact Assessments of Suspected Carcinogens, 41 Fed. Reg. 21,402, 21,405 (1976). Yet, EPA has concluded that many uses of neonics provide benefits solely because they are commonly used. *See, e.g.*, Dino. PID at 36 ("Benefits are considered to be high for this use of dinotefuran as data showed that an average of 139,000 lbs. are applied annually."); Imid. PID at 48 ("Benefits were considered high for this use for imidacloprid, as it accounts for 75% of turf treated with neonicotinoids."). Use is not an appropriate proxy for benefit; the fact that a pesticide is heavily used does not necessarily mean that it has concrete advantages that accrue to the pesticide user or society. For example, EPA has concluded that soybean seed treatments "likely provide $0 in benefits to growers" in many circumstances despite their widespread use. Treated Soybean Assessment at 1-2. Use of an environmentally harmful pesticide when it provides "$0 in benefits" is *per se* unreasonable.

EPA must assess whether use of neonics produces tangible benefits that justify their many risks of concern. In the agricultural context, this means assessing whether neonics meaningfully increase crop yield or decrease production costs when compared with alternative measures—including non-chemical means—or when no pest control is used at all. *See* 41 Fed. Reg. 21,405 ("For agricultural pesticides, the analysis will focus on the impacts on farmers, farm productivity, and consumer costs associated with farm productivity."). In the residential context, it means assessing whether neonic use is actually reducing pests in the home, or whether the products are routinely used preventatively where no pests are present. Only by looking beyond usage rates to any tangible advantages of neonic use can EPA arrive at a registration decision that comports with FIFRA.

Finally, EPA's analysis of usage rates produces absurd results that undermine the purpose of FIFRA. Because the volume and acreage of use appears not to factor into EPA's cost analysis, any pesticide—no matter how harmful—will pass EPA's balancing test if it is used commonly enough. This approach perpetuates use of pesticides with substantial environmental, social, and economic costs without any demonstration of tangible benefits. This is unreasonable and violates FIFRA.

38. EPA fails to provide support for its pervasive assumption that proposed mitigation will reduce risk to the environment or human health. The purpose of mitigation is necessarily to lessen the environmental, economic, and social costs of a pesticide use to ensure the use satisfies the FIFRA standard. For this reason, EPA proposes mitigation where it finds costs that exceed benefits. However, EPA provides no analysis or evidence that its proposed mitigation for neonic uses will, in fact, lessen risks of neonic use. EPA's assumption that these measures will prevent unreasonable adverse effects on the environment is entirely unsupported; its conclusion that neonics satisfy the FIFRA standard is, therefore, unlawful.

Indeed, EPA frequently justifies its mitigation proposals without reference to risk reduction. Instead, the agency focuses on whether the proposed mitigation will impose burdens on applicators. But a mitigation measure that fails to reduce costs of use, even if it preserves

purported benefits, does not function to mitigate unreasonable risk. EPA's analysis perversely leads the agency to recommend mitigation measures that will, by the agency's own estimation, have little effect on the costs of use. *See, e.g.*, Imid. PID at 44 ("The average annual application rate for imidacloprid is 0.11 lbs. AI/A on caneberries . . . therefore for cases like caneberries, limited impacts of the proposed mitigation are expected."). EPA cannot finalize its registration decision without analyzing and explaining how its proposed mitigation will sufficiently reduce identified risks and costs in order to ensure neonic registrations satisfy the FIFRA standard.

39. EPA violates its own regulations governing registration review by failing to publish final risk assessments. EPA releases the PIDs without publishing several key revised or final RAs, such as for risks to aquatic ecosystems. Agency regulations, however, state that it "*will* publish a notice in the Federal Register *announcing the availability of a revised risk assessment*, an explanation of any changes to the proposed document, and its response to comments." 40 C.F.R. § 155.53(c) (emphasis added). Instead of publishing revised risk assessments for aquatic harms and non-pollinator risks, EPA relies solely on brief responses to comments on its draft risk assessments, scattered among different documents. But these responses fail to fully explain fundamental changes to EPA's analysis that impact its conclusions in the PIDs. The pesticide office must publish complete revised assessments—including all risk and benefit findings underlying its policy decisions—for public comment and peer review before they are finalized. This is the only way that the public, stakeholders, other federal agencies and offices, states and tribes, and experts can provide fully informed peer review and comments. Other federal chemical evaluation programs do this, such as the EPA Integrated Risk Information System, and the NIEHS National Toxicology Program. EPA's failure to do so undermines the public participation process contemplated by FIFRA and violates EPA's regulations.

b. The Federal Food, Drug, and Cosmetics Act

EPA has proposed increasing tolerances for imidacloprid, clothianidin, thiamethoxam, and dinotefuran on certain commodities. Imid. PID at 58; C&T PID at 106-109; Dino. PID at 16-17. EPA's explanation for these increases is that they "harmonize" tolerances with Codex and Canadian Maximum Residue Limits. However, the FDCA provides that EPA "may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i). "Safe" means that EPA has determined 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." *Id.* § 346a(b)(2)(A)(ii). EPA established current tolerances because it determined that residues at that level, and not above that level, are safe within the meaning of the Food Act. *See, e.g.*, Imidacloprid; Pesticide Tolerances, 66 Fed. Reg. 18,554 (Apr. 10, 2001) (establishing tolerances for imidacloprid on citrus and determining that "there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to imidacloprid residues."). It cannot now increase these tolerances, simply to align with international standards not governed by the Food Act. Because EPA has not determined that increased tolerances are safe as defined by the FDCA, its proposal to increase them is unsupported, divorced from the statutorily prescribed considerations for establishing tolerances, and illegal.

c. The Endangered Species Act

Before finalizing its registration review decision, EPA must engage in formal consultation under Section 7 of the ESA. Section 7 requires that all agencies "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification" of designated critical habitat. 16 U.S.C. § 1536(a)(2). Correspondingly, an agency must determine "at the earliest possible time" whether its action "may affect" an ESA-listed species or its critical habitat; if it determines that there "may" be an effect, consultation is required. 50 C.F.R. § 402.14(a). EPA's risk assessments demonstrate that consultation is required here.[83]

Neonic contamination of the environment affects listed species. EPA has explained, for example, that "ecosystems at potential risk from clothianidin are extensive in scope due to the wide geographic distribution of potential clothianidin application sites." Cloth. Ecological RA at 15. This applies equally to all neonics, as each active ingredient is registered for use on a broad variety of crops as well as residential and commercial settings. Given neonics' propensity to persist and migrate throughout the environment, neonic use causes widespread contamination well beyond the site of application. As a result, countless listed species are exposed to neonics.

Moreover, the RAs demonstrate that neonics are toxic to a wide array of taxa that include listed species. For example, imidacloprid is "highly toxic to birds," Imid. PID at 21, "very highly toxic to adult honey bees" used as a surrogate for other bees, Imid. Pollinator RA at 28, and "very highly toxic to both freshwater and saltwater invertebrates." Imid. Aquatic RA at 86. Assessments for other neonics contain similar statements. Based on this widespread exposure and the high toxicity of neonics, their continued registration may affect listed species, meaning EPA must engage in consultation prior to its final determination. That includes an interim registration review decision: EPA may not sign a final interim registration review decision without engaging in consultation required under the Endangered Species Act.

d. The PID Dockets are Incomplete

The PID Dockets are incomplete because they are missing full documentary support for models and scientific studies relied upon in the neonic risk assessments. In short, it is impossible for the public to fully evaluate and critique EPA's PIDs because of the absence of important information from the public dockets, including data, study results, and models.

Although most models are briefly described in docketed documents, they are not fully documented with detailed information on their structure or inputs in a way that would allow the

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[83] As EPA has acknowledged, registration review is agency action subject to Section 7. *See, e.g.*, Imid. PID at 4. 59; C&T PID at 4, 76. *Cf. Ctr. for Biological Diversity v. EPA*, 847 F.3d 1075, 1092 (9th Cir. 2017) (re-registration is agency action requiring consultation).

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public to critically examine them. For example, EPA apparently changed modeling parameters for its aquatic risk assessment in response to public comments. *See* Imid. PID at 13; C&T PID at 15-16. However, the resulting Comparative Aquatic RA not only fails to adequately explain EPA's risk conclusions for aquatic life, *see supra*, Argument 14, but the revised model is not available for public review. *See generally* Comparative Aquatic RA. Similarly, the Agency discusses and relies upon dozens of scientific studies, many submitted by the registrant, which are merely summarized in the documents contained in the dockets. The reports of the studies along with full supporting documentation are not included in the dockets. As a result, it is difficult or impossible to view the data underlying EPA's risk determinations.

Full documentation of all studies relied on in support of tolerances and registrations is required to be submitted by the registrant by FDCA section 408(d) and FIFRA sections 3(c)(1)(F) and 3(c)(2)(A). Detailed data requirements are set forth in 40 C.F.R. Part 158 and the associated data guidelines. Notwithstanding the extensive informal public participation and docketing procedures announced and practiced by EPA in its registration processes, EPA has failed to document and docket the basic information upon which it is relying for its decisions. This has deprived Environmental Groups and the public of a full and fair opportunity to comment on these issues.

For example, the ornamental benefits assessment prepared by AgInformatics on behalf of registrants is not in the online docket. While this docket is allegedly in the public reading room, social distancing measures in response to the Covid-19 pandemic largely prevent the public from accessing these and other documents available only for in-person inspection. Indeed, the reading room was closed on March 31, 2020. EPA cannot rely on documents that are difficult or impossible to access during the PID comment period. A second example is EPA's Benefits of Neonicotinoid Seed Treatments to Soybean Production (Oct. 15, 2014), which appears to have been removed from all neonic dockets.

Additionally, EPA added numerous data evaluation records and other summaries to the registration review dockets on April 29, 2020—five days before the ultimate comment deadline and twenty-six days *after* the original comment deadline of April 3, 2020.[84] Still more were added on April 24, 2020.[85] These documents pertain to portions of the PIDs that EPA intends to finalize in its interim decision, such as mitigation to protect pollinators. Environmental Groups and other commenters have had no opportunity to review these documents, understand how they influence EPA's registration review decisions, and comment on their adequacy. EPA's

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[84] Documents include: EPA-HQ-OPP-2011-0581-0464, EPA-HQ-OPP-2011-0581-0373, EPA-HQ-OPP-2011-0581-0456, EPA-HQ-OPP-2011-0581-0466, EPA-HQ-OPP-2011-0581-0458, EPA-HQ-OPP-2011-0581-0470, EPA-HQ-OPP-2011-0581-0453, EPA-HQ-OPP-2011-0581-0469, EPA-HQ-OPP-2011-0581-0463, EPA-HQ-OPP-2011-0865-1224, EPA-HQ-OPP-2011-0865-1228, EPA-HQ-OPP-2011-0865-1234, EPA-HQ-OPP-2011-0865-1221, EPA-HQ-OPP-2011-0865-1225, EPA-HQ-OPP-2011-0865-1229, EPA-HQ-OPP-2011-0865-1223, EPA-HQ-OPP-2011-0865-1227, EPA-HQ-OPP-2011-0865-1220, EPA-HQ-OPP-2011-0865-122, EPA-HQ-OPP-2011-0865-1226, EPA-HQ-OPP-2011-0865-1233, EPA-HQ-OPP-2011-0865-1232, EPA-HQ-OPP-2011-0865-1231, EPA-HQ-OPP-2011-0865-1230.

[85] Documents include: EPA-HQ-OPP-2011-0920-0793, EPA-HQ-OPP-2011-0920-0796, EPA-HQ-OPP-2011-0920-0794, EPA-HQ-OPP-2011-0920-0797, EPA-HQ-OPP-2011-0920-0795.

regulations require the agency to provide a comment period of at least sixty days for interim registration review decisions, *see* 40 C.F.R. § 155.56, .58, and state that it will generally allow thirty days for draft risk assessments, *id.* § 155.53. EPA cannot finalize its interim registration review decisions without allowing the public to review these additional documents.

To the extent that studies, models, reports, and assessments relied upon by registrants to support continued registration and tolerances for neonics have not been supported by full documentation in the PID dockets, such studies and models cannot properly be relied upon by the Agency to support continuance of neonic registrations and tolerances.

IV. CONCLUSION

For the foregoing reasons, finalizing the neonic PIDs would violate FIFRA, the FDCA, the ESA. EPA must cancel any registered use for which it cannot provide substantial evidence for its conclusion that the use satisfies the FIFRA standard. 7 U.S.C. § 136a(c)(5)(C).

Respectfully Submitted,

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