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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY, and PESTICIDE ACTION NETWORK NORTH AMERICA, *Plaintiffs,* v. U.S. ENVIRONMENTAL PROTECTION AGENCY, and MICHAEL S. REGAN, in his official capacity as Administrator of the U.S. Environmental Protection Agency, *Defendants*.	Case No. 23-cv-2714 **COMPLAINT FOR DECLARATORY AND EQUITABLE RELIEF** Administrative Procedure Act Case

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INTRODUCTION AND OVERVIEW

1. This is a case for declaratory and equitable relief. It challenges Defendant U.S. Environmental Protection Agency's (EPA) denial of Plaintiffs' 2017 legal rulemaking petition, which urged EPA to close the regulatory loophole allowing seeds coated with systemic pesticides (coated seeds) to evade the registration and labeling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Despite the risks to pollinators, birds, and other wildlife, EPA continues to exempt these harmful pesticide products from FIFRA's requirements. As a result of EPA's decision, these pesticides will continue to have significant, adverse effects on wildlife, our environment, and our food system.

2. Congress tasked EPA with the duty to regulate the use of pesticide products to protect public health and the environment. To this end, EPA must ensure that pesticides are properly registered under FIFRA and meet its safety standard. Nevertheless, EPA has decided that coated seeds fall under the Treated Article Exception (TAE), a regulation that exempts certain articles from FIFRA. The agency's conclusion—upon which the rulemaking petition denial is based—is arbitrary and capricious, violating both the APA and FIFRA. Further, the TAE itself as applied to coated seeds is contrary to FIFRA's mandate to protect humans and our environment from unreasonable adverse effects of pesticides.

3. Coated seeds are crop seeds that have been coated with systemic pesticides, primarily neonicotinoids: a class of insecticides with highly toxic effects on birds, bees, butterflies, and other insects and wildlife. Neonicotinoids and other systemic pesticides absorb into the plant's circulatory system as the plant grows. Importantly, these systemic pesticides are predominately intended to have an external pesticidal effect on pests and predators of the growing plant. The growing plant from a coated seed is many thousands of times larger than the seed, and attractive to vastly different non-target wildlife, such as pollinators that are crucial to our food system.

4. Coated seeds are used widely and have devastating environmental impacts. **First**, coated seeds represent the vast majority of all neonicotinoid pesticide uses: in fact, approximately 95% of the land area in the United States treated with any neonicotinoid insecticide is treated via planting coated seeds.[1] **Second**, systemic pesticides spread to all the tissues of plants grown from coated seeds, which is thousands of times larger than the seed, greatly increasing the exposure of non-target species to these toxins. And **third**, it is well known that the pesticide coating does not stay on seeds. Instead, coatings come off the seeds during transport, handling, and planting, and once in the soil, and enter the surrounding environment via dust, residue, and runoff. Overall, as little as 2-3% of the coating is actually taken up by the plant,[2] leaving over 95% in the surrounding environment, contaminating the air, soil, vegetation, and water. Both pathways increase the risk of exposure and serious injury for beneficial insects, pollinators, and birds, including threatened and endangered species. Neonicotinoids have also contributed to the widespread decline of bee populations and other widespread ecological effects, including harm to aquatic life, impacts so severe they are being called a second *Silent Spring*.[3]

5. Despite these devastating adverse impacts, EPA currently exempts coated seeds entirely from FIFRA's pesticide registration requirements. EPA acknowledges that—absent the application of the Treated Article Exemption—these pesticidal seeds meet the

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[1] Petition at 2 (citing Thomas Steeger, Envtl. Fate & Effects Div., Off. of Pesticide Programs, EPA, Presentation: Bee Health in the USA & the Debate About Neonicotinoids 8 (Apr. 11, 2014)).

[2] Christian H. Krupke et al., *Beyond the Headlines: The Influence of Insurance Pest Management on an Unseen, Silent Entomological Majority*, 4 FRONTIER SUSTAINABLE FOOD SYS. 4595855 (2020).

[3] *See, e.g.,* The Editorial Board, *Risking Another Silent Spring*, THE NEW YORK TIMES (Jun. 30, 2014), https://www.nytimes.com/2014/07/01/opinion/risking-another-silent-spring.html; Jason Bittel, *Second Silent Spring? Bird Declines Linked to Popular Pesticides*, NAT'L GEOGRAPHIC (July 9, 2014), https://www.nationalgeographic.com/history/article/140709-birds-insects-pesticides-insecticides-neonicotinoids-silent-spring; George Monbiot, *Ban Neonicotinoids Now – To Avert Another Silent Spring*, THE GUARDIAN (July 15, 2014), https://www.theguardian.com/commentisfree/2014/jul/15/ban-neonicotinoids-another-silent-spring-pesticide-moratorium.

broad definition of "pesticides" in FIFRA and thus would so be regulated.[4] But rather than register coated seeds as pesticide products (which would include an enforceable label with required use limitations and instructions and the mitigation of impacts), EPA asserts that coated seeds fall under the agency's Treated Article Exemption (TAE), 40 C.F.R. §152.25(a); 7 U.S.C. § 136w(b).

6. The TAE reads in full:

> Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

40 C.F.R. §152.25(a).

7. EPA rests its petition denial on the claims that, not only are the seed and plant an "article" under the exception, but the seed and living plant are the exact same article. *See* Petition Denial at 33–35. According to EPA, because a seed (the "article" treated) becomes a living plant, protection beyond the seed itself and the presence of neonicotinoids in the living tissues of the whole plant does not negate the application of the TAE. *Id*. Thus, for EPA's interpretation in the Denial to make logical sense, it would have to equate the seed and the whole plant, as EPA has stated in numerous places that only articles treated for the *sole protection* of the article *itself* may be exempted under the TAE.[5]

8. But the exemption's plain language forecloses this possibility. First, seeds and plants are *living organisms*, not mere "articles" or "substances" under ordinary rules of construction. Indeed, all other TAE substances bear this out: they are all inanimate products, not living flora. Second, if there is any article here, the "article" must be the

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[4] Letter from EPA to Center for Food Safety re: 2017 Petition 29 (Sept. 27, 2022) [hereinafter Petition Denial].

[5] *E.g.*, EPA, *Consumer Products Treated with Pesticides*, https://www.epa.gov/safepestcontrol/consumer-products-treated-pesticides (for antimicrobial consumer products--the biggest category of treated articles--to be exempt, "the sole purpose of treatment is to protect the product itself").

seed, which is substantially different from a whole living *plant*. But because neonicotinoids are primarily applied to coated seeds to protect the growing plant—not the seed—from pests, coated seeds are not treated with pesticides solely to protect the "article," aka the seed. To equate the seed, which is living and part of the larger plant, with a whole living plant that is thousands of times larger, does not find support in either common sense, or the canons of construction. Finally, the vast majority of the seed coating does not remain on the seed and thus does not protect it as a coating as the TAE exemption intends; instead, the coating sloughs off and has vast and devastating impacts on the environment. As a result, EPA's decision to exempt coated seeds under this regulation is arbitrary and capricious.

9. In the alternative, Plaintiffs also bring an as-applied challenge to the TAE as *ultra vires* and arbitrary, capricious, and unlawful. Because FIFRA prohibits EPA from registering any pesticide product with unreasonable adverse effects on the environment, it necessarily follows that EPA cannot exempt products with unreasonable adverse effects on the environment—such as contributing to worldwide bird and bee declines and widespread harm to aquatic organisms—from FIFRA to get around its statutory duties. Coated seeds do not fit the FIFRA exemption for pesticides of a character "not requiring FIFRA regulation," 7 U.S.C. § 136w(b). EPA's exemption is thus contrary to FIFRA. Instead, EPA must ensure that these pesticidal seeds meet the FIFRA safety standard (not causing unreasonable adverse effects as currently used) and require enforceable labeling as with all other pesticides.

10. Because coated seeds are exempted from registration, they also do not carry enforceable labels, which are the law for those using and disposing of pesticides. If EPA regulated coated seeds the way it does any other pesticide, it would be required to assess data specific to coated seeds' impact, rather than merely the active ingredient in the liquid coating products. It would have to weigh the harms of coated seeds, which are massive, and supported by substantial evidence, against their benefits (shown to be minimal or nonexistent) in support of any coated seed product registration. Finally, if

coated seeds were not exempted, they would be counted as pesticides for the various state data collection efforts and investigations of bee kills and other wildlife harms.

11. Notably, this case is not about what the result of EPA's registration process should be, if and when it is properly applied to coated seeds. Rather, this case is only about that EPA must apply that registration process to coated seeds and stop exempting them from it.

12. Accordingly, this Court should declare EPA's petition denial violates the APA and FIFRA and set it aside. It should further order EPA to properly assess and register coated seeds under FIFRA's registration requirements and grant any other relief necessary to remedy the injuries to Plaintiffs and their members.

JURISDICTION

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 (federal question) and 1346 (United States as Defendant).

14. Plaintiffs have a right to bring this action pursuant to the APA. 5 U.S.C. §§ 551–559, 702–706.

15. The relief requested is specifically authorized pursuant to 28 U.S.C. §§ 1651 (writs) and §§ 2201 to 2202 (declaratory relief), as well as under the APA, 5 U.S.C. §§ 701–706. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201 (declaratory judgments).

DIVISIONAL ASSIGNMENT

16. Pursuant to Civil L.R. 3-2(c) and (d), this action should be assigned to the San Francisco Division or the Oakland Division because a substantial part of the events or omissions giving rise to the claim occurred in the county of San Francisco. The Court assigned the prior case, to which Plaintiffs have filed a concurrent motion to relate, *see below*, to the San Francisco Division.

VENUE

17. This Court is the proper venue for this action under 28 U.S.C. § 1391(e) because one or more Plaintiffs reside in this District.

18. Plaintiffs Center for Food Safety and Pesticide Action Network North America filed suit regarding the undue delay in answering the petition that is the subject of this action in this Court on December 14, 2021. *See Center for Food Safety v. U.S. EPA*, No. 21-9640. Accordingly, Plaintiffs are filing a motion to relate this case concurrently with this Complaint.

PARTIES

I. Plaintiffs

19. Plaintiff **Center for Food Safety** (CFS) is a nationwide nonprofit organization headquartered in San Francisco, with offices in Portland, Oregon and Washington, D.C., that aims to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. CFS has over a million members across the country, including many thousands of conservationists, gardeners, farmers, and beekeepers adversely affected by neonicotinoids (neonic) coated seeds. CFS and its members are being, and will be, adversely affected by EPA's continued failure to address the risks from coated seeds. CFS combines myriad tools and strategies in pursuing its goals, including public education, grassroots organizing and campaigns, media, outreach, policy advocacy, and litigation. CFS's member action alerts also generate public education and engagement with governmental officials on issues related to addressing the health and environmental impacts of industrial agriculture, and promoting a healthier, more sustainable food system. Collectively, the dissemination of this material makes CFS an information clearinghouse for public involvement and governmental oversight of all aspects of industrial agriculture, including pesticides.

20. Since its inception twenty-five years ago, CFS has had a flagship program on pesticides and pollinators, with multiple staff dedicated to it: science, policy, campaign, and legal. CFS's pesticide program has long advocated for rigorous, science-based safety testing and proper regulation of new pesticide product uses prior to any use, in a manner that minimizes negative impacts such as the increased use of pesticides and mortality to non-target species and addresses loopholes like the one at issue here. This specifically

has included the issue of neonicotinoids and coated seeds. CFS has commented on numerous agency actions for pesticides, submitted petitions to agencies, and litigated public interest cases to prevent environmental harm.

21. Plaintiff **Pesticide Action Network North America** (PANNA) is a Berkeley, California-based, nonprofit corporation that serves as an independent regional center of Pesticide Action Network International, a coalition of public interest organizations in more than ninety countries. It brings this action on behalf of itself and its members, particularly small-scale farmers, beekeepers, farmworkers, and indigenous members. For nearly thirty years, PANNA has worked to replace the use of hazardous pesticides with healthier, ecologically sound pest management across the United States and around the world. PANNA provides scientific expertise, public education and access to pesticide data and analysis, and policy development and coalition support to more than 100 affiliated organizations in North America. PANNA has more than 50,000 members across the United States. PANNA's members live, work, farm, and recreate in areas of the country adversely affected by coated seeds.

II. Defendants

22. Defendant **U.S. EPA** is the federal agency tasked with administering FIFRA. EPA is responsible for registering all pesticides used in the United States and ensuring compliance with all applicable laws and regulations under FIFRA. As the action agency, EPA must also comply with the ESA's substantive and procedural requirements.

23. Defendant **Michael S. Regan** is the Administrator of EPA. He is responsible for ensuring compliance with all applicable laws and regulations, including FIFRA and the ESA. Plaintiffs are suing Defendant Regan in his official capacity.

LEGAL BACKGROUND

I. FIFRA

24. FIFRA is the statute by which EPA oversees the manufacture, sale, and use of a broad range of chemicals and biological pest controls. 7 U.S.C. §§ 136–136y. FIFRA's

primary purpose is to protect human health and the environment. Pub. L. No. 92-516, 86 Stat. 973 (1972).

25. The main mechanism for regulating pesticides is the pesticide registration process and the resulting label. 7 U.S.C. § 136a(a). Before any pesticide can be used in the United States, EPA must first register the pesticide by issuing a license that provides all the terms and conditions for the lawful sale, distribution, and use of the pesticide. *Id.* § 136a(c). The terms and conditions specify the exact product, as well as its approved uses (e.g., where it can be used, how it can be applied, what crops it can be sprayed on, and mitigation). *See* 40 C.F.R. §§ 152.115, § 156.10.

26. These use instructions and approved uses appear on the label, which is the main way that pesticides are regulated. End users are required by law to follow the label. 7 U.S.C. § 136j(a)(2)(G).

27. In registering pesticides and establishing the subsequent label and use restrictions, the core standard is the "unreasonable adverse effects" standard. That is, EPA applies a cost-benefit analysis "to ensure that there is no unreasonable risk created for people or the environment from a pesticide." *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 522–23 (9th Cir. 2015). That cost-benefit analysis "is the critical determination that the pesticide complies with FIFRA's safety standard." *Nat. Res. Def, Council v. EPA*, 38 F.4th 34, 53 (9th Cir. 2022) (emphasis added). Congress anticipated that EPA's balancing of costs and benefits would "take every relevant factor [the agency] can conceive of into account," S. Rep. 838, 92d Cong. 2d Sess., reprinted in 1972 U.S.C.C.A.N. 3993, 4032, and thus defined "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).

28. FIFRA defines "pesticide" very broadly as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." *Id.* § 136(u)(1). The term "pest" includes insects, bacteria, and microorganisms. *Id.* § 136(t).

Thus, herbicides, fungicides, insecticides like neonicotinoids, rodenticides, and so forth are all subcategories of the broader category of pesticides.

29. EPA may not register a pesticide unless it first determines and supports with substantial evidence that the pesticide "will perform its intended function without unreasonable adverse effects on the environment; and when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C)–(D). An "unreasonable adverse effect on the environment" includes "any unreasonable risk to [people] or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb).

30. In registering pesticides, EPA completes risk assessments for humans and the environment, and then a "cost-benefit" analysis that considers the adverse impacts of the pesticide's use on the broader environment, as well as farmers and the public, before approving pesticides and under what use conditions. EPA must also comply with the Endangered Species Act when it registers a pesticide. 16 U.S.C. § 1536(a)(2); *Wash. Toxics Coal. v. EPA,* 413 F.3d 1024, 1031–32 (9th Cir. 2005).

31. A pesticide is considered unregistered under FIFRA if its claims differ substantially from the claims made for the registered pesticide, or if its composition differs from the composition of the registered pesticide. 7 U.S.C. § 136j(a)(1)(B), (C). A new registration is required for a pesticide containing a new active ingredient or a new use of an existing registered pesticide. 40 C.F.R. § 152.403.

32. FIFRA allows EPA to exempt certain substances that otherwise meet the definition of pesticides, but only in specific enumerated circumstances. Namely, the "Administrator may exempt . . . any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter." 7 U.S.C. § 136w(b).

33. In 1988, EPA implemented regulations establishing the Treated Article Exemption (TAE) pursuant to its FIFRA authority to exempt pesticides "of a character" not requiring FIFRA regulation. 40 C.F.R. § 152.25(a); 7 U.S.C. § 136w(b)). Under the TAE, EPA has determined that "treated articles or substances" "to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified." 40 C.F.R. § 152.25. The TAE defines "treated articles or substances" as "[a]n article or substance treated with . . . a pesticide *to protect the article or substance itself* . . . if the pesticide is registered for such use." *Id.* § 152.25(a) (emphasis added). EPA regulations exemplify this as "paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation." *Id.*

II. APA

34. The APA sets forth the requirements for federal agency decision making, including agency rulemakings. The APA also establishes a right of judicial review to challenge agency action, for "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." 7 U.S.C. § 702.

35. As to judicial review of agency action, under the APA, courts shall "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Id.* § 706(2)(A), (C).

36. To satisfy the APA's requirements for agency decision making, an "agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quotation marks omitted). By contrast, agency action is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that

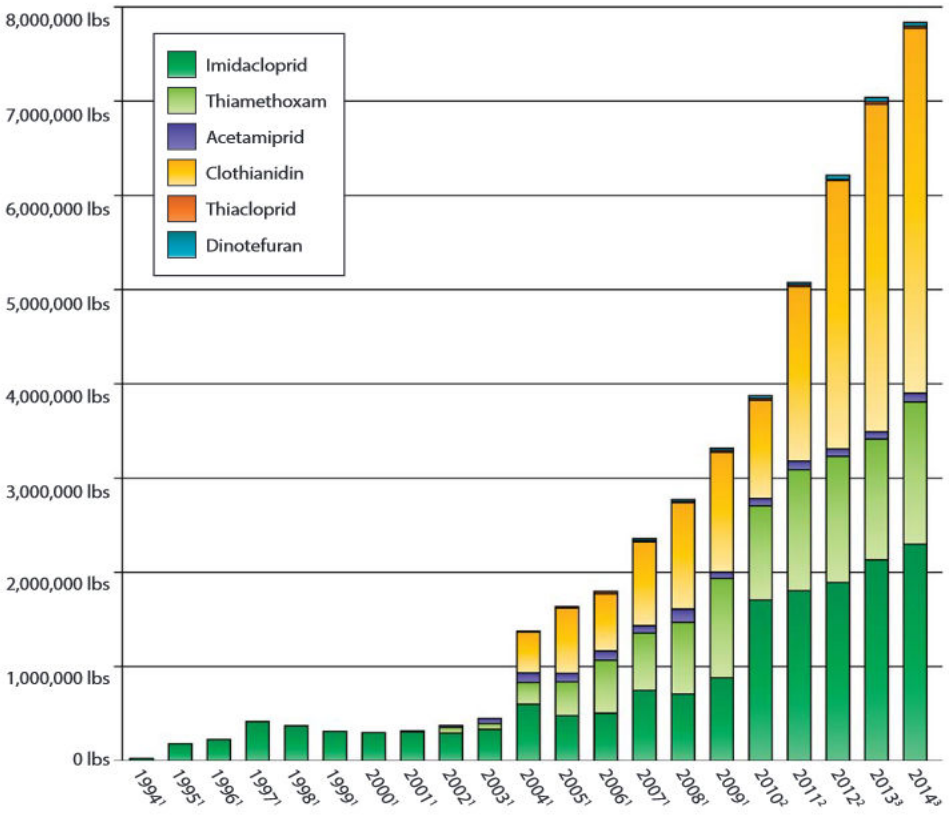
runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id*

FACTUAL BACKGROUND

I. Neonicotinoids

37. Neonicotinoids are a relatively new and potent class of insecticides that kill insects by attacking their nervous systems, resulting in paralysis and death. Introduced in the 1990s, they have already become the most widely used insecticides in the world (see graph below.[6] The three major members of this class are imidacloprid, thiamethoxam and clothianidin, registered by EPA in 1994, 2000 and 2003, respectively.[7]

Estimated Annual Agricultural Use of Neonicotinoids in the United States From 1994 to 2014[8]



[6] Thomas J. Wood & Dave Goulson, *The Environmental Risks of Neonicotinoid Pesticides: A Review of Evidence Post 2013*, 24 ENV'T SCI. POLLUTION RES. 17285, 17285 (2017).

[7] Thomas Steeger, Envtl. Fate & Effects Div., Off. of Pesticide Programs, EPA, Presentation: Bee Health in the USA & the Debate About Neonicotinoids 7 (Apr. 11, 2014))

[8] JENNIFER HOPWOOD ET AL., XERCES SOC'Y FOR INVERTEBRATE CONSERVATION, HOW NEONICOTINOIDS CAN KILL BEES 5 fig.3.2 (2016).

38. Neonicotinoids are primarily coated onto seeds of corn, soybeans, and dozens of other crops, but are also sprayed onto crop foliage or applied directly to soil.

39. Four properties make these insecticides extremely hazardous to beneficial insects and other organisms:

i. First, neonicotinoids are incredibly potent. Ingestion of just 4 billionths of a gram is sufficient to kill a honeybee,[9] while mayfly nymphs are immobilized by four weeks' exposure to the infinitesimal quantity of 30 parts per trillion (ppt) imidacloprid in water.[10]

ii. Second, they are quite resistant to breakdown, and so persist and even accumulate in soil and sediment over years.[11]

iii. Third, neonicotinoids are water-soluble and highly mobile, meaning they are readily moved by rainfall from soil into streams and other surface water, and are also prone to leach into groundwater.[12]

iv. Finally, they are absorbed by young plants and distributed internally throughout their tissues, making the nectar, pollen, and other plant parts highly toxic.

40. Hundreds of scientific studies demonstrate the lethal and multitude of adverse sub-lethal effects of neonicotinoids on honeybees, bumblebees, solitary bees, ground beetles, butterflies, moths, bats, and birds,[13] while increasing evidence also

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[9] See adult acute oral toxicity, 48-hour LD_{50} (a "lethal dose" for 50% of a test population exposed to it for 48 hours) = 0.0037 ug clothianidin per bee per day, equivalent to 3.7 billionths of a gram. EPA, FINAL BEE RISK ASSESSMENT TO SUPPORT THE REGISTRATION REVIEW OF CLOTHIANIDIN & THIAMETHOXAM 32 tbl.1.3 (Jan. 14, 2020), https://www.regulations.gov/search?filter=epa-hq-opp-2011-0865-1164.

[10] See bolded mayfly value of 0.03 ug/liter = 30 parts per trillion, with the corresponding chronic aquatic benchmark set at 10 parts per trillion. EPA, PRELIMINARY AQUATIC RISK ASSESSMENT TO SUPPORT THE REGISTRATION REVIEW OF IMIDACLOPRID 80 tbl.4-8 (Dec. 22, 2016), https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1086.

[11] Dave Goulson, *An Overview of the Environmental Risks Posed by Neonicotinoid Insecticides,* 50 J. APPLIED ECOLOGY 977, 981 fig.2 (2013).

[12] Steeger, *supra* note 7, at 8–9.

[13] *See generally* Wood & Goulson, *supra* note 6.

suggests neonicotinoids directly and indirectly harm fish, amphibians, reptiles, and mammals, including humans.[14]

41. The negative impacts of neonicotinoids on terrestrial and aquatic invertebrates have widespread and long-lasting effects on entire ecosystems, including the loss of food sources and reduced soil nutrient cycling.[15] "The consequences of losing the invertebrate fauna due to continuous exposure to ubiquitous residues of neonicotinoids . . . are thus far reaching and cannot be ignored any longer." *Id.* at 11785.

42. In 2013, the European Union partially banned the outdoor use of imidacloprid, thiamethoxam, and clothianidin with bee-attractive crops due to acute and chronic risks to bees, including colony-level threats.[16] The EU expanded its neonicotinoid ban to all field crops in 2018, based on an exhaustive review by the European Food Safety Authority of the growing evidence that neonicotinoids harm wild pollinators as well as honeybees.[17]

II. Neonicotinoid-Coated Seeds

43. The predominant use of neonicotinoids is the treatment of crop seeds, resulting in a seed coating that often includes fungicides as well. As the seed sprouts and grows into a seedling, the neonicotinoid is absorbed from the seed's surface into the plant and distributed internally to all the plant's tissues via its circulatory system. Because

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[14] J.P. Van der Sluijs et al., *Conclusions of the Worldwide Integrated Assessment on the Risks of Neonicotinoids & Fipronil to Biodiversity & Ecosystem Functioning*, 22 ENV'T. SCI. POLLUTION RES. 148, 151(2015).

[15] *See generally* Lennard Pisa et al., *An Update of the Worldwide Integrated Assessment (WIA) on Systemic Insecticides, Part 2: Impacts on Organisms & Ecosystems*, 28 ENV'T SCI. POLLUTION RES.11749 (2021).

[16] COMMISSION IMPLEMENTING REGULATION (EU) No 485/2013 (May 24, 2013) amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam, and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:139:0012:0026:en:PDF.

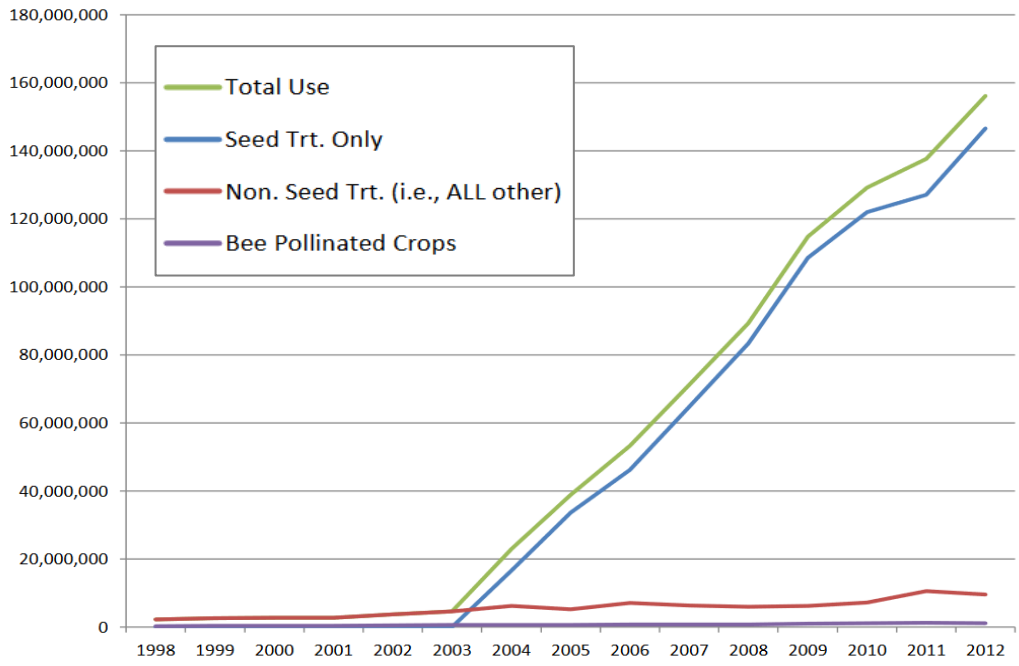
[17] Bill Chappell, *EU to 'Completely Ban' Outdoor Use of Pesticides Blamed for Devastating Bees,* THE TWO-WAY, NAT'L PUB. RADIO (Apr. 27, 2018), https://www.npr.org/sections/thetwo-way/2018/04/27/606355288/eu-to-completely-ban-outdoor-use-of-pesticides-blamed-for-devastating-bees.

neonicotinoids infuse pollen, nectar, sap, leaf, stalk, root and other tissues, insects feeding on virtually any part of the plant are poisoned.

44. In the U.S., dozens of crops are grown from neonicotinoid-treated seed, including corn, soybeans, wheat, canola, potatoes, sunflowers, cotton, and numerous vegetables.[18]

45. Overall, neonicotinoid-coated seeds were planted on 147 million acres of crops in 2012, *nearly half of all the cultivated cropland* in the United States,[19] versus just 10 million acres treated in other ways with these insecticides (see graph below). From 2012 to 2014, at least 90% of corn (approximately 81 of 90 million acres) was grown from coated seeds.[20]

Total U.S. Neonic Treated Acreage From 1998 to 2012[21]



[18] According to EPA, thiamethoxam, clothianidin, and imidacloprid are registered for seed treatment use on 102, 61, and 39 crops, respectively. *See* CFS, Comments on Draft Biological Evaluations for Neonicotinoid Insecticides Clothianidin, Imidacloprid, & Thiamethoxam, 2 (Oct. 25, 2021) [hereinafter CFS Comments on Draft Neonic BEs].

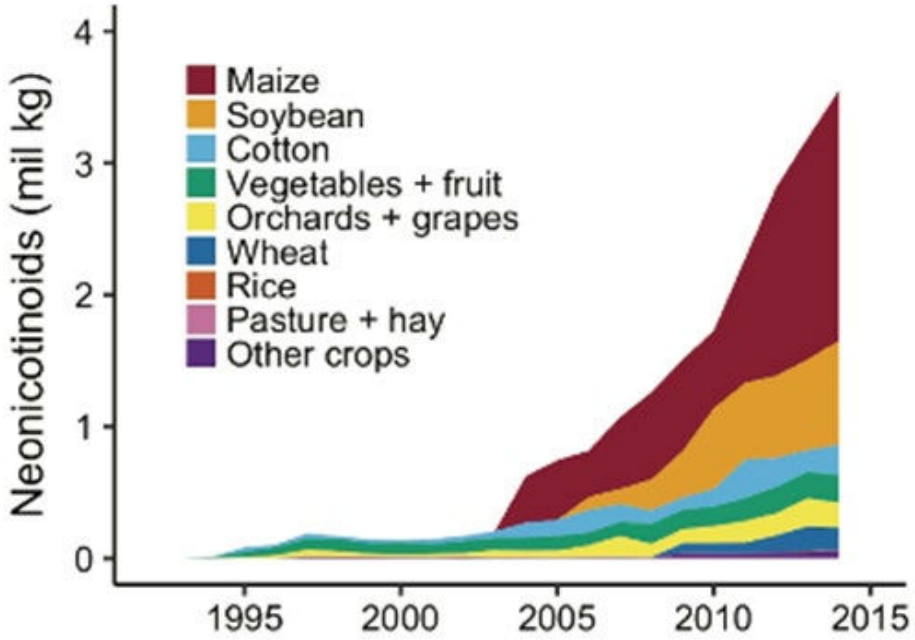
[19] In 2012, there was 310.2 million acres of cultivated cropland in the United States. U.S. DEPT. OF AGRIC. (USDA), NAT. RES. CONSERVATION SERV. (NRCS), 2017 NATIONAL RESOURCES INVENTORY: SUMMARY REPORT 2–3 (2020).

[20] *See* Claudia Hitaj et al., *Sowing Uncertainty: What We Do and Don't Know about the Planting of Pesticide-Treated Seed*, 70 BIOSCIENCE 390, 393 (2020).

[21] Steeger, *supra* note 7, at 8.

46. Corn, soybeans, wheat, and cotton represent 88% of total neonicotinoid use by weight, nearly all applied as coatings to seed (see graph below).[22]

Neonicotinoid Use By Crop From 1992 to 2014[23]



47. Importantly, this massive use of coated seeds is *not* in response to pest outbreaks. And dozens of studies have demonstrated that coated seeds provide little or no yield or economic benefit in corn, soybeans, canola, beans, wheat and other crops.[24] Even an EPA study concluded that neonicotinoid seed treatments "provide *negligible overall benefits* to soybean production in most situations," while 74% of agricultural experts surveyed by EPA as to how neonicotinoid seed coatings affect soybean yield responded that yield either stayed the same or decreased.[25]

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[22] U.S. GEOLOGICAL SURVEY, *Pesticide National Synthesis Project*: *1992-2019 State-Level Crop Group Dataset*, https://water.usgs.gov/nawqa/pnsp/usage/maps/county-level/.

[23] John F. Tooker et al., *Neonicotinoid Seed Treatments: Limitations & Compatibility With Integrated Pest Management*, AGRIC. & ENV'T LETTERS, Oct. 19, 2017, at 3.

[24] Peer-reviewed studies reviewed in: S. STEVENS AND P. JENKINS, CFS, HEAVY COSTS: WEIGHING THE VALUE OF NEONICOTINOID INSECTICIDES IN AGRICULTURE (Abigail Seiler & Larissa Walker 2014) [hereinafter HEAVY COSTS]; P. JENKINS, CFS, NET LOSS: ECONOMIC EFFICACY & COSTS OF NEONICOTINOID INSECTICIDES USED AS SEED COATINGS: UPDATES FROM THE UNITED STATES & EUROPE (Larissa Walker & Courtney Sexton 2016).

[25] CLAYTON MYERS & ELIZABETH HILL, EPA, BENEFITS OF NEONICOTINOID SEED TREATMENTS TO SOYBEAN PRODUCTION 1, 9 (Oct. 15, 2014) (emphasis added).

48. According to agronomists, the reasons for this lack of benefit are two-fold. First, the pests targeted by seed treatments (e.g., wireworms, cutworms, bean leaf beetles) are sporadic in time and space, and rarely cause significant damage even when they are present. Second, seed treatments simply do not help for later-season pests like soybean aphids, because the neonicotinoid coating has dissipated from plant tissues by the time the pests attack in the summer.[26]

49. That most seed coatings represent unnecessary environmental pollution across tens of millions of cropland acres is also demonstrated historically. Well under 50% of corn and 10% of soybean acres were treated with insecticides each year from the 1950s to 1990s; yet since 2012, at least 90% of corn and 76% of soybeans have been grown from treated seed.[27]

50. Thus, in most cases seed coatings are used prophylactically, violating a fundamental tenet of Integrated Pest Management (IPM) principles of agriculture: apply a pesticide only if a pest is present at economically damaging levels.[28] IPM approaches involving uncoated seeds and pesticide applications on a strictly "as needed" basis can increase yield while sharply reduce overall pesticide use.[29]

51. The widespread deployment of neonicotinoid seed coatings reflects neither pest management needs nor farmer choice. In fact most crop seeds are pretreated with neonicotinoids by the pesticide manufacturer or seed dealer, making it difficult for farmers to obtain untreated seed.[30] One survey showed 21% of corn and 15% of soybean farmers would reduce or eliminate neonicotinoid seed treatments if the seed variety they

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[26] Tooker et al., *supra* note 23, at 3; Wayne Bailey et al., *The Effectiveness of Neonicotinoid Seed Treatments in Soybea*n 2 (2015).

[27] Hitaj et al., *supra* note 20, at 391–93.

[28] Jason R. Pecenka et al., *IPM Reduces Insecticide Applications by 95% While Maintaining or Enhancing Crop Yields Through Wild Pollinator Conservation*, PNAS USA, Oct. 25, 2021, at 1, 4.

[29] *See generally id.*; *see also* HEAVY COSTS, *supra* note 24, at 10.

[30] Myers & Hill, *supra* note 25, at 11–12 (noting that 9 out of 20 soybean experts surveyed by EPA indicated that soybean seed *not* treated with neonicotinoids is either "difficult to obtain" (8 experts) or "not available" (1 expert)).

wanted were available untreated.[31] Farmers have far less knowledge about the pesticides coating their seeds when they buy them, or what purpose they might serve, as compared to the pesticides they apply in the field.[32] Despite this evidence, in the Petition Denial (at 16) and elsewhere, EPA assumes seed treatments are "chosen" by farmers.[33]

A. Labeling and Seed Bags/Tags

52. EPA currently requires labels to be placed onto bags or other seed containers or affixed to the tags of these unregistered coated seeds, via the label of the liquid coating pesticide products.

53. As EPA states in the Petition Denial: "the seed bag tag labeling is the primary means by which instructions are communicated to downstream distributors, sellers, and users, typically the farmers, of such treated seed." Petition Denial at 2.

54. While these seed bag or container labels include sparse warnings superficially aimed at protecting pollinators and other environmental values, they have proved utterly inadequate to reduce or mitigate the harm caused by contaminated neonic dust, the grown plants themselves, or the disposal of coated seeds.

55. Most importantly, as EPA acknowledges in its Petition Denial, these seed bag labels are legally *unenforceable* because they are not "pesticide labels." Petition Denial at 41. EPA maintains that while the use of those coated seeds inconsistent with the bag tags would mean that the "treated article, *i.e.*, the treated seed, does not meet the 'registered for such use' criterion and the exemption does not apply," nonetheless "EPA agrees with the Petition that it is this misuse of an unregistered pesticide that is *not currently enforceable under FIFRA section 12*." *Id.* (emphasis added).

56. As stated in the Petition, the lack of enforceable labels on seed bags not only fails to ensure safe use by farmers but also impacts how regulators investigate and respond to incidents like bee kills. Petition at 29–30.

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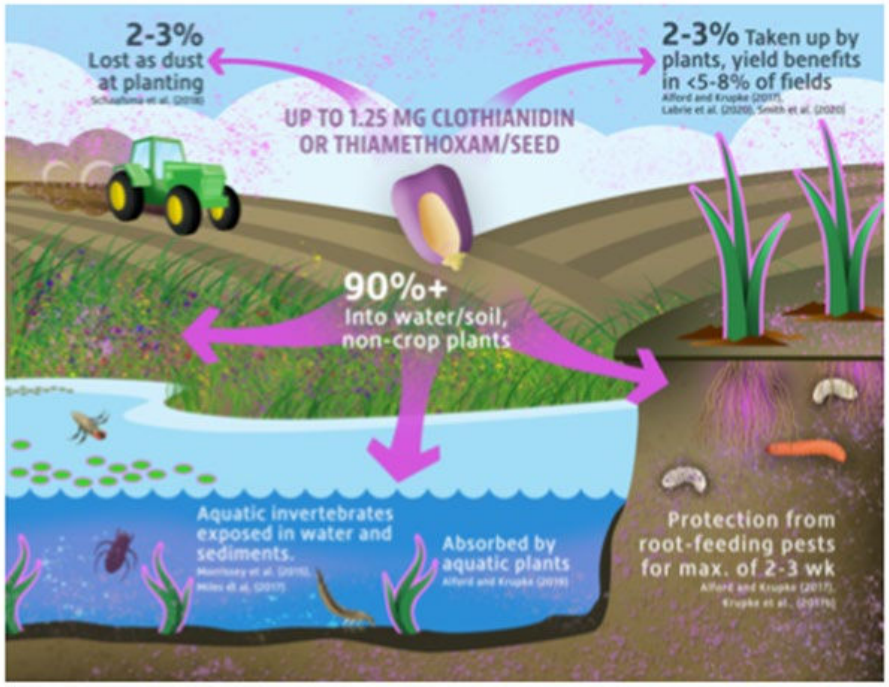
[31] Hitaj et al., *supra* note 20, at 399.
[32] *Id.* at 399–400.
[33] CFS Comments on Draft Neonic Bes, *supra* note 18. EPA failed to correct its error in the final biological evaluations.

57. Thus, in practice, use of coated seeds contrary to the seed bag and tags is not a substitute for registration—in fact has no legal or practical consequences under FIFRA—nor do the seed bag tags offer any protection from the adverse impacts of coated seeds.

B. Environmental Effects

58. Over 95% of the neonicotinoids in seed coatings are typically lost to the environment. In the case of corn, 2-3% of the coating is shorn off the seed into the talc or other lubricant used to prevent seeds from sticking in the planting box. This toxic seed dust is then expelled and broadcast across the landscape (see figure below). Once in the ground, the growing seedling absorbs as little as 2-3% of the neonicotinoid coating, while the remaining >95% disperses in soil water and then runs off into waterways or leaches into groundwater. Coated seeds not sufficiently covered by soil, as often occurs, are consumed by foraging birds, and disposal of surplus coated seeds also pollutes the environment, as discussed further below.

Schematic Representation of the Environmental Fate & Transport of Neonicotinoid Active Ingredients Applied to Crop Seeds[34]



[34] Krupke et al , *supra* note 2, at 3.

1. Impacts to Pollinators and Other Land-Based Beneficial Insects

59. Many beekeepers have observed toxic dust clouds billowing from seed planting machines, spreading neonicotinoids into integral bee habitat. Honeybee kill incidents caused by coated seeds have numbered in the hundreds and the true number is likely far higher.[35] These incidents have killed hundreds of millions of individual bees due to acute dust-off events. Sublethal doses can result in honeybee colony damage through compromising the behavior and immunity of bees,[36] and the health of entire colonies, contributing to substantial losses under the additional stress of pathogens and parasites.[37] Despite these studies finding neonicotinoids exacerbate the impact of parasites, EPA instead relies upon mistaken information about honeybee pathogens from USDA agricultural economists,[38] and offers no explanation for the 32% drop in honey production per colony since the turn of the century (Petition Denial at 17).

60. Neonicotinoids are such incredibly potent bee-killers that their broad-scale proliferation via seed coatings has dramatically increased the overall toxicity of U.S. agriculture over the past several decades. "Insect toxic load"—a metric that adjusts the amount of insecticides used by their acute oral lethality to honey bees—increased nine-fold from just 1997 to 2012 (see graph below).[39]

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[35] Petition at 21; *see generally* Christina H. Krupke et al., *Multiple Routes of Pesticide Exposure for Honey Bees Living Near Agricultural Fields*, 7 PLoS ONE e29268 (2012).

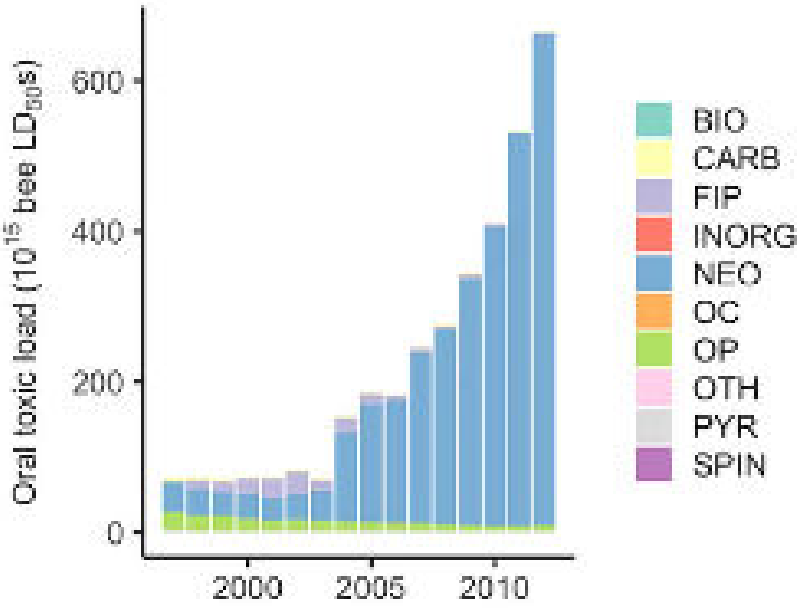
[36] John Bryden et al., *Chronic Sublethal Stress Causes Bee Colony Failure*, 16 Ecology Letters 1463, 1463 (2013); Nadejda Tsvetkov et al., *Chronic Exposure to Neonicotinoids Reduces Honey Bee Health Near Corn Crops*, 356 Science 1395 (2017).

[37] *See generally* Claudia Dussaubat et al., *Combined Neonicotinoid Pesticide & Parasite Stress Alter Honeybee Queens' Physiology & Survival*, 6 Sci. Rep. 31430 (2016); Julia Grassl et al., *Synergistic Effects of Pathogen & Pesticide Exposure on Honey Bee (Apis Mellifera) Survival & Immunity*, 159 J. Invertebrate Pathology 78086 (2018).

[38] Petition Denial at 16–17 (citing study at n.51 for 2006 as the year the fungal parasite *Nosema cerenae* was first detected in the U.S., when in fact *Nosema ceranae* was first detected in 1995, the year after the first neonicotinoid, imidacloprid, was introduced. *See* Francisco Sanchez-Bayo et al., *Are Bee Diseases Linked to Pesticides? A Brief Review*, 89-90 Env't Int'l 7, 8 (2016) (citing Chen et al. 2008)).

[39] Margaret R. Douglas et al., *County-Level Analysis Reveals A Rapidly Shifting Landscape of Insecticide Hazard to Honey Bees*, 10 Sci. Reps. 797 at 3 fig.2c (2020).

National Trends in Weight & Toxicity Basis By Insecticide Class From 1997 to 2012[40]



61. The main driver of this trend is coatings on corn and soybean seeds, crops that had previously *not* been extensively treated with insecticides of any sort (*supra*).[41] Because of their extremely high potency, as well as the vast extent of use (roughly 150 million acres), by 2012 neonicotinoids alone comprised 98% of oral insect toxic load, while all other insecticides combined represented just 2% (see graph above). The most dramatic increases occurred in the Heartland (121-fold increase) and the Northern Great Plains (53-fold increase), where the majority of corn and soybeans, overwhelmingly treated with neonicotinoids, are grown.

62. Non-commercial native bees are also highly exposed to neonicotinoids,[42] which are not only found in crops grown from treated seeds but are also widely detected in the nectar and pollen of wild plants.[43] Crucially, unlike commercial bees, native bees

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[40] *Id.*

[41] Margaret R. Douglas & John F. Tooker, *Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides & Preemptive Pest Management in U.S. Field Crops*, 49 ENV'T SCI. & TECH. 5088 (2015).

[42] U.S. GEOLOGICAL SURV., *Native Bees Are Exposed to Neonicotinoids & Other Pesticides* (Nov. 4, 2015), https://www.usgs.gov/programs/environmental-health-program/science/native-bees-are-exposed-neonicotinoids-and-other.

[43] Cristina Botias et al., *Contamination of Wild Plants Near Neonicotinoid Seed-Treated Crops, & Implications for Non-Target Insects*, 566 SCI. OF TOTAL ENV'T 269, 271 (2016).

are mostly ground nesting bees, and thus exposed to neonicotinoid contamination of soil, as well as water and crop and non-crop plants.

63. In an article published in *Science*, researchers found that bumblebee colonies foraging on crops grown from treated seed grew more slowly and suffered an 85% reduction in production of new queens.[44] Another study in *Nature* similarly revealed reductions in bumblebee colony growth and reproduction, and reductions in wild bee density and nesting, in and around rape (canola) grown from neonicotinoid-treated seed.[45] Dozens of studies confirm the lethal and sublethal impacts of neonicotinoids to native bees,[46] including one that found neonicotinoid-treated canola seed is a key factor in the extinction of wild bee species in the United Kingdom.[47]

64. Bumblebees are far more vulnerable than honeybees to the harms of neonicotinoids, and EPA's honeybee-focused assessment scheme misses critical factors, such as the exposure of these ground-nesters to soil contaminated by neonicotinoid seed coatings, and the fact that bumblebee queens are exposed to neonicotinoids while foraging, unlike non-foraging honeybee queens.[48]

65. In fact, most wild bees are solitary, meaning that loss of a single nesting adult would have far more dire consequences for the population than death of an individual honeybee, whose loss is buffered by the large number and efficient reproduction of other workers in large honeybee colonies. Petition at 22–23. Also, species such as bumblebees, ground-nesting mining bees, alkali bees, squash bees, and long-horned sunflower bees are devastated by repeated, persistent use of coated seeds. Adverse impacts to other species of native bees that are not ground nesters have also

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[44] Penelope R. Whitehorn et al., *Neonicotinoid Pesticide Reduces Bumble Bee Colony Growth & Queen Production*, 336 SCI. 351, 351 (2012).

[45] Maj Rundlof et al., *Seed Coating With A Neonicotinoid Insecticide Negatively Affects Wild Bees*, 521 NATURE 77, 77–79 (2015).

[46] *See generally* Wood & Goulson, *supra* note 6.

[47] Ben Woodcock et al., *Impacts of Neonicotinoid Use on Long-Term Population Changes in Wild Bees in England*, NATURE COMMS., Aug. 2016, at 1–2.

[48] Kimberly A. Stoner, *Current Pesticide Risk Assessment Protocols Do Not Adequately Address Differences Between Honey Bees (*Apis Mellifera*) & Bumble Bees (*Bombus Spp.*)*, FRONTIERS IN ENV'T SCI., Dec. 2016, at 2–4.

been identified through exposure routes such as contamination of nesting materials. The harm to pollinators harms U.S. agriculture, which relies on wild and managed pollinators alike to pollinate food crops.

66. And it is not only pollinators that are impacted. Slugs that consume neonicotinoid-coated soybean seeds and seedlings take the insecticide into their tissues; while they are unaffected, beneficial predatory ground beetles that prey upon them are killed, resulting in higher slug populations that lower soybean yield.[49] More broadly, a meta-analysis found that seed-applied neonicotinoids reduced the abundance of "natural enemies" (beneficial insects that prey upon pests).[50] Beneficial insects that are negatively impacted include pink lady beetles and parasitoid wasps.[51]

2. Impacts to Aquatic Organisms

67. Because neonicotinoids are water soluble, they increasingly contaminate our nation's streams and rivers,[52] and leach into groundwater (including private drinking water wells).[53]

68. Neonicotinoids are frequently detected in streams of the Midwest,[54] where the predominant use of these compounds by far is to coat corn and soybean seeds.

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[49] Margaret R. Douglas et al., *Neonicotinoid Insecticides Travels Through a Soil Food Chain, Disrupting Biological Control of Non-Target Pests & Decreasing Soya Bean Yield*, 52 J. APPLIED ECOLOGY 250, 251 (2014).

[50] Margaret R. Douglas & John F. Tooker, *Meta-Analysis Reveals That Seed-Applied Neonicotinoids & Pyrethroids Have Similar Negative Effects on Abundance of Arthropod Natural Enemies*, PEER J., 2016, at 3.

[51] JENNIFER HOPWOOD ET AL., XERCES SOC'Y FOR INVERTEBRATE CONSERVATION, BEYOND THE BIRDS AND THE BEES: EFFECTS OF NEONICOTINOID INSECTICIDES ON AGRICULTURALLY IMPORTANT BENEFICIAL INVERTEBRATES 9–10 (2013).

[52] ENV'T HEALTH PROGRAM, U.S. GEOLOGICAL SURV., *First National-Scale Reconnaissance of Neonicotinoid Insecticides in United States Streams* (Aug. 18, 2015), https://www.usgs.gov/programs/environmental-health-program/science/first-national-scale-reconnaissance-neonicotinoid.

[53] U.S. GEOLOGICAL SURV., *Prevalence of neonicotinoid insecticides in paired private-well tap water and human urine samples in a region of intense agriculture overlying vulnerable aquifers in eastern Iowa* (Feb. 4, 2023), https://www.usgs.gov/publications/prevalence-neonicotinoid-insecticides-paired-private-well-tap-water-and-human-urine.

[54] *See generally* Michelle L. Hladik et al. *Widespread Occurrence of Neonicotinoid Insecticides in Streams in a High Corn & Soybean Producing Region*, USA, 193 ENV'T

Supra. Thus, the source of this stream contamination is a combination of neonicotinoid-contaminated seed dust and runoff carrying some portion of the 95% or more of the neonicotinoid coating that is not absorbed by the plant into waterways.

69. Aquatic invertebrates are especially sensitive to neonicotinoids, suffering both lethal and sublethal impacts at extremely low concentrations that have been exceeded in waterways around the world.[55] For instance, the abundance of mayflies (whose larvae are aquatic) in the Upper Mississippi River and Western Lake Erie Basin declined by over 50% from just 2012 to 2019, a phenomenon the scientists link to the year-round contamination of ten Great Lakes tributaries with neonicotinoid insecticides at concentrations up to 40 times higher than EPA's chronic safety threshold.[56] Like many insects, mayflies are an important resource for fish and birds, and also make significant contributions to nutrient cycling.[57]

3. Impacts to Birds

70. Bird species are being exposed to and harmed by coated seeds.[58] A major review by the American Bird Conservancy (ABC Report) stated that a *single* corn kernel treated with any of the common neonicotinoids could kill a songbird and just one-tenth of

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POLLUTION 189 (2014); *see also* U.S. GEOLOGICAL SURV., *Neonicotinoid Insecticides Documented in Midwestern U.S. Streams* (Jul. 21, 2014), https://www.usgs.gov/programs/environmental-health-program/science/neonicotinoid-insecticides-documented-midwestern-us.

[55] Christy A. Morrissey et al., *Neonicotinoid Contamination of Global Surface Waters & Associated Risk To Aquatic Invertebrates: A Review*, 74 ENV'T INT'L 291, 292 (2015); *see generally* CFS, WATER HAZARD: AQUATIC CONTAMINATION BY NEONICOTINOID INSECTICIDES IN THE UNITED STATES (2015); *see generally* CFS, WATER HAZARD 2.0: CONTINUED AQUATIC CONTAMINATION FROM NEONICOTINOID INSECTICIDES (2017); U.S. GEOLOGICAL SURV., *Ecological Consequences of Neonicotinoid Mixtures in Streams* (Apr. 13, 2022), https://www.usgs.gov/publications/ecological-consequences-neonicotinoid-mixtures-streams.

[56] Phillip M. Stepanian et al., *Declines in an Abundant Aquatic Insect, The Burrowing Mayfly, Across Major North American Waterways*, 117 PNAS 2987, 2989–90 (2020); *see generally* Michelle L. Hladik et al., *Year-Round Presence of Neonicotinoid Insecticides in Tributaries to the Great Lakes*, USA, 235 ENV'T POLLUTION 1022 (2018).

[57] Stepanian et al., *supra* note 56, at 2989.

[58] PIERRE MINEAU & CYNTHIA PALMER, AM. BIRD CONSERVANCY, THE IMPACT OF THE NATION'S MOST WIDELY USED INSECTICIDES ON BIRDS 5–9 (2013) [hereinafter ABC Report].

a treated corn kernel is enough to adversely affect a songbird's reproduction. Petition at 16 (citing ABC Report).

71. Small to medium-sized birds are at risk of death from consuming *just one to four small seeds* of crops like sorghum or wheat, a credible risk given shallow planting and many birds' predilection for energy-rich seeds.

72. Birds can also be harmed by eating neonicotinoid-intoxicated organisms like insects, slugs, or earthworms.

73. In addition to bird deaths from ingesting neonicotinoid-coated seeds, research has demonstrated sublethal effects in songbirds, such as reduced body fat and disorientation, which can reduce migration survival as well as reproduction, with the potential for population-level impacts.[59]

74. Also of great concern are neonicotinoids' indirect impacts on birds via reducing populations of their insect prey, thus depriving them of food resources.[60] Scientists in The Netherlands documented significantly sharper declines in insect-eating bird populations from 2003 to 2010 in areas with higher surface-water concentrations of imidacloprid, trends which only began in the mid-1990s, coincident with the 1994 introduction of imidacloprid.[61]

4. *Impacts to Humans*

75. Humans are increasingly exposed to neonicotinoids through the food supply and drinking water.[62] Neonicotinoids have been found in fruits such as apples, cherries, and strawberries, as well as honey and baby food. Neonicotinoids are ubiquitous in surface waters and may be contaminating aquifers. Human urine samples from 2015 and

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[59] Margaret L. Eng et al., *A Neonicotinioid Insecticide Reduces Fueling & Delays Migration in Songbirds*, 365 NATURE 1177, 1177–79 (2019); Margaret L.Eng et al., *Imidacloprid & Chlorpyrifos Insecticides Impair Migratory Ability in a Seed-Eating Songbird*, SCI. REPORTS, 2017, at 2–3

[60] Dave Goulson, *Pesticides Linked to Bird Declines*, 511 NATURE 295 (2014).

[61] Caspar A. Hallmann et al., *Declines in Insectivorous Birds Are Associated with High Neonicotinoid Concentrations*, NATURE, 2014, at 1.

[62] *See* Letter from Environmental Health Scientists and Health Professionals to EPA (Jan. 14, 2020), https://www.nrdc.org/sites/default/files/letter-wheeler-neonic-pesticides-20200114.pdf.

2016 show that at least half the U.S. population over three years of age was exposed to neonicotinoids.[63]

76. Incident reports from EPA itself show acute poisoning from non-agricultural uses of neonicotinoids. The symptoms are consistent with clinical signs and symptoms of poisoning by a neurotoxic agent.[64]

77. There are also major chronic toxicity concerns. Epidemiological studies have found suggestive evidence that neonicotinoid exposure may be linked to developmental or neurological effects including malformations of the developing heart and brain, autism spectrum disorder, and a cluster of symptoms including memory loss and finger tremors, and further research is required to fully understand the spectrum of potential health harms. *Id.* There is also persuasive evidence from animal[65] and cell culture[66] studies that imidacloprid is an endocrine disruptor that potentiates the obesity-promoting and insulin-resistance effects of a high-fat diet, thus contributing to one of the most daunting human health challenges of the 21st century: the epidemic of type II diabetes. Coated seeds have facilitated the increased use and spread of neonicotinoids through the environment, heightening the risks to humans as well as the environment.

5. *Harm From Disposal of Coated Seeds*

78. Pesticide labels include protective instructions on proper disposal of the pesticide as well. However, as discussed *supra* given the lack of enforceable or adequate labeling of coated seeds due to their exemption from registration, their disposal is unregulated under FIFRA. This has played out in at least one horrendous, ongoing public

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[63] Maria Ospina et al., *Exposure To Neonicotinoid Insecticides in the U.S. General Population: Data From the 2015-2016 National Health & Nutrition Examination Survey*, ENV'T RSCH., Sept. 2019, at 10.

[64] *See* Letter to EPA, *supra* note 62, at 2.

[65] *See generally* Quancai Sun et al., *Imidacloprid Promotes High Fat Diet-Induced Adiposity & Insulin Resistance in Male C57BL/6J Mice*, 64 J. AGRIC. FOOD CHEMICALS 9293 (2016).

[66] *See generally* Yooheon Park et al., *Imidacloprid, A Neonicotinoid Insecticide, Potentiates Adipogenesis in 3T3-L1 Adipocytes*, 61 J. AGRIC. FOOD CHEMISTRY 255 (2013).

health and environmental crisis, and major questions remain as to how neonicotinoid coated seeds are disposed under the EPA's exemption.

79. Recently a whole community suffered from this unregulated disposal of coated seeds. In Nebraska, a bioethanol company (AltEn, LLC) fed surplus neonicotinoid coated corn seeds into its bioethanol plant, resulting in water and soil polluted with neonicotinoids at levels posing serious health threats to people and animals in Mead and greater Saunders County.[67] Mead is a town of 569 about 40 miles north of Lincoln and home to the AltEn plant, which opened in 2015.

80. Between 2015 and 2021, people in and around Mead reported terrible odors, eye and throat irritation, sneezing, coughing, and nosebleeds. Pet dogs grew ill, staggering about with dilated pupils. Residents even found themselves with rare infections and other ongoing health problems. [68]

81. One resident's dogs became violently ill after consuming material spread on fields near her home in spring 2018, material which she later discovered was a byproduct of the ethanol production process sold to farmers by the AltEn plant. *Id*.

82. The impact on bees and other pollinators was devastating, with colonies of bees dead, and birds and butterflies afflicted with neurological damage. Beekeeper Judy Wu-Smart found that every hive she deployed at the Eastern Nebraska Research and Extension Center near Mead since 2017—36 in all, each with between 40,000 and 60,000 bees—had collapsed. Wu-Smart found clothianidin residues on milkweed leaves she

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[67] Carey Gillam, *'There's a Red Flag Here': How an Ethanol Plant is Dangerously Polluting a US Village*, THE GUARDIAN (Jan. 10, 2021), https://www.theguardian.com/us-news/2021/jan/10/mead-nebraska-ethanol-plant-pollution-danger; Chris Dunker, *'Chemicals don't just disappear' — Persistence by researchers, residents uncovers pesticide contamination at Mead plant*, LINCOLN J. STAR (Feb. 7, 2021), https://journalstar.com/news/local/chemicals-dont-just-disappear-persistence-by-researchers-residents-uncovers-pesticide-contamination-at-mead-plant/article_8d31dc75-dcdf-5ed5-b263-c4e158b4a11c.html#tracking-source=home-top-story; *see also*, *Bad Seed: Mead's fight against a toxic ethanol plant* (Nov. 19. 2021), https://journalstar.com/search/?nsa=eedition&app=editorial&d1=&d2=&s=start_time&sd=desc&l=25&t=article%2Cvideo%2Cyoutube%2Ccollection&q=bad+seed+mead&d1=&d2=.

[68] Dunker, *supra* note 67.

sampled from a nearby waterway ranging from 3,000 to 5,700 parts per billion, the highest level ever collected from natural field vegetation and hundreds of times higher than the levels known to affect honeybees. *Id*.

83. Tests on the "soil conditioner" sold by the plant to local farmers revealed clothianidin levels as high as 427 parts per million (for comparison, the highest clothianidin residue level permitted on pome fruit, e.g., apples, is just 1 part per million). *Id*.[69] As reported in the Lincoln Journal Star, "At those levels, the byproduct sold by AltEn was being applied at the suggestion of an agronomist to area farm ground at more than *85 times* the maximum recommended by the seed company, according to the state Ag Department's report."[70]

84. The plant's wastewater lagoon contained clothianidin at the astronomical level of 31,000 parts per billion, which is 620,000 times higher than EPA's aquatic life benchmark for chronic effects to invertebrates (0.05 ppb), as well as ultra-high levels of thiamethoxam (24,000 ppb) and imidacloprid (312 ppb), both more than 30,000 times higher than their respective aquatic life benchmarks.[71]

85. The Nebraska Department of Agriculture said it could do little to address the harm to bees, because pollinator protection laws are for misuse of a *pesticide*, which of course this was not, because of EPA's exemption for coated seeds. This is the same enforcement problem that beekeepers routinely face when dust-off events kill massive numbers of their bees.

86. Residents who reported the debacle to EPA said the agency's response was that it could not do anything about the problem.[72] Specifically, EPA cited its own Treated

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[69] 40 C.F.R. § 180.586. Tolerances for thiamethoxam are much lower. *Id*. § 180.565.

[70] Dunker, *supra* note 67.

[71] Gillam, *supra* note 67; *see also* EPA, *Aquatic Life Benchmarks & Ecological Risks Assessments for Registered Pesticides*, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/aquatic-life-benchmarks-and-ecological-risk.

[72] Chris Dunker, *Public Records Reveal Frustration as State Sought to Deal with Pesticide Dangers From Ethanol Plant*, LINCOLN J. STAR (Nov. 21, 2021), https://journalstar.com/news/state-and-regional/nebraska/public-records-reveal-frustration-as-state-sought-to-deal-with-pesticide-dangers-from-ethanol-plant/article_60cc64ea-0e7b-5081-8148-d453be8cce90.html.

Article Exemption as why the agency had no authority to do anything about the disposal of coated seeds for ethanol production, which is specifically allowed on EPA's seed bags/tags. *Id.* It was only due to investigative journalism and community action that state regulators and legislators finally acted, closing the ethanol plant and requiring cleanup, and passing a law outlawing the use of coated seeds in ethanol production if the byproducts could not be consumed by livestock or applied to farmland. *Id.*

87. Now that AltEn and the other ethanol manufacturer that accepted coated seeds have shut down, it is unclear where seed companies are sending this toxic seed waste.[73]

III. EPA's (Lack of) Oversight of Neonicotinoid-Coated Seeds

88. EPA regulates neonicotinoid insecticides under FIFRA's pesticide registration program for individual active ingredients and pesticide products containing them. However, EPA does not currently *regulate seeds that have been coated* in neonicotinoids.

89. As explained below, this is a major regulatory gap because neonicotinoid-coated seeds fall plainly within FIFRA's broad definition of "pesticide," which includes not just sprayed or granular pesticides but "*any substance* or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 7 U.S.C. § 136(u)(1) (emphasis added). Thus, because coated seeds are "pesticides" under FIFRA's broad definition, EPA must properly review and approve these products before they can be sold or used in the United States.

90. Further, because FIFRA prohibits EPA from registering any pesticide product with unreasonable adverse effects on the environment, it necessarily follows that EPA cannot *exempt* products with unreasonable adverse effects on the environment (such as contributing to worldwide bee and bird declines and harm to aquatic life across the country) from FIFRA to get around its statutory duties.

[73] Lisa Held, *When Seeds Become Toxic Waste*, CIVIL EATS (Apr. 5, 2022), https://civileats.com/2022/04/05/when-seeds-become-toxic-waste/.

91. As explained below, EPA's current regulatory regime for just the liquid neonicotinoid and systemic pesticide coatings is wholly insufficient for assessment or mitigation of the adverse effects of coated seeds. And the lack of enforceable labels that would otherwise be present on a registered pesticide under FIFRA handcuffs EPA and states, preventing regulatory authorities from establishing and enforcing meaningful rules to prevent or at least mitigate the devastating harms caused by coated seeds.

A. Treated Article Exemption

92. Instead of registering coated seeds as pesticide products under FIFRA, EPA improperly claims that these products are exempt from FIFRA's pesticide registration requirements under its Treated Article Exemption (TAE), 40 C.F.R. § 152.25(a). *See* Petition Denial at 2.

93. EPA issued the TAE in 1988. Neither the text of the regulation or the accompanying Federal Register notice mentioned pesticide-coated seeds. Nor could EPA fully consider the effects of these seeds when it promulgated this exemption because neonic coated seeds were not widely used in agriculture until the early 2000s.

94. Much later, in 2003, EPA and the Pest Management Regulatory Agency (PMRA) of Canada issued a joint paper called *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States*, which clarified that the TAE only excludes treated seeds "for the protection of the [seed] *itself*," meaning "the pesticidal protection imparted to the treated seed *does not extend beyond the seed itself* to offer pesticidal benefits or value attributable to the treated seed."[74] The Harmonization Paper otherwise provided no coverage or analysis of systemic pesticides or neonicotinoid-coated seeds.

[74] EPA, OPP-00675, JOINT REGULATORY DIRECTIVE: HARMONIZATION OF REGULATION OF PESTICIDE SEED TREATMENT IN CANADA & THE UNITED STATES 1–2 (Apr. 11, 2003), https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2003/harmonization-regulation-pesticide-seed-treatment-canada-united-states-dir2003-02.html (emphasis added).

95. Following EPA's own conclusion in the Harmonization Paper, coated seeds should be *excluded* from the TAE because the vast majority of the pesticidal effects indisputably extend far beyond the seed itself, with 95% or more of the coating going into the environment. Yet, EPA's denial of Plaintiffs' petition is based on EPA's interpretation that the TAE *does* include systemic coated seeds, despite the intended and actual pesticidal effects extending far beyond the seeds themselves, because the seed and the plant are the same "article." Petition Denial at 33–36. *See infra*.

96. Unlike coated seeds, none of the other exempted treated "articles" are living or can grow into a larger "article" thousands of times larger on their own. Other TAE examples include the two from the regulation itself: (1) paint treated with a pesticide to protect the paint coating, and (2) wood products treated to protect the lumber or other wood-based product against insect or fungus infestation. Further examples include antimicrobial products that do not make public health claims that extend beyond the protection of the article itself, including inanimate articles like toothbrushes, toys, kitchen accessories, mattresses, and clothing.[75]

97. Although EPA stated in a 2013 guidance for inspections of bee kills that treated seed and its dust-off may be exempted from registration under the treated article exemption,[76] EPA studiously avoided making this interpretation formal or final in any final agency action until September 2022, when it finally denied Plaintiffs' 2017 Petition and explained why it considered coated seeds to fall within the limited scope of the TAE. *See* Petition Denial at 2.[77]

98. EPA's decision to extend the TAE to coated seeds not only violates the plain language and purpose of the exemption, but also FIFRA's unreasonable adverse effects

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[75] EPA, Pesticide Registration (PR) Notice 2000-1: Notice to Manufacturers, Formulators, Producers and Registrants of Pesticide Products (Mar. 6, 2000).

[76] EPA, Guidance for Inspecting Alleged Cases of Pesticide-Related Bee Incidents, 7–8 (May 9, 2013).

[77] *Anderson v. McCarthy*, No. C 16-00068 WHA, 2016 WL 6834215 (N.D. Cal. Nov. 21, 2016) (granting motion to dismiss complaint against EPA based on 2013 Bee Inspection statement as lacking challengeable final agency action).

standard. EPA cannot exempt a pesticide that violates this standard, *i.e.*, that the pesticides as commonly used will not cause unreasonable adverse effects to the environment. Thus, EPA's interpretation of the TAE is arbitrary and capricious, and unlawful under the APA.

C. Previous Litigation: *Anderson et al. v. McCarthy*

99. It was not Plaintiffs' first choice to have to file an APA rulemaking petition in order to get judicial review of EPA's decision to apply the TAE to coated seeds. First, over seven years ago, on January 6, 2016, Plaintiff CFS filed a case directly challenging EPA's position that coated seeds are exempt from the requirements of FIFRA. *See Anderson v. McCarthy*, No. C 16-00068 WHA, 2016 WL 6834215 (N.D. Cal. Nov. 21, 2016).

100. Specifically, plaintiffs in that case sought review of a 2013 guidance document issued by EPA stating that coated seeds may be exempted from FIFRA requirements under the TAE. Plaintiffs argued that the 2013 Guidance was a final agency action establishing the coated seeds exemption that exceeded EPA's statutory authority, violated APA's rulemaking requirements, and was arbitrary and capricious. Plaintiffs also argued that EPA's "non-enforcement policy" for coated seeds was an unlawful abdication of the agency's duties under FIFRA.

101. The case was decided only on procedural grounds. After first denying a motion to dismiss and ordering production of the administrative record, the court subsequently concluded that while it was "most sympathetic to the plight of our bee population and beekeepers," there was no final agency action that could be subject to judicial review. *Id.* at *13. Thus, EPA's use of the TAE for coated seeds evaded review.

D. Plaintiffs' 2017 Petition & Undue Delay Litigation

102. Accordingly, shortly after the court dismissed the first coated seeds case, on April 26, 2017, Plaintiffs submitted a rulemaking petition to EPA, calling on the agency to amend the TAE to close the loophole for dangerous coated seeds. Specifically, the Petition requested that EPA amend the TAE to clarify that it does not apply to seeds coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the

plant instead of pests of the seed itself; or in the alternative, publish a final, formal, agency interpretation in the Federal Register stating that the TAE does not apply to coated seeds. In addition, the Petition requested that EPA analyze the potential human health and environmental risks of coated seeds under the ESA and enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product coated with systemic pesticides.

103. On December 25, 2018, EPA opened a sixty-day public comment period in response to Plaintiffs' Petition.[78] EPA received thousands of comments highlighting EPA's flawed basis for exempting coated seeds as treated articles, as well as the harm caused to pollinators, birds, aquatic organisms, and the environment as a result and urging EPA to regulate the seeds as pesticides.

104. Despite that, EPA never responded to the petition. Thus, after years of inaction, Plaintiffs sued EPA for undue delay under APA for its failure to respond to the Petition in a timely manner. *CFS v. EPA*, No. 21-cv-9640 (N.D. Cal. Dec. 14, 2021) (Corley, J.). As a result of that lawsuit, EPA agreed via settlement to respond to the Petition by September 30, 2022. This case is a result and continuation of that undue delay lawsuit and settlement.

E. EPA's 2022 Petition Denial

105. Pursuant to that settlement, on September 27, 2022, EPA issued a final response to the Petition. In this response, EPA refused to amend the TAE or its interpretation thereof, noting that the TAE "appropriately covers any seed treated with . . . registered pesticide product[s]" so long as use of the seeds are "consistent with all [labeling] instructions" and "claims made for the seed treatment are limited to seed and what the seed becomes." Petition Denial at 2.

106. While EPA agreed that coated seeds do qualify as "pesticides" under FIFRA, it asserts for the first time in the Petition Denial that coated seeds belong under the TAE

[78] *See* Petition Seeking Rulemaking or a Formal Agency Interpretation for Planted Seeds Treated with Systemic Insecticides: Request for Comment, 83 Fed. Reg. 66,260 (Dec. 26, 2018).

because the neonic coating is for the protection of the "article" itself,[79] which is both the seed and the whole living plant. Petition Denial at 33-35. EPA states:

> the plain language of the regulatory text, specifically the parenthetical text, supports that the exemption *allows protection that extends to other forms of the treated article or substance after the specified article or substance is treated and used*. The parenthetical example includes as potentially exempted both the paint that is treated and the treated paint after it is used and becomes a different form of the original treated product, i.e., the "paint coating." Thus, EPA reads this regulatory text to similarly apply to the article treated, *i.e.*, the seed, and the treated article in use and what the article becomes, *i.e.*, the seed after it is planted.

Id. at 33 (emphasis added).

107. EPA compared the seed-to-living-plant "article" to antimicrobial plastics used to create fabric, "where, for example, the plastic is used to create spun fibers or threads which are then used to produce fabric and textile products." *Id.* EPA reiterated several times that the TAE covers the "treated article and *what the treated article may become* when it is in use," under its plain language. *Id.* at 36 (emphasis added). EPA also maintains that it makes no difference that over 95% of the seed coating comes off, because, even though the intent of the exemption is that the pesticidal effect be for the treated article itself, the regulation according to EPA does not require the pesticide treating the article to "generally be contained by the article or substance in use." *Id.* at 34-35.

108. EPA also responded to comments in its Petition Denial, including commenters' point that because EPA does not exempt the plants containing Plant Incorporated Protectants (PIPs), it should not exempt coated seeds.

[79] Notably EPA's petition denial position on this crucial point conflicts with previous stated positions, as in the 2003 Harmonization Paper that was the subject of the prior pre-petition litigation, that seeds treatments are exempt if they protect the seed itself. *See supra* p. 30.

109. PIP Plants are genetically engineered to express pesticides in all their living tissues.[80] PIPs and neonicotinoid seed coatings are strikingly similar: (1) Both endow the seed with the capacity to apply insecticidal compounds to the resulting plant; and (2) neither involves the typical external routes of pesticide application, that is, to the foliage of the plant itself, or to the soil or water it requires for growth. Both infuse all the resulting plant's tissues, systemically, with insecticidal compounds. The only difference between PIPs and coated seeds that systemically infuse a plant with pesticides is that PIPs are engineered into the plants genes whereas coated seeds are coated in liquid pesticides that are systemic and therefore move throughout all the living tissues of the growing plant.

110. PIP plants and plants grown from coated seeds also share another important trait: they are not inanimate articles but instead *living* plants that have pesticidal residues in the living tissues, including pollen, nectar, and dew which are attractive to pests and beneficial insects alike.

111. EPA exercises direct regulatory control over PIP Plants in one important respect: it has set up registration, data, and other assessment parameters specific to PIP-containing seeds to mitigate evolution of pest resistance by lessening the pests' exposure to the PIP, so-called "insect resistance management" (IRM). This regulation specific to PIP Plants makes sense, as naturally their requirements are different than non-living pesticide delivery like spraying or broadcasting granules.

112. A primary component of EPA's regulation is prescribing the permissible proportions and planting configurations of PIP-containing and non-PIP-containing seeds that a farmer can plant on their farm, known as "refuge" requirements.[81] Examples include

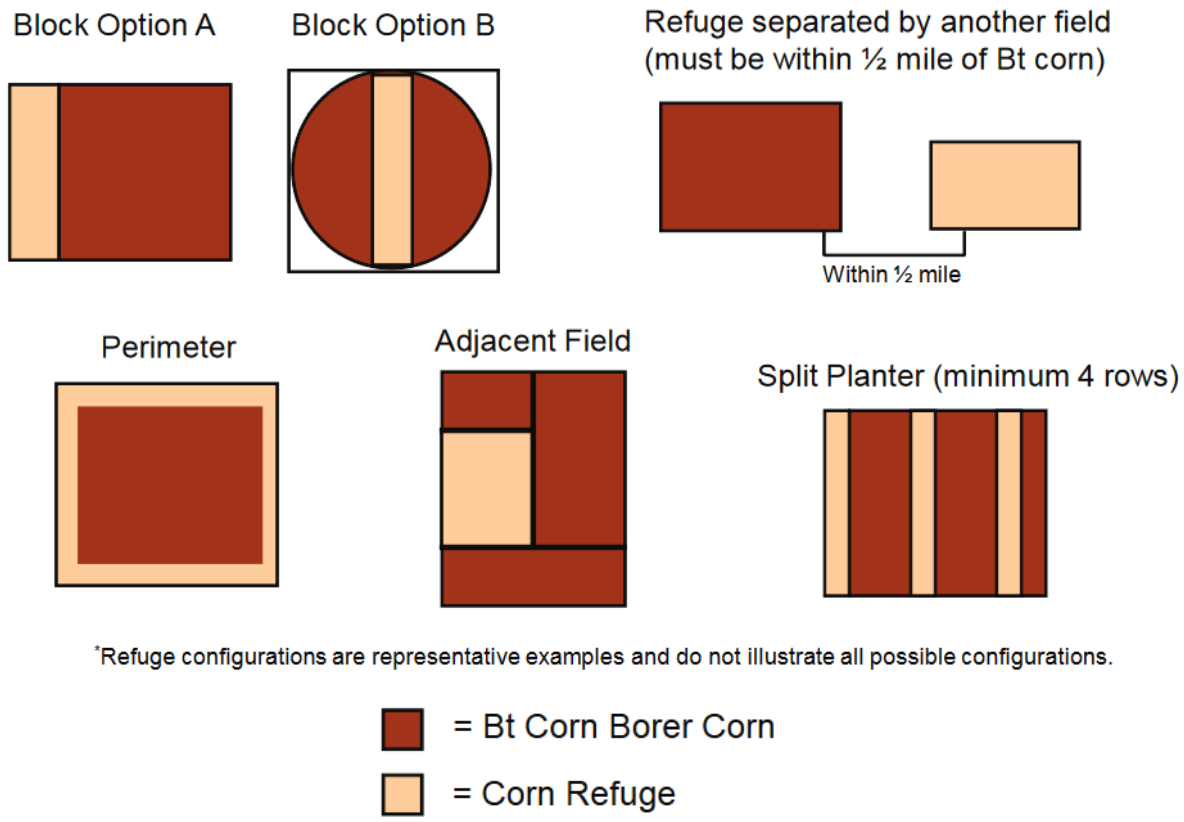
[80] *Overview of Plant-Incorporated Protectants*, EPA (last updated Oct. 31, 2022), https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants.

[81] *Insect Resistance Management for Bt Plant-Incorporated Protectants*, *The Role of Refuges in Resistance Management*, EPA (last updated Nov. 14, 2022), https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/insect-resistance-management-bt-plant-incorporated.

a requirement to plant contiguous blocks of 20% non-PIP seed and 80% PIP seed; another is to plant a blend of 5% non-PIP and 95% PIP seeds.[82] See figure below.

Refuge Configuration Examples for Bt Corn Borer Corn[83]

(single trait Bt corn hybrids with Lepidoptera protection)



113. Thus, in the case of PIPs Plants, EPA (1) recognized that it can regulate a living plant because of its pesticidal effects under the broad definition of a pesticide under FIFRA; (2) recognized a pesticidal seed and plant-specific risk, and (3) established specific regulations to address it. Yet, despite regulating neonicotinoids under FIFRA and long recognizing the risks of coated seeds, EPA still exempts them under the TAE, gutting its authority to both require mitigation of the uniquely seed-associated risks they present and enforce violations of those mitigation measures.

114. As to PIPs, in the Petition Denial EPA stated:

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[82] *Id.* at *Current Refuge Strategies for Bt corn and Bt cotton.*

[83] EILEEN CULLEN ET AL., UNIV. OF WISCONSIN-EXTENSION, INSECT RESISTANCE MANAGEMENT & REFUGE REQUIREMENTS FOR BT CORN 2 fig.1 (2008), http://corn.agronomy.wisc.edu/Management/pdfs/A3857.pdf.

> EPA need not conclude, as comments suggest, that the seed, seedling, and plant are the same article based on regulations at 40 C.F.R. Part 174 [for PIPs]. As explained in this response, the plain language of the treated article exemption supports application of the exemption to the seed article that is treated, even if there are additional claims relating to seedlings. Notably, the unique pesticides addressed by Part 174, i.e., plant-incorporated protectants (PIPs), are not subject to the treated article exemption for reasons articulated in 40 C.F.R. 174.1 (because the characteristics of PIPs "distinguish them from traditional chemical pesticides," PIPs are subject to "different regulatory requirements, criteria, and procedures than traditional chemical pesticides"). Rather, PIPs must be registered under FIFRA if not exempt under 40 C.F.R. Part 174, and living plants containing the PIP may be exempt from FIFRA requirements pursuant to 40 C.F.R. 152.20(a).

Petition Denial at n.85.

115. EPA also noted that it "does not agree with the Petition claims relating to EPA assessments," claiming that EPA already adequately assesses "both the use of the treating pesticide on a seed crop and use of the treated seed" when it approves the separate liquid coating products or otherwise assesses the active ingredients. Petition Denial at 2, 10–15. This rationale is also arbitrary and capricious and contrary to the record, as discussed directly below.

116. Overall EPA's interpretation of the TAE is arbitrary and capricious and thus unlawful under the APA. EPA's application of the TAE to coated seeds also contradicts the plain text and purpose of the exemption and exceeds EPA's statutory authority under FIFRA.

F. EPA's Inadequate Assessment of Coated Seeds in Liquid Coating Product Registration and Other Reviews

117. EPA claims in its Petition Denial that registration of coated seeds as pesticides is not required or practically necessary because the agency already adequately assesses the impacts of coated seeds in its registration of the liquid coating products, as well as nationwide ESA consultations and registration reviews of the active ingredients (ongoing right now, with a 2026 deadline). Petition Denial at 26. This is wrong because EPA does not meaningfully take coated seeds into account in these assessments, claiming

that its review of impacts from liquid sprays or soil applications are sufficient. EPA's assessments fail to capture the devastating impacts from seed coating dust-off, as well as from contamination of surface water, non-crop vegetation, and soil from seed coatings. Neither does EPA meaningfully assess neonicotinoid-coated seeds' impacts to threatened and endangered species. And as stated above, because coated seeds make up over 90% of the neonicotinoid use in agriculture, this is therefore a massive oversight in EPA's existing risk assessments.

118. This has tremendous adverse consequences: as explained above, coated seeds cause significant pesticidal effects beyond the seed (or even the whole plant) because of the movement of the coating off the seed. Depending on the crop, over 95% of the insecticide is either scraped off the seeds and blown away as dust during machine planting or sloughed off into the surrounding soil and groundwater.[84] Seeds coated in neonicotinoids are causing bird declines.[85] Because of the toll from this pesticidal effect beyond the "article" (seed or plant), coated seeds do not qualify for exemption from regulation. 7 U.S.C. § 136w(b) (allowing EPA to exempt pesticides "of a character not requiring registration under FIFRA"); CFS Petition at 33 ("Given that EPA is not allowed to register a pesticide which will cause unreasonable adverse effects on the environment, it follows that EPA may not exempt pesticides that would cause unreasonable adverse effects on the environment. Put another way, EPA could not lawfully determine that a pesticide that causes "unreasonable adverse effects on the environment" is "of a character which is unnecessary to be subject to" FIFRA.").

1. Dust-Off

119. As to the dust-off from neonic-coated seeds, EPA acknowledges it is a pathway responsible for "numerous incidents of honey bee mortality" and is a "route of

[84] Petition at 10 (citing Goulson, *supra* note 60).
[85] *Id.*

concern, given that bee kill incidents have been associated with planting of clothianidin or thiamethoxam-treated corn."[86]

120. Nevertheless, EPA does not conduct any assessment of the risks posed by neonicotinoid-laced seed dust to honey bees or any other non-target organism.[87] EPA's pretext for this failure is that assessing seed dust-off is difficult: dust-off depends upon "multiple factors," and because EPA "lacks reliable methods" for assessing it, the Agency can only "qualitatively characterize[] concerns with dustoff"—that is, merely *describe* the bee kill incidents it causes. Petition Denial at 12–13.

121. Yet EPA has had over a decade to develop quantitative risk assessment methods, given widely reported bee kills from dust-off dating back to at least 2008 in Germany and 2012 in the United States.[88] And numerous studies made available to EPA provide relevant methods and data. These include measurements of the neonicotinoid concentrations in bees exposed at various distances from planting machine exhaust;[89] the finding that up to 12.6% of the clothianidin coating on a corn seed is expelled from planters;[90] and a geospatial study finding that "over 94% of honey bee foragers throughout

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[86] EPA, Final Bee Risk Assessment to Support the Registration Review of Clothianidin & Thiamethoxam, at 30, 58 (Jan. 14, 2020), https://www.regulations.gov/document/EPA-HQ-OPP-2011-0865-1164 [hereinafter Final Bee Assessment – Clothianidin & Thiamethoxam].

[87] In its bee risk determination for imidacloprid-treated seed, "drift of abraded seed coat dust is not considered." *See* EPA, Final Bee Risk Assessment to Support the Registration Review of Imidacloprid, at 313, n.12 (Jan. 14, 2020), (referencing tbl. 7-1 at 309-313) https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1611 [hereinafter Final Bee Assessment – Imidacloprid]. Similarly, despite its admission of numerous bee kills, for risk assessment purposes EPA assumes that honey bees have "negligible" exposure to clothianidin and thiamethoxam seed coatings in the field where the seeds are planted and no off-field exposure. Final Bee Assessment – Clothianidin and Thiamethoxam, *supra* note 86, at 78–79, fig.3.1.

[88] Final Bee Assessment – Clothianidin and Thiamethoxam, *supra* note 86, at 58 (citing Pistorius et al. 2009 and Forster et al. 2009 for Germany, and Krupke et al. 2012 for the United States).

[89] Andrea Tapparo et al., *Assessment of the Environmental Exposure of Honeybees to Particulate Matter Containing Neonicotinoid Insecticides Coming From Corn Coated Seeds*, 46 ENV'T SCI. & TECH. 2592 (2012).

[90] Arthur W, Schaafsma et al., *The Role of Field Dust in Pesticide Drift When Pesticide-Coated Maize Seeds are Planted with Vacuum Type-Planters*, 74 PEST MGMT. SCI. 323 (2018).

the state of Indiana are at risk of exposure to varying levels of neonicotinoid insecticides, including lethal levels, during sowing of maize."[91] Nonetheless EPA has chosen not to utilize these or many other available studies to develop a dust-off risk assessment. Without quantitative assessment, there cannot be effective mitigation (leaving aside that labels on seed bags and tags are per se unenforceable).

122. Instead of effective mitigation, EPA says it is working with neonicotinoid manufacturers on "best management practices" and new technologies to reduce dust-off, referencing a meeting involving mostly pesticide industry officers that took place a decade ago.[92] Yet available evidence suggests little has come of this collaboration. As one purported solution, EPA cites "alternative fluency agents" (replacing talc and graphite as lubricants in seed planter boxes with alternate lubricants). Petition Denial at 13. However, research demonstrates that a Bayer Fluency Agent does not reduce toxic seed dust-off versus using talc or graphite.[93]

123. In any case, whatever new technologies or techniques may prove to be effective must be mandated by law and enforced. Without enforceable regulation of treated seeds, EPA will be unable to require they be used to prevent or at least mitigate the massive bee kills being caused by seed dust drift.

2. Aquatic Contamination

124. Neonicotinoid-coated seeds similarly contaminate surface waters, which EPA acknowledges is both extensive and lethal. Imidacloprid concentrations in streams, rivers, lakes, and drainage canals "routinely exceed" safety thresholds for aquatic

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

[92] *See* Final Bee Assessment – Imidacloprid, *supra* note 87, at 44, n.11. Cited hyperlink is broken, correct link is as follows: https://www.epa.gov/pollinator-protection/2013-summit-reducing-exposure-dust-treated-seed.

[93] KIMBERLY A. STONER, CONNECTICUT AGRICULTURAL EXPERIMENT STATION, BEST MANAGEMENT PRACTICES FOR FARMERS USING SEEDS TREATED WITH NEONICOTINOID INSECTICIDES, 4 (2017).

invertebrates by one to two orders of magnitude (10 to 100 times).[94] Clothianidin has been detected in 75% of samples taken from Iowa streams at levels up to 0.257 ug/l,[95] over five times the chronic safety threshold of <0.050 ug/l.[96]

125. Yet even though seed treatments represent roughly 90% of total neonicotinoid use and 95% of seed coatings are lost to the environment, *see supra*, EPA's models tell it that the remaining 10% of neonicotinoid use (comprising of soil and foliar applications) accounts for substantially more runoff. Petition Denial at 13.[97] This apparent paradox is explained by the fact that EPA's modeling assumes that none of the neonicotinoid on treated seeds planted deeper than two centimeters (0.8") runs off, because this places the pesticide-coated seed below the 2-cm runoff extraction zone of the model.[98]

126. If the model predictions were correct, there would be virtually no clothianidin in Iowa streams, because nearly all the clothianidin used in the state is

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[94] EPA, Preliminary Aquatic Risk Assessment to Support the Registration Review of Imidacloprid, at 9–10 (Dec. 22, 2016), https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1086.

[95] Michelle L. Hladik et al., *Widespread Occurrence of Neonicotinoid Insecticides in Streams in a High Corn & Soybean Producing Region*, USA, 193 ENV'T POLLUTION 189, 191 (2014).

[96] EPA, Clothianidin – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review, at 59 tbl. 3-7 (Nov. 27, 2017), https://www.regulations.gov/document/EPA-HQ-OPP-2011-0865-0242 [hereinafter Clothianidin – Aquatic & Non-Pollinator Risk Assessment]. The chronic safety threshold is the maximum concentration of clothianidin in water that is deemed safe for aquatic insects exposed to it over an extended period, the no observed adverse effect concentration (NOAEC).

[97] In support of this contention, EPA misleadingly states that the "overall mass" of neonicotinoids contained in seed treatments is less than that which is sprayed on foliage or applied to soil (Petition Denial at 13), when what EPA means here is that the amount of neonicotinoid applied *per acre* is often greater with foliar sprays than coated seeds. But because acres planted with coated seeds is 15-fold greater than the area receiving soil/foliar applications, the "overall mass" of neonicotinoids in seed coatings is correspondingly higher. *See* Steeger, *supra* note 7; *see also* Petition Denial at 9.

[98] Steeger, *supra* note 7

applied to corn seeds,[99] which are planted at an average depth of more than two centimeters, below the model's "runoff extraction zone."[100] Yet as noted above, this neonicotinoid is in fact found in 75% of Iowa stream and river samples, often at levels injurious to aquatic life. Thus, EPA's model predictions that are contradicted by real-world, empirical test data.

127. Several factors may explain EPA's modeling errors. First, neonicotinoids from seed coatings reach the soil surface by capillary action during dry conditions, or via the deposition of the windblown seed dust that EPA refuses to account for, resulting in 14-fold higher neonicotinoid concentrations in surface soil dust compared to the top five centimeters of soil; in either case, rainfall can then easily wash it from the soil surface into streams.[101] Second, seed dust laden with neonicotinoids can be blown directly onto surface waters.[102] And finally, the routine detection of neonicotinoids in subsurface water draining corn and soybean fields suggests that excess seed coating sloughing off the seed and into the soil is in fact vulnerable to runoff, as pesticide experts in Vermont[103] and California[104] informed EPA, contrary to the Agency's model.

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[99] U.S. Geological Survey, Pesticide National Synthesis Project, 1992-2019 State-Level Crop Group Dataset, https://water.usgs.gov/nawqa/pnsp/usage/maps/county-level. Because it breaks down into clothianidin, thiamethoxam could also contribute to clothianidin contamination, but in Iowa nearly all thiamethoxam is likewise used to treat corn and soybean seeds.

[100] Clothianidin – Aquatic & Non-Pollinator Risk Assessment, *supra* note 96, at 73–74 tbl.4–5, n.4. Because corn and wheat seed are typically planted more than 2 centimeters deep, EPA's model predicts "EECs [estimated environmental concentrations] of zero," meaning zero runoff and zero risk to aquatic organisms.

[101] V. Limay-Rios et al., *Neonicotinoid Insecticide Residues in Soil Dust & Associated Parent Soil in Fields With A History of Seed Treatment Use On Crops In Southwestern Ontario*, 35 ENVTL. TOXICOLOGY & CHEMISTRY 303 (2016).

[102] *Id.*

[103] Nathaniel Shambaugh, Retired Pesticide Chemist, Vermont Agency of Agriculture, Food & Markets, Comment to EPA on its Preliminary Aquatic Risk Assessment to Support Registration Review of Imidacloprid (July 14, 2017), https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0844-1175.

[104] Pamela Wofford, Cal. Dept. of Pesticide Regulation, Comment to EPA on its Preliminary Aquatic Risk Assessment to Support Registration Review of Imidacloprid (July 5, 2017), https://www.regulations.gov/comment/EPA-HQ-OPP-2008-0844-1116.

128. Further, to mitigate the harms to aquatic life, EPA proposed "additional *advisory* label language."[105] However, again as EPA acknowledges, the labeling on coated seed bags and tags is not enforceable and does not carry the same legal weight as the labels on pesticide products.

3. Non-Crop Pollen and Nectar

129. Neonicotinoid seed coatings are absorbed by the growing crop seedling and infuse every tissue of the plant, including pollen and nectar, which is an important route of exposure for various species of bees and other pollinators. However, wild plants growing near crop fields also contain neonicotinoids.

130. For instance, one study conducted in an agricultural region of England planted to oilseed rape (canola) and wheat grown from treated seeds found that a surprising 97% of the neonicotinoids brought back in pollen to honey bee hives came from wildflowers.[106]

131. Similarly, researchers measured insecticide levels in the beebread (the mixture of pollen and nectar or honey that bees consume) of honey bee hives placed in New York apple orchards and found that most of the pesticidal risk to honeybees was attributable to pesticides found in non-apple pollen (likely pollen from wildflowers and other sources), particularly the neonicotinoid thiamethoxam.[107]

132. These studies and many others demonstrate that EPA's risk assessment of this exposure route—confined to neonicotinoids in the nectar and pollen of bee-attractive *crops*—is deficient, since pollinators are exposed not only via crops but also via wildflowers growing across the landscape, and not only during the period of crop bloom, but through much of the year.

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[105] EPA, Proposed Interim Decision on Registration Reviews of Clothianidin & Thiamethoxam, at 50 (Jan. 21, 2020), https://www.regulations.gov/document/EPA-HQ-OPP-2011-0581-0362 (emphasis added).

[106] Cristina Botías et al., *Neonicotinoid Residues in Wildflowers, A Potential Route of Chronic Exposure For Bees*, 49 ENV'T SCI, & TECH. 12731 (2015).

[107] Scott H. McArt et al., *High Pesticide Risk to Honey Bees Despite Low Focal Crop Pollen Collection During Pollination of a Mass Blooming Crop*, 7 SCI. REP. 46554 (2017).

4. Other Routes of Exposure

133. EPA also acknowledges—but fails to assess—risks ensuing from other routes of exposure associated with seed coatings. The majority of wild bee species, including bumble bees, nest in the ground and have contact exposure to neonicotinoids in the soil (*supra*). EPA concedes that soil may be "an important route of exposure," but then fails to quantitatively assess this route because its assessment scheme focuses on honeybees, which have less exposure to soil.[108] Similarly, EPA fails to assess exposure or associated risks from ingestion of neonicotinoid-contaminated surface water, plant guttation fluids, or honey dew.[109]

5. Threatened and Endangered Species

134. As to risks to threatened and endangered species, EPA has discounted and/or failed to consider harm from coated seeds just as the Agency did in its general ecological risk assessment under FIFRA. Had EPA actually assessed the impacts from coated seeds, its ESA determinations and jeopardy findings would have shown adverse effects and jeopardy to more protected species.

135. The U.S. Fish and Wildlife Service (FWS) found that neonicotinoids generally have contributed to the endangerment of several threatened and endangered pollinator species, including the Rusty Patched Bumble Bee, Dakota Skipper Butterfly, and Poweshiek Skipperling Butterfly.[110]

136. EPA issued Biological Evaluations (aka effects determination) for neonicotinoids on June 16, 2022, where it considered impacts to 1,821 species whose

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[108] Final Bee Assessment – Clothianidin & Thiamethoxam, *supra* note 86, at 30, 55, 118-19.
[109] *Id.* at 30.
[110] U.S. Fish & Wildlife Serv., Endangered Species Status for Rusty Patched Bumble Bee, 82 Fed. Reg. 3186, 3190, 3201 (Jan. 11, 2017) (reporting that neonicotinoids harm bees and "it is reasonable to conclude that rusty patched bumble bees may be more exposed to insecticides used as seed treatments"); U.S. Fish & Wildlife Serv., Threatened Species Status for Dakota Skipper & Endangered Species Status for Poweshiek Skipperling, 79 Fed. Reg. 63672, 63737 (Oct. 24, 2014).

habitats overlap with the areas where pesticides are used.[111] For clothianidin, EPA found that 1,225 species (67%) and 446 critical habitats are likely to be adversely affected. For thiamethoxam, EPA found that 1,396 species (over 76%) and 644 critical habitats are likely adversely affected. And for imidacloprid, EPA found likely adverse effects for 1,445 species (nearly 80%) and 658 critical habitats.

137. Despite finding massive impacts to listed species in these nationwide BEs for the neonicotinoids active ingredients, EPA nonetheless discounts *seed treatment* use of neonicotinoids in the Biological Evaluations, which are designed to guide the expert wildlife agencies in their Biological Opinions (the assessments that determine whether an action will jeopardize the continued existence of a given species and/or provide expert mitigation measures to avoid jeopardy).

138. For instance, EPA excluded the amount of these active ingredients coated onto seeds from its estimates of "national annual total agricultural usage" of each major neonicotinoid.[112] And after noting that "numerous clothianidin incidents involving mortality to foraging honey bees" through "contact with abraded seed coat dust during planting," EPA nevertheless stated that "this exposure route was not quantitatively considered."[113] In a similar vein, EPA relied upon the erroneous aquatic modeling described above to claim that foliar and soil treatment (flowable uses) result in greater neonicotinoid concentrations in surface water than seed treatments, and on those grounds assumes it can dispense with quantitative assessment of seed treatment risks.[114]

139. EPA subsequently proposed on May 5, 2023, that of the listed species likely to be adversely affected by the three major neonicotinoids, nonetheless over 200 were

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[111] *EPA Finalizes Biological Evaluations Assessing Potential Effects of Three Neonicotinoid Pesticides on Endangered Species*, EPA (last updated Jun. 22, 2022) https://www.epa.gov/pesticides/epa-finalizes-biological-evaluations-assessing-potential-effects-three-neonicotinoid.

[112] CFS Comments on Draft Neonic Bes, *supra* note 18, at 1–4.

[113] EPA, *Final National Level Listed Species Biological Evaluation for Clothianidin*, app. 4-5 (last updated May 5, 2023), https://www.epa.gov/endangered-species/final-national-level-listed-species-biological-evaluation-clothianidin.

[114] *Id.* at 1–2.

jeopardized by them, and over thirty critical habitats at risk of adverse modification or destruction.[115] Roughly 80% of the species EPA predicts to be jeopardized are plants, with their continued existence threatened by the neonicotinoids' indirect effects: namely, severe impacts on insects pollinators, without which these plants cannot reproduce.[116]

140. In making these jeopardy predictions, it appears that EPA ignored the impacts of drifting, neonicotinoid-laced seed dust merely because it is not equivalent to "spray drift" from foliar applications.[117] Moreover, it does not appear that EPA properly accounted for the contribution of seed treatments to contamination of surface waters and associated risks to aquatic life. For instance, none of the neonicotinoid-using crop scenarios that resulted in EPA's draft jeopardy predictions involved corn (save one), even though treated corn seed is doubtless a major source of neonicotinoid exposure of and risk to aquatic invertebrates as well as pollinators.[118]

141. Proper assessment of seed treatments would have almost certainly led EPA to find jeopardy for still more species, given the fact that corn is the most widely planted crop in the U.S., grown on some 90 million acres annually, virtually all from treated seed, which represents the single largest use of neonicotinoids and doubtlessly overlaps with numerous additional listed species' habitats.

142. Accordingly, these recently issued ESA assessments for neonicotinoids generally illustrate yet again the core problem with EPA's treatment of coated seeds: by exempting them from FIFRA, they do not regulate them as pesticides and thus their risk

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[115] EPA, IMIDACLOPRID, THIAMETHOXAM & CLOTHIANIDIN: DRAFT PREDICTIONS OF LIKELIHOOD OF JEOPARDY AND ADVERSE MODIFICATION FOR FEDERALLY LISTED ENDANGERED & THREATENED SPECIES & DESIGNATED CRITICAL HABITATS (May 1, 2023).

[116] *Id.* at 78, 102, 124 (citing "indirect effects, including impacts on pollination and seed dispersal mechanisms" for each of the three neonicotinoids).

[117] *Id.* at 19 ("However, while dustoff may occur, seed treatments were not expected to have spray drift concerns.").

[118] *Id.* at 44–152. Corn is not listed as a use in any of the entries of Tables 5-2 through 6-6 as a use contributing to exposure of a jeopardized species, save for the Attwater's prairie chicken (tbl. 5-15, p. 71), which is presumably jeopardized by consuming treated corn seed.

assessments under FIFRA and the ESA fail to adequately account for or mitigate for the grave adverse effects they cause.

143. In sum, EPA's current registration of liquid coating products and reviews of the active ingredients as a whole fail to fully assess the myriad impacts to non-target and imperiled wildlife from neonic coated seeds.

IV. Harm to Plaintiffs

144. EPA's unreasonable interpretation of the TAE and exemption of coated seeds from registration under FIFRA adversely affects Plaintiffs and their members by increasing the risks associated with coated seeds, including the loss of birds, pollinators, aquatic species, and ecosystem services in agricultural production areas.

145. EPA's failure to properly assess the harmful effects of coated seeds, in violation of FIFRA, also adversely affects Plaintiffs and their members by increasing the risks to public health and the environment, including threatened and endangered species.

146. Plaintiffs' members have concrete interests in public health and the environment, and these interests are—and will continue to be—adversely affected by EPA's continued failure to assess the risks associated with coated seeds and unreasonable interpretation of its statutory and regulatory duties. Specifically, Plaintiffs' members are suffering and will continue to suffer from the increased risks associated with coated seeds, including the loss of birds, the loss of honey bees and the effects on farming and beekeeping; the loss of butterflies, aquatic species, and other important species; the adverse effects on public health and the environment; the loss of ecosystem functioning; and other direct and indirect effects on their wellbeing, livelihoods, properties, economic investments, hobbies, and personal interests. Plaintiffs' members have myriad interests in the natural environment and birds, endangered species, honey and wild native bees, and other pollinators—environmental, conservation, professional, recreational, and aesthetic interests—continue to be injured by EPA's failure to properly regulate coated seeds.

147. EPA's exemption of coated seeds from FIFRA also directly harms the Plaintiff organizations, who have been forced to expend resources to address this loophole that would otherwise go to mission-critical programs. Plaintiffs CFS and PANNA have had to expend resources to attempt local and state-level regulation of neonic-coated seeds to fill the gap left at the federal level due to EPA's exemption.

148. The requested relief will redress these harms by requiring EPA to fulfill its statutory duties to protect the environment from the adverse effects of coated seeds. If EPA grants the Petition, it will regulate coated seeds as the pesticides they are, meaning they would be subject to the full review process of registration (including data requirements specific to the coated seeds and not just the liquid coating products) and would have enforceable label language that includes use instructions and any mitigation of harms required to meet the FIFRA safety standard. This could—and should—result in less use of these prophylactic pesticides because EPA will be required to assess the benefits of neonic-coated seeds versus their specific harms, and as outlined in the Petition and above, the harms far outweigh the benefits of pre-treated seeds. Further, coated seeds being a registered pesticide redresses Plaintiffs' harms in other ways, like being counted in use data in states that collect such data and being considered "pesticides" in bee kill investigations.

FIRST CLAIM FOR RELIEF

VIOLATION OF THE APA

The Petition Denial is Arbitrary and Capricious Because EPA's Interpretation of the TAE is Unreasonable under the APA

149. Plaintiffs incorporate by reference all allegations contained in ¶¶ 1 to 148.

150. In September 2022, EPA issued a final response to Plaintiffs' petition for rulemaking regarding neonic coated seeds. In its response, EPA refused to take the actions requested. *See* Petition Denial at 2. EPA's petition denial constitutes a final agency action subject to judicial review under the APA. *See* 5 U.S.C. § 551(13) ("agency action" includes "agency . . . denial" or "failure to act").

151. Under the APA, this Court shall "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A). Agency action is arbitrary and capricious where, as here, EPA entirely failed to consider an important aspect of the problem or offered an explanation for its decision that runs counter to the evidence.

152. In the denial letter, EPA finally provided a formal interpretation of the TAE and its application to coated seeds. *See* Petition Denial at 2. The TAE only exempts "[a]n article or substance treated with, or containing, a pesticide *to protect the article or substance itself*," "if the pesticide is registered for such use." 40 C.F.R. § 152.25(a) (emphasis added). EPA claimed that coated seeds belong under the TAE because the neonic coating protects the entire "article" (both the seed and the plant it becomes). *See* Petition Denial at 33–35. EPA also concluded that even if the "benefits" of this coating go beyond the seed itself, the existence of neonicotinoids in the tissue of a plant does not negate the application of the TAE because coated seeds are living plants. *Id*.

153. EPA's interpretation violates the plain and unambiguous language of the TAE because coated seeds are not inanimate articles, they are living organisms. Nor is the seed the same thing as the larger plant, from which the pesticide has vastly different adverse effects on the environment. Nor does the coating protect only the seed; over 95% of it comes off the seed and contaminates soil, water, and surrounding vegetation.

154. First, coated seeds do not merely protect an inanimate article. Unlike the explicit examples in the TAE—treated wood and paint—these seeds and the plants they grow into are empirically different from all the rest of the articles exempted under the TAE. These other TAE articles are antimicrobial consumer products like toothbrushes, clothing, and bathmats; they could not be more different than a living organism.

155. Second, even if coated seeds are an article, coated seeds grow into whole plants that are hundreds or thousands of times larger than the original seed. This larger plant grown from a coated seed attracts very different species than a seed, and exposes wildlife, including crucial pollinators, to neonicotinoids through all parts of the living plant.

EPA's interpretation of the TAE equating the seed and future plant ignores the effects of systemic pesticides on plant tissues, which can significantly increase the risk of exposure and injury to endangered species and pollinators that rely on these plants for food or habitat. Systemic pesticides in plant tissues increase injury and death for insects in the surrounding area because non-target species are more likely to use above-ground seedlings and mature plants for habitat than seeds planted in the soil. The plants grown from these seeds also increase the widespread effects of such pesticides on the surrounding environment by increasing the movement of systemic pesticides throughout the air, water, and soil.

156. Finally, in agronomic reality, the seed coating actually does not remain on the "article" and over 95% of it enters the environment via runoff, dust, and other pathways; its effects are not for the treatment of the article itself. This is a much broader impact on the environment then other "treated articles."

157. Further, the larger structure of the TAE demonstrates that the exemption is only intended to cover products with no more than minimal effects on the environment. Other pesticides exempted because they were "determined to be of a character not requiring regulation under FIFRA" include things like food, natural cedar, pheromone traps, and a long list of "minimum risk pesticides" including things like cinnamon oil, garlic oil, peppermint, and white pepper. 40 C.F.R. § 152.25(b), (d), (e), (f). These are very different from coated seeds, which are linked to significant and widespread adverse effects, and can kill a songbird with a single seed.

158. EPA's formal interpretation of the TAE and coated seeds in its Petition Denial is that the seed is the same as the plant grown from the seed and both are the "treated article." However, the language of the TAE is clear and unambiguously forecloses this conclusion, and EPA's interpretation is not entitled to deference. *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). Because the TAE does not cover the seed coated in systemic pesticides or the plant grown from this seed, EPA must assess and regulate these products under FIFRA, including mitigating their adverse effects through enforceable labeling.

159. In sum, EPA's interpretation of the TAE is inconsistent with the plain text of the exemption, its history and purpose, as well as the overall structure and design of FIFRA's registration scheme.

160. Even if the language of the TAE is ambiguous, EPA's interpretation is unreasonable because, for the same reasons stated above, neonic-coated seeds are far beyond the zone of any ambiguity in the TAE, based on its text, structure, history and purpose.

161. Therefore, EPA's Petition Denial was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). EPA's Petition Denial has harmed—and continues to harm—Plaintiffs and their members.

SECOND CLAIM FOR RELIEF

VIOLATION OF THE APA AND FIFRA

EPA's Petition Denial is Arbitrary and Capricious Because EPA's Interpretation of the TAE Exceeds its Statutory Authority under FIFRA

162. Plaintiffs incorporate by reference all allegations contained in ¶¶ 1 to 148.

163. In the alternative to Claim One, EPA violated the APA and FIFRA by improperly applying the TAE to neonicotinoid-coated seeds with adverse effects on non-target insects, resulting in widespread effects on entire ecosystems, including the decline in overall bee populations, harm to birds and aquatic life, and loss of soil productivity in agricultural areas. EPA's application of the TAE to such seeds exceeds EPA's statutory authority under FIFRA, is arbitrary and capricious, and thus unlawful under the APA.

164. As discussed above, over 95% of neonicotinoid coatings come off coated seeds when transporting, storing, handling, planting, and disposing of these products, resulting in higher concentrations of these pesticides in the surrounding air, water, and soil, and a higher risk of injury and death for non-target species that become exposed to these pesticides in the environment. The effects on non-target species have widespread impacts on entire ecosystems, including decline in overall bee populations, habitat loss, and reduced pollination and crop yields. Evidence shows that neonicotinoids from coated seeds are entering waterways and can harm aquatic species. They can harm insects in the

soil, reducing nutrient cycling and other ecosystem functions. Systemic pesticides can also travel via dust in the air, falling on and contaminating marginal vegetation and increasing risks for pollinators.

165. Coated seeds pesticidal effects extend far beyond the seed itself and the plants grown from them because neonicotinoids are highly mobile and persistent in the environment, and the pesticide coatings on these seeds move easily via the air, soil, and water. Because the toll from this pesticidal effect go far beyond the "article" (seed or plant), coated seeds cannot qualify for the FIFRA statutory exemption for pesticides "of a character not requiring registration under FIFRA." 7 U.S.C. § 136w(b). Put simply, coated seeds *are* pesticides requiring registration. Thus, under FIFRA itself, EPA's TAE improperly exempted such seeds from FIFRA's registration requirements.

166. Moreover, EPA's interpretation contradicts the purpose of FIFRA's registration requirements, in violation of the APA and FIFRA. Because FIFRA prohibits EPA from registering any pesticide product with unreasonable adverse effects on the environment, it necessarily follows that EPA cannot exempt products with unreasonable adverse effects on the environment (such as contributing to worldwide bee declines and widespread freshwater contamination) from FIFRA to get around its statutory duties. Thus, by the plain text of the statute and its purpose, EPA cannot lawfully determine that coated seeds are "of a character not requiring regulation under FIFRA" because these pesticides have significant and unreasonable adverse effects on the environment that do and should require FIFRA regulation.

167. EPA's current assessment of active ingredients and products do not adequately assess the effects of coated seeds. EPA does not quantify the impacts from coated seeds, including dust-off, contamination of wild and non-crop vegetation, water contamination, and harms from the disposal of coated seeds, ignoring the vast majority of the use of neonicotinoid active ingredients.

168. Accordingly, because coated seeds have significant adverse effects on the environment, EPA cannot continue to avoid its duty to review, balance the costs and

benefits, and mitigate harm by unilaterally exempting coated seeds from FIFRA. EPA's failure to do so has harmed—and continues to harm—Plaintiffs and their members, and this Court can remedy these injuries by ordering EPA to complete registration for coated seeds and granting other appropriate relief.

169. In sum, EPA has exceeded its statutory authority by applying the TAE to coated seeds, in violation of FIFRA and the APA. Under the APA, this Court shall "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction [or] authority." 5 U.S.C. § 706(2)(C).

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

1. Declare that EPA's petition denial violated the APA by interpreting the TAE to include coated seeds with pesticidal effects that drastically exceed the seed itself.
2. Declare that coated seeds do not qualify as TAE articles.
3. Declare that EPA's petition denial violated the APA and FIFRA by applying the TAE to coated seeds contrary to FIFRA.
4. Vacate, or set aside, EPA's petition denial as to its unlawful interpretation of the TAE and its application to coated seeds.
5. Vacate the TAE as applied to coated seeds;
6. Award Plaintiffs attorneys' fees and all other reasonable expenses incurred in pursuit of this action; and
7. Grant any other such relief as the Court deems just and proper.

DATE: May 31, 2023

Respectfully submitted,

/s/ Kristina Sinclair

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CENTER FOR FOOD SAFETY

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