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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY and PESTICIDE ACTION NETWORK NORTH AMERICA, *Plaintiffs,* v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY and MICHAEL REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *Defendants.*	Case No. 21-9640 **COMPLAINT FOR DECLARATORY AND EQUITABLE RELIEF** Administrative Procedure Act Case

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Plaintiffs Center for Food Safety and Pesticide Action Network North America (Plaintiffs) on behalf of themselves and their members, allege as follows:

INTRODUCTION

1. This is an action for declaratory and equitable relief challenging the failure of the United States Environmental Protection Agency (EPA or the agency) to answer Plaintiffs' 2017 legal rulemaking petition, which the agency is required to do by law. The 2017 petition called on EPA to close a regulatory loophole that allows seeds coated with systemic pesticides (coated seeds) to evade the registration and labeling requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA's failure to respond to the petition and close the loophole means these pesticides are continuing to cause environmental harm unabated.

2. Coated seeds are crop seeds that have been coated with systemic pesticides, primarily neonicotinoid insecticides. Insecticides are a subcategory of pesticides. Neonicotinoids and other systemic pesticides are absorbed into the plant's circulatory system as the plant grows and are predominately intended to have an external pesticidal effect on pests and predators of the growing plant. Crops grown from coated seeds—including corn, soybean, and sunflower—cover almost 180 million acres of U.S. farmland each year. This is the equivalent acreage of over one- and one-half Californias.

3. Coated seeds have devastating environmental impacts. First, the pesticidal coating does not remain on the seed. The prophylactic pesticide coatings abrade off the seed as dust during planting, or slough off the seed into the surrounding soil. Overall, only 5% of the prophylactic coating is taken up by the plant,[1] leaving 95% to contaminate the air, soil, vegetation, and waterways. Second, beyond coating the seed itself, these systemic pesticides spread through all living tissues of the growing plant, protecting the plant from pests but also spreading the poisonous effects to non-target species. As a result of both these pathways, beneficial insects, valuable pollinators, and birds—including threatened and endangered insects and birds protected under the Endangered Species Act (ESA)—are killed or injured. The most dramatic impacts of

[1] R. Sur & A. Stork, *Uptake, Translocation and Metabolism of Imidacloprid in Plants*, 56 Bulletin of Insectology 35-40 (2003).

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coated seeds have come in the mass die-offs of honey bees and wild native bees they have caused. Excessive honey bee mortality and related wild pollinator declines are a major crisis for American agriculture.

4. Currently EPA entirely exempts coated seeds from FIFRA's pesticide's premarket licensing, registration, assessment, and labeling regime. Instead the agency has a de facto practice of applying the "Treated Article" Exemption in its regulations, 40 C.F.R. §152.25(a), despite the plain language of the Treated Article Exemption foreclosing the possibility that coated seeds are treated articles. Because the coated seeds are not treated primarily to protect the seed itself, but rather to protect the *growing plant*, they cannot be properly exempted as "treated articles" under the regulation. As a result, EPA has completely failed to assess the risks of these unregulated pesticides. It has also never provided the public with any justification for its exemption or codified that practice in its regulations.

5. On January 6, 2016, CFS filed a case challenging EPA's position that coated seeds are exempt from the requirements of FIFRA, as stated in the agency's 2013 Guidance for Inspecting Alleged Cases of Pesticide-Related Bee Incidents. EPA moved to dismiss the case on grounds that its 2013 guidance was not final agency action and thus not justiciable. The court denied EPA's motion.[2] However at the summary judgment stage after review of the full administrative record the court held the 2013 guidance was not final agency action and therefore unreviewable.[3]

6. In summary, the Court granted summary judgment to EPA because the agency had never actually publicly and formally admitted its Treated Seeds policy for exempting coated seeds. Instead the agency has for decades intentionally evaded any judicial review by failing to issue any final agency action on the topic.

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[2] *Anderson v. McCarthy*, No. C 16-00068 WHA, 2016 WL 2770544, at *3 (N.D. Cal. May 13, 2016).

[3] *Anderson v. McCarthy*, No. C 16-00068 WHA, 2016 WL 6834215, at *4 (N.D. Cal. Nov. 21, 2016).

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7. Accordingly, on April 26, 2017, CFS filed a formal rulemaking petition. The petition was a comprehensive 43-page scientific and legal document detailing the numerous environmental impacts that the broad use of coated seeds causes, outlining EPA's authority under FIFRA, and explaining why EPA's position is incorrect. The petition was supported by 81 citations and supporting documents filed concurrently. Thus the petition provided both a legal blueprint and legal impetus for EPA to either (1) amend the Treated Article exemption to clarify that it does not apply to seeds coated with systemic pesticides, or (2) in the alternative publish a final, formal, agency interpretation in the Federal Register stating that EPA interprets the Treated Article Exemption not to apply to coated seeds. CFS further requested that EPA enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product that is coated with a neonicotinoid or other systemic pesticidal chemical. CFS urged the agency to grant the requests within 180 days of filing. Eleven organizations and beekeepers endorsed the petition, including American Beekeeping Federation, American Bird Conservancy, American Honey Producer's Association, Pollinator Stewardship Council, Bret Adee, Jeff Anderson, Lucas Criswell, Gail Fuller, and David Hackenberg. The petition is attached as Exhibit A.

8. In December 2018, EPA opened a public notice and comment period in response to the petition.[4] Many commenters were concerned that EPA's hands-off approach to coated seed regulation has a devastating impact on bees and other pollinators.[5] Commenters agreed that the Treated Article Exemption should not apply to coated seeds because that interpretation is contrary to the purposes and intent of FIFRA,[6] and that EPA is "improperly using the treated article exemption as a way to abdicate itself of its duties under FIFRA."[7]

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[4] EPA, *Petition Seeking Revised Testing Requirements of Pesticides Prior to Registration; Request for Comment*, 83 Fed. Reg. 66260 (Dec. 26, 2018).

[5] EPA, *Petition Seeking Revised Testing Requirements of Pesticides Prior to Registration*, Docket No. EPA-HQ-OPP-2018-0805-0009, 0013, 0015, 0024, 0040, 0083 (Dec. 2018).

[6] *Id.* at EPA-HQ-OPP-2018-0805-0083.

[7] *Id.* at EPA-HQ-OPP-2018-0805-0069.

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9. EPA's failure violates the mandates of the Administrative Procedure Act (APA), because EPA cannot unlawfully withhold or unreasonably delay a petition response. 5 U.S.C. § 706(1). Nearly five years after Plaintiffs first lodged the 2017 Petition, EPA has still failed to respond. Irreparable environmental harm has continued unanalyzed and unabated in the interim. Plaintiffs' interests are continuing to be harmed by EPA's inaction and lack of oversight regarding coated seeds.

10. Accordingly, this Court should hold that EPA's failure to act in response to the petition violates the APA and order EPA to respond to Plaintiffs' 2017 Petition by a Court-ordered date certain and without further unlawful delay.

JURISDICTION

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

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

13. 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).

VENUE

14. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e) because one or more Plaintiffs reside in this District.

PARTIES

Plaintiffs

15. Plaintiffs Center for Food Safety (CFS) is a nationwide nonprofit organization with offices in San Francisco, California, Portland, Oregon, and Washington, DC. Founded in 1997, CFS's mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. CFS has over a million members, including members in every state across the country, including many thousands of conservationists, gardeners, farmers, and

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beekeepers. CFS and its members are being, and will be, adversely affected by EPA's continued failure to answer CFS's legal petition and address the risks from coated seeds.

16. CFS combines myriad tools and strategies in pursuing its goals, including public education, grassroots organizing and campaigns, media, outreach, and when necessary public interest litigation and/or legal rulemaking petitions. CFS's membership 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.

17. Since its inception twenty-five years ago CFS has had a flagship program on pesticides and pollinators, with multiple staff—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 various cases to prevent environmental harm.

18. Plaintiff Pesticide Action Network of 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

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where pesticides such as the neonicotinoid insecticides are applied, and in which the pesticides and contaminated dust drift and transport occurs, and thus have a strong interest in ensuring that EPA protect public health and the environment from this contamination. PANNA's members are highly concerned by the effects of the unregulated neonicotinoid-coated seeds on honey bees, bumble bees, butterflies, beneficial invertebrates, wild pollinators, water, aquatic invertebrates, food chains, ecosystem sustainability generally, and ultimately on humans via food and water consumption. The lack of enforceable labeling on these pesticidal seeds, and their prophylactic overuse, violate bedrock principles PANNA seeks to protect as far as only using pesticides as a last resort, and then only when they have strong and clear warnings and enforceable use directions. PANNA has repeatedly called on EPA to eliminate the coated seeds' exemption from registration as pesticides, including by joining the 2017 petition.

Defendants

19. Under FIFRA, Defendant EPA is charged with the pre-market assessment and registration of pesticides, including the systemic pesticides used on coated seeds.

20. Defendant Michael Regan is sued in his official capacity as Administrator of the EPA. As Administrator, Mr. Regan has ultimate responsibility for EPA's activities and policies.

21. Mr. Regan and EPA are collectively referred to herein as EPA or the agency.

LEGAL AUTHORITY

I. ADMINISTRATIVE PROCEDURE ACT

22. Pursuant to the APA, agencies must "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e). A "rule" is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4).

23. The APA requires an agency to conclude a matter presented to it, such as a legal petition like the one at issue here, "within a reasonable time." *Id.* § 555(b). If an agency denies a petition in whole or in part, it must provide "[p]rompt notice" to the petitioner. *Id.* § 555(e).

24. The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." *Id.* § 702. "Agency

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action" is defined to include not just affirmative agency action but also the "failure to act," *id.* § 551(13), such as the failure to respond to a legal petition.

25. Under the APA, courts "shall compel agency action unlawfully withheld or unreasonably delayed," *id.* § 706(1), and "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," *id.* § 706(2)(A).

II. FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

26. FIFRA controls the manufacture, sale, and use of a broad range of chemicals and biological pest controls. 7 U.S.C. §§ 136–136y. As Congress explained, FIFRA's primary purpose is to protect human health and the environment. Pub. L. No. 92-516, 86 Stat. 973 (1972).

27. Pursuant to FIFRA, every pesticide must undergo registration with EPA before distribution or sale. 7 U.S.C. § 136a(a). A "pesticide" is defined very broadly, to mean "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 other microorganisms, *id.* § 136(t).

28. 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. § 36a(c)(5)(C), (D).

29. 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 an active ingredient that has not been previously registered. 40 C.F.R. § 152.403. A new registration is also required prior to a new use of an existing registered pesticide. *Id.*

30. With regard to exemptions from FIFRA, the "Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines

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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).

31. EPA's implementing regulation for such exemptions provides that treated articles or substances are not regulated. 40 C.F.R. § 152.25. A treated article or substance is one which is "treated with, or containing, a pesticide to protect the article or substance itself." *Id.* § 152.25(a). 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.*

STATEMENT OF FACTS

Neonicotinoid Pesticides

32. Neonicotinoids are a class of insecticide chemically similar to nicotine, which disrupt the central nervous system of insects resulting in paralysis and death. Lower-level exposure has sublethal effects on insects, which include reductions in growth and reproduction, weakened immunity to parasites and viral diseases, and impaired learning and foraging behavior. These pesticides are systemic: unlike contact pesticides, which remain on the surface of the treated plant or seed, systemic pesticides are taken up by the growing seedling and transported to all its tissues (leaves, flowers, roots and stems, and pollen and nectar).

33. Neonicotinoids are highly soluble in water and quite persistent in the environment. Thus, it is not surprising to find neonicotinoids transported away from the initial application area to pollute surface water and groundwater. For instance, a survey conducted by the U.S. Geological Survey from 2012 to 2014 found one or more neonicotinoids present in 63% of the streams that were tested in 24 states and Puerto Rico.[8]

34. Neonicotinoids are the most widely used class of insecticides in the world. Studies show they are extremely harmful to pollinators, and strongly implicated in bee declines worldwide.

35. An authoritative 2014 global review of over 800 published studies conducted under

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[8] Michelle Hladik & Dana Kolpin, *First National-scale Reconnaissance of Neonicotinoid Insecticides in Streams Across the USA*, 13 Env't Chemistry 12-20 (2016), https://pubs.er.usgs.gov/publication/70156299.

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the auspices of the International Union for the Conservation of Nature (IUCN) determined that neonicotinoids are dangerously overused and should be restricted. A 2021 update to this review finds still more evidence of harms, linking neonicotinoid exposure to declines in wild bee and butterfly populations, warning that neonicotinoids' extreme toxicity to aquatic invertebrates "eliminates entire populations from the affected areas," and thereby threatens entire ecosystems.[9]

36. In 2018, the European Union (EU) banned the primary neonicotinoids from all outdoor use. The United Nations states that neonicotinoids are so hazardous that their use should be severely restricted. Several states in the United States have also restricted neonicotinoid usage to protect bees and other pollinators. At the federal level, EPA has acknowledged the dangers of neonicotinoids and regulates them under FIFRA.

Neonicotinoid-Coated Seeds

37. While neonicotinoids themselves are regulated by EPA under FIFRA, EPA does not currently regulate neonicotinoid-coated *seeds*. However systemic neonicotinoid-coated seeds plainly fit within FIFRA's broad definition of "pesticide": they are a "mixture of substances that are intended to prevent, destroy, repel or mitigate a pest," and thus they should require pesticide registration approval prior to any sale or use. 7 U.S.C. § 136(u)(1). Instead, EPA has a de facto policy of treating them as exempt from the requirements of FIFRA and not requiring any registration.

38. Coated seeds are coated with liquid formulations of neonicotinoid chemicals, essentially turning the seeds into pesticide delivery devices. After the seeds germinate, the chemical coating delivers the active ingredient of the pesticide into the tissues of plants, via the growing plants' circulatory system. The tissues are typically hundreds or even thousands of times larger in dimension and mass than the seed itself, and are fundamentally different from a biological standpoint. The pesticide coating protects the plant from some insects; the coatings do not, in the vast majority of their uses, protect the seed itself against any disease or other risk to the seed.

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[9] Dave Goulson et al., *An Update of the Worldwide Integrated Assessment (WIA) on System Insecticides Part 2: Impacts on Organisms and Ecosystems*, 28 Env't Sci. Pollution & Rsch. 11749-97 (2021).

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39. Reviewing the many pesticide product labels that EPA has registered since 2010 reveals that in the vast majority of those labels the neonicotinoid ingredients are intended to protect the growing crop plants. Few of those labels explicitly claim protection of the planted seed itself by the neonicotinoid ingredient.

40. Crop seeds coated with neonicotinoid throughout the United States, include but are not limited to:

- Canola
- Field and sweet corn
- Cotton
- Cucurbits
- Legume vegetables
- Potatoes
- Soybean
- Sunflowers
- Wheat

41. These seeds are used on nearly 180 million acres across the United States, representing the vast majority of systemic insecticide use and covering close to one-fifteenth of the entire land surface of the lower forty-eight states.

42. Despite being used over such a large land area, neonicotinoid seed treatments provide little or no benefit. They are largely ineffective on corn's worst pest, corn rootworm,[10] and an EPA study showed that any benefits of neonicotinoid seed treatments to soybean farmers were "negligible."[11] Despite this, seed companies often give farmers little or no choice of uncoated seeds, particularly uncoated corn seed.

43. Planting coated seeds results in exposure of non-target organisms even in those frequent instances when pests are not present at damaging levels. Such prophylactic or "insurance-

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[10] Marlin Rice, *Seed-Treatment Insecticides: What Can We Expect in Terms of Broad-Spectrum Control of Soil Insects?* Proc. of Ind. Crop Advisory Conf. (2004).

[11] U.S. Environmental Protection Agency, *Benefits of Neonicotinoid Seed Treatments to Soybean Production* (Oct. 15, 2014).

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based" use of pesticides is contrary to Integrated Pest Management (IPM), which strives to eliminate senseless pesticide applications.[12]

Environmental Effects

44. Neonicotinoids associated with coated seeds are found widely throughout the environment, and the agricultural landscape is up to 48 times more toxic to insects than it was 25 years ago.[13]

45. Since neonicotinoids are systemic, they are found in the crops grown from treated seeds including the leaves, pollen, and nectar. Neonicotinoids disrupt the central nervous system of insects, and do not discriminate between target and non-target insects, so affect insects and pollinators such as bees that consume the nectar or pollen of the treated crop.

46. On average only 5% of the neonicotinoid coating is absorbed by the crop, leaving roughly 95% of the active ingredient to diffuse into the surrounding soil and soil water, and eventually into waterways. In addition, neonicotinoid coatings are abraded off into the talc or other lubricant added to seed boxes to prevent coated seeds from sticking together, and the neonicotinoid-rich lubricant dust lost during planting travels long distances on the wind during planting. In short, the bulk of the coating does not remain in or on the treated articles: the seeds. The result is widespread contamination of the air, soil, marginal vegetation, waters, neighboring farms, and beehives. Pesticide contamination thus results on vast areas extending far beyond the planted fields, affecting non-target organisms.

47. Neonicotinoids persist in the environment, creating the potential for increasing concentrations in the soil over time with repeated use, exacerbating risks to non-target organisms.

48. The effects on wildlife range from direct harm to both managed and wild bees and other beneficial terrestrial insects, to contaminated runoff decimating aquatic invertebrates, to

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[12] Jacob Pecenka et al., *IPM Reduces Insecticide Applications By 95% While Maintaining Or Enhancing Crop Yields Through Wild Pollinator Conservation*. 118 Proc. Nat'l Acad. Sci. USA (2021).

[13] Kendra Klein & Anna Lappé, *America's agriculture is 48 times more toxic than 25 years ago. Blame neonics*, The Guardian (Aug. 2019).

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both acute and chronic effects on birds that ingest the coated seeds. Traces of residual neonicotinoids can have a mixture of lethal and sublethal effects on a wide range of taxa.

49. Many beekeepers have observed toxic dust clouds billowing from seed planting machines, spreading neonicotinoids into integral bee habitat. Honey bee kill incidents caused by coated seeds have numbered in the hundreds and the true number is likely far higher. These incidents have killed hundreds of millions of individual bees due to acute dust-off kills and chronic damage to bee hives. Sublethal doses can result in honey bee colony damage through chronic effects, which compromise the behavior and immunity of bees, and the health of entire colonies, contributing to substantial losses under the additional stress of pathogens and parasites.

50. Harm to noncommercial bees and other pollinators is equally deadly. 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 has also been identified through exposure routes such as contamination of nesting materials. The harm to pollinators harms U.S. agriculture, which relies on wild pollinators to pollinate food crops.

51. Because neonicotinoids are water soluble, increasing contamination of ditches, streams, groundwater, lakes, rivers, and marine areas is being documented, with coatings applied to crop seeds a primary source of the contamination. The three major neonicotinoids were found to be prevalent throughout the year in sampled tributaries to the Great Lakes, the largest freshwater ecosystem in the world. EPA has found ongoing chronic effects for many aquatic invertebrates and some groups likely to suffer acute effects. Aquatic invertebrates are core contributors to nutrient cycling, water quality, and aquatic food webs that support fish and wildlife, so lethal and sublethal effects to these organisms can have far-reaching consequences.

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52. 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.[14]

53. Bird species are being exposed to and harmed by coated seeds. 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. Birds could also be harmed by eating neonicotinoid-intoxicated organisms like slugs or earthworms. In addition to direct mortality to birds from ingesting neonicotinoid-coated seeds, research has demonstrated sublethal effects, such as reduced body fat and disorientation.

54. Coated seeds have been documented as seriously harming humans and pet dogs despite neonicotinoids supposedly not affecting large mammals. In Nebraska, a bioethanol company fed surplus neonicotinoid coated corn seeds into its bioethanol plant, resulting in polluted water and soil to levels posing serious health threats to people and animals. Tests on the corn waste emanating from the plant revealed neonicotinoid levels as high as 427,000 parts per billion, emphasizing the need for proper regulation of coated seeds and strict enforcement. People reported eye and throat irritation and nosebleeds. Pet dogs grew ill, staggering about with dilated pupils, while colonies of bees died, and birds and butterflies were afflicted with neurological damage as well. Residents who reported the debacle to EPA said the agency's response was that it did not think it could do anything about the problem.[15]

55. Humans are increasingly getting exposed to neonicotinoids through the food supply and water contamination. Neonicotinoids have been found in fruits such as apples,

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[14] Margaret Douglas et al., *Neonicotinoid Insecticides Travels Through A Soil Food Chain, Disrupting Biological Control Of Non-Target Pests And Decreasing Soya Bean Yield*, 52 J. of Applied Ecology 250-260 (2014).

[15] 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, *Public records reveal frustration as state sought to deal with pesticide dangers from ethanol plant*, Lincoln Journal 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.

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cherries, and strawberries, as well as honey and baby food. Neonicotinoids are ubiquitous in surface waters and may be contaminating aquifers. Human urine samples show that at least half the U.S. population is exposed to neonicotinoids on a regular basis. 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, though further research is called for. Coated seeds have facilitated the increased use and spread of neonicotinoids through the environment, heightening the risks to the environment, wildlife, and humans.

Harm to Endangered and Threatened Species

56. Pesticide escape into the environment associated with coated seeds affects a vast number of non-target species, including those protected under the ESA.

57. The Fish and Wildlife Service (FWS) found that neonicotinoid-coated seeds were strongly implicated as a factor endangering the Rusty Patched Bumble Bee. Pollinators such as the Rusty Patched Bumble Bee foraging on treated plants are exposed to the chemicals directly. Coated seed technology allowed neonicotinoids to become large-scale, preemptive pesticides, and that increased use is correlated with a precipitous decline of the species.

58. Two butterflies, the Dakota skipper (*Hesperia dacotae*) and Poweshiek skipperling (*Oarisma poweshiek*), listed under the ESA in 2014 also had neonicotinoid-coated seeds explicitly singled out by the FWS as a significant factor that led to their listings.

59. On August 26, 2021, EPA released draft ESA Biological Evaluations (BE) for neonicotinoids to evaluate their effects on species and their critical habitat. EPA's draft BEs showed widespread harm was predicted. For example, the agency expects nearly 80% of all endangered species—1,445 different kinds of plants and animals—are likely to be "adversely affected" by the neonicotinoid imidacloprid, and the pesticide will adversely modify the designated critical habitats of 658 species.

60. However, in the draft BEs EPA did not even conduct a quantitative risk assessment of ecological harm from neonicotinoid seed treatments, and moreover failed to even provide any

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estimate of the total amount applied to seeds, despite the fact that seed treatments are by far the major use of these insecticides.

The Treated Article Exemption

61. EPA first issued the Treated Article Exemption, 40 C.F.R. § 152.25(a), in 1988. Neonicotinoid-coated seeds were neither mentioned in the regulation text nor in the Federal Register notice accompanying the exemption, and were not in use in agriculture at the time.

62. By the early 2000, coated seeds were coming into use in agriculture. And in 2003, EPA and the Pest Management Regulatory Agency of Canada jointly issued a paper called *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States* (Harmonization Paper). The Harmonization Paper concluded that coated seeds should be *excluded* from the Treated Article Exemption: "The term 'for the protection of the [seed] itself' means that the pesticidal protection imparted to the treated seed does not extend beyond the seed itself."[16] The Harmonization Paper otherwise provided no coverage or analysis of systemic pesticides or neonicotinoid-coated seeds.

63. Despite this interpretation EPA has instead persisted in practice in its view that the Treated Article Exemption *does* include systemic coated seeds, despite the intended and actual pesticidal effects extending far beyond the articles (seeds) themselves. At the same time the agency has studiously avoided making this interpretation formal or final in any final agency action.

64. In practice EPA neither requires registration of the seeds nor imposes enforceable labeling on their bags or tags, labeling that would otherwise be required under FIFRA.

65. Not only does the extension of the Treated Article Exemption to these pesticidal seeds violate the exemption's plain language, it also violates the basic FIFRA safety standard. EPA cannot exempt a pesticide that violates this safety standard, *i.e.*, that the pesticides *as commonly used* will not cause unreasonable adverse effects to the environment.

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[16] *Harmonization of Regulation of Pesticide Seed Treatment in Canada and the United States* April 11, 2003, pp. 1-2, (Joint Regulatory Directive of EPA and the Pest Management Regulatory Agency of Canada), perma.cc/3MUH-B9VQ.

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Anderson et al. v. McCarthy[17]

66. On January 6, 2016, CFS filed a case challenging EPA's position that coated seeds are exempt from the requirements of FIFRA.

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

68. The case was decided on procedural grounds. After first denying a motion to dismiss and ordering production of the administrative record, on cross motions for summary judgment the court concluded that while it was "most sympathetic to the plight of our bee population and beekeepers," there was not any EPA final agency action on the issue that could be challenged.[18]

Plaintiffs' 2017 Petition

69. EPA is tasked with regulating the use of pesticidal products in order to protect public health and the environment. Pub. L. No. 92-516, 86 Stat. 973. As part of that responsibility, EPA must ensure that pesticides are registered under FIFRA. Nevertheless, EPA continues to insist that coated seeds fall under the Treated Articles Exemption.

70. In addition to failing to comply with FIFRA by declining to require registration of coated seeds, EPA has so far also failed to comply with mandates in the ESA that require consideration of the adverse impacts of coated seeds on threatened and endangered species, 16 U.S.C. § 1536.

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[17] *Anderson v. McCarthy*, No. C 16-00068 WHA, 2016 WL 6834215 (N.D. Cal. Nov. 21, 2016).

[18] *Id.* at *13.

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71. A few months after the court dismissed the first coated seeds case, on April 26, 2017, Plaintiffs submitted a legal petition for rulemaking to EPA urging the agency to remedy those failures, on behalf of itself and 10 other entities. Specifically, the petition requested, *inter alia*, that EPA take the following actions:

(1) Amend 40 C.F.R. § 152.25(a) to clarify that it does not apply to seeds for planting 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

(2) In the alternative publish a final, formal, agency interpretation in the Federal Register stating that EPA interprets the exemption in 40 C.F.R. § 152.25(a) not to apply to seeds for planting coated with systemic pesticides, such as the neonicotinoids, that are intended to kill pests of the plant instead of pests of the seed itself.

(3) Analyze the potential human health and environmental risks of coated seeds under the ESA; and

(4) Enforce FIFRA's numerous pesticide registration and labeling requirements for each separate crop seed product that is coated with a neonicotinoid or other systemic insecticidal chemical.

72. On December 25, 2018, EPA opened a sixty-day public comment period in response to Plaintiffs' petition. 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). The comment period ran until March 26, 2019 and attracted 16,343 comments.

73. Public comments highlighted the agency's flawed basis for exempting coated seeds as treated articles, as well as the harm EPA's insufficient regulation of coated seeds has caused and is causing to pollinators, birds, aquatic organisms, and the environment.

74. In the approximately five years since Plaintiffs filed the petition, the agency still has not issued a response or answer to the petition in whole or in part.

EPA's Ongoing Failure to Meaningfully Examine or Regulate Coated Seeds

75. Despite refusing to codify the loophole for coated seeds, EPA is very aware that neonicotinoids are used on coated seeds, and that they are creating lasting environmental damage. As long ago as 2003, EPA assessments showed that exposure to treated seeds posed toxic risks to

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birds and mammals. Since then, EPA has conducted risk assessments and studied the impacts of neonicotinoids on pollinators but has routinely ignored the contribution of coated seeds.

76. EPA requires labels to be placed onto the bags or other containers, or onto the affixed tags, of the unregistered pesticidal seeds, which include some sparse warnings superficially aimed at protecting pollinators and other environmental values. While these amount to admissions of the seeds' harmful pesticidal effects, the label language itself is unenforceable by EPA's own statements and its inactions.

77. Even were they enforceable, the bag labels are inadequate to protect against the vast spectrum of environmental and economic impacts, including, but not limited to, death of pollinators, damage to soil and aquatic life, lethal and sublethal effects on birds, and harm to ESA-protected species.

78. In its proposed interim registration review for the neonicotinoid imidacloprid, published in January 2020, EPA decided that this pesticide was too hazardous to be applied via on-farm seed treatment activities to canola, millet, and wheat, even when wearing the maximum possible protective clothing. EPA therefore added the statement "Must be applied in commercial seed treatment facilities only" to the label.[19] Yet despite acknowledging that seed treatment was the primary method for dispersing these hazardous chemicals, EPA did not fully analyze the environmental impacts of this use.

79. Perhaps most problematically, EPA has never provided the public with any justification for treating coated seeds as exempt from the registration and labeling requirements of FIFRA.

EPA's Failure to Respond to the 2017 Petition

80. Almost five years have passed since Plaintiffs filed its 2017 legal petition providing the legal blueprint and impetus for EPA to amend its regulations to make clear that coated seeds are not covered by the Treated Article Exemption and to enforce the requirements of FIFRA. Yet EPA still has not responded to that petition.

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[19] EPA, *Imidacloprid Proposed Interim Registration Review Decision, Case Number 7605*, at 41 (Jan. 2020).

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81. The APA requires that agencies respond to petitions within a reasonable time and without undue delay. While the reasonableness of the time taken by the agency to respond varies depending on the circumstances, it does not usually extend to years like it has here and particularly not in these circumstances. Subsequent to the 2018 comment period, EPA has gone silent and has not indicated any timeline by which it will answer the 2017 Petition. Five years is an especially egregious delay in cases like this where the delay involves danger to the environment and/or public health. Pollinators, threatened and endangered species, American agriculture, human health, and the environment have all suffered because of EPA's failure to regulate. EPA acknowledges the risks of neonicotinoid pesticides and has cancelled the registration of several neonicotinoids in the past, but continually refuses to address the most common form in which neonicotinoids are used – as seed coatings. Because EPA has not yet acted on coated seeds, the environmental damage caused by coated seeds has likely compounded, endangering human health and hastening the insect apocalypse.

Harm to Plaintiffs

82. EPA's failure to respond to the petition injures Plaintiffs' informational and organizational interests, and injures Plaintiffs members' interests.

83. Plaintiffs have a right under the APA to a timely response to their rulemaking petition, and are injured by EPA's failure to provide it, in violation of the APA.

84. EPA's unlawful delay in responding to the 2017 Petition injures Plaintiffs by, *inter alia*, denying them important and urgently needed information about EPA's oversight of pesticidal coated seed products in the form of a petition response—a response to which the Plaintiffs is statutorily entitled under the APA. By denying Plaintiffs the vital and urgent information in a petition response, EPA's failure to respond to the 2017 Petition has violated Plaintiffs' procedural and substantive rights under the APA.

85. Additionally, EPA's failure to act on the petition directly harms Plaintiffs' concrete organizational interests by impeding their abilities as public interest nonprofit organizations to facilitate public involvement in governmental decision-making, and by foreclosing the statutory right that allows for public participation through petitions for rulemaking. As such, EPA's failure

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to act has effectively negated Plaintiffs' right to petition a federal agency for rulemaking under the APA.

86. Further, EPA's continued failure to respond to the 2017 Petition deprives Plaintiffs of a decision on the Petition's merits and, if necessary, the opportunity to seek judicial review of EPA's final decision.

87. Plaintiffs' members' concrete interests in their health and environmental protection, are being and will be adversely affected by EPA's continued failure to respond to the 2017 Petition. Specifically, Plaintiffs' members are suffering or will suffer an ongoing threat to their health, their children's health, and, for farmers and beekeepers, their livelihoods, as well as the health of the natural environment. Plaintiffs members' myriad interests in the natural environment and 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 answer the petition and regulate coated seeds.

88. The requested relief will redress these harms by requiring EPA to respond to the Petition, resulting either in a response that fulfills EPA's statutory duties by protecting public health and the environment from the risks of coated seeds, and/or a final agency action that Plaintiffs may challenge in federal court if they disagree with the agency's response, in whole or in part. Both results would provide Plaintiffs organizations with APA-mandated information, securing their procedural right to receive a timely response to a legal petition for rulemaking and safeguarding their members' interests.

CLAIM FOR RELIEF

VIOLATION OF THE APA

89. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 88 *supra*.

90. EPA is an "agency" under the APA. *See* 5 U.S.C. §§ 551(1), 701(b)(1). The APA requires agencies to "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." *Id.* § 553(e); *see id.* § 551(4) (defining "rule" as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret,

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or prescribe law or policy"). The APA right to petition encompasses the right to petition for a new, revised, or final rule concerning EPA oversight of pesticides and related substances such as coated seeds. *See id.* §§ 551, 553(e).

91. Upon receipt of an APA petition, EPA has a duty to provide a timely response to the petitioners. *Id.* § 555(e) ("Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person . . ."). Such response must be substantive—*i.e.*, it must either grant or deny the petition, in whole or in part.

92. EPA cannot "unlawfully withhold or unduly delay" the Petition response, *id.* § 706(1), which it has here, for nearly five years, with environmental harm ongoing unabated.

93. The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." *Id.* § 702. Agency action includes agencies' failure to act, as here. Plaintiffs and its members are adversely affected by EPA's past and continued failure to respond to the 2017 Petition.

94. The APA states that a reviewing court "shall" interpret statutes and "compel agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1). EPA's failure to respond to and act on the 2017 Petition constitutes unlawfully withheld and unreasonably delayed agency action.

RELIEF REQUESTED

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

(1) Declaring that EPA has violated the APA by failing to provide a timely response to the 2017 Petition;

(2) Declaring that EPA continues to be in violation of the APA by failing to respond to the 2017 Petition;

(3) Ordering EPA to respond to the 2017 Petition by a Court-ordered date certain, by no more than 90 days;

(4) Retaining jurisdiction of this action to ensure compliance with this Court's decree;

(5) Awarding Plaintiffs attorneys' fees and all other reasonable expenses incurred in pursuit of this action; and

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(6) Granting other such relief as the Court deems just and proper.

Respectfully submitted this 14th day of December, 2021, in San Francisco, California.

/s/Sylvia Shih-Yau Wu
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