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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY, CALIFORNIANS FOR PESTICIDE REFORM, CENTER FOR ENVIRONMENTAL HEALTH, 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. 3:22-cv-6001 **COMPLAINT FOR DECLARATORY AND EQUITABLE RELIEF** Administrative Procedure Act Case

Plaintiffs Center for Food Safety, Pesticide Action Network North America, Center for Environmental Health, and Californians for Pesticide Reform (collectively 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) to answer Plaintiff Center for Food Safety's (CFS) 2017 legal rulemaking petition (the 2017 Petition), which the agency is required to do by law. The 2017 Petition called on EPA to amend its pesticide registration regulations to assess whole pesticide formulations and commonly used pesticide mixtures in all parts of its pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA's failure to respond to the petition and failure to test whole formulations means EPA may be allowing pesticide use in ways that have "unreasonable adverse effects on the environment," in direct contravention of the agency's mandate under FIFRA. 7 U.S.C. § 136a(c)(5)(C)). The 2017 Petition is attached as Exhibit A.

2. Under FIFRA, EPA is tasked with protecting human health and the environment from the use of pesticides. Pesticides are made up of one or more active ingredients, as well as inactive, or "inert," ingredients.[1] An active ingredient is an ingredient in a pesticide that is designed to kill, harm, or repel the target pest.[2] An inert ingredient, or "inert", is an ingredient in a pesticide formulation or tank mixture that may not control the target pests, but is included in the pesticide formulation or mixture for other purposes, such as increasing the effectiveness of the active ingredient, ensuring the stability of the pesticide mixture, or altering the volatility and drift

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[1] Committee on Ecological Risk Assessment under FIFRA and ESA, National Research Council, *Assessing Risks to Endangered and Threatened Species from Pesticides* 65 (2013) [*hereinafter* NRC].

[2] EPA, *Basic Information about Pesticide Ingredients*, https://www.epa.gov/ingredients-used-pesticide-products/basic-information-about-pesticide-ingredients#:~:text=An%20%E2%80%9Cactive%20ingredient%E2%80%9D%20prevents%2C,for%20product%20performance%20and%20usability.

properties of the pesticide.[3] The statutory definition of a pesticide is broad, and covers the entire pesticide formulation, including both active and inert ingredients.

3. Even though they are not the active component, inert ingredients often make up the majority of a pesticide formulation, sometimes constituting 99.99% of the volume.[4] And while inert ingredients may or may not have a direct effect on the target pests, they can nonetheless be toxic, biologically active, and hazardous. Over half of so-called inert ingredients approved by the EPA for use in pesticide formulations are considered hazardous air and water pollutants of at least moderate risk.[5] In fact, inert ingredients can be *more* toxic than active ingredients to non-target species.[6]

4. In addition to being toxicologically concerning on their own, inert ingredients often increase the toxicity of active ingredients. Inert ingredients can act synergistically to "meaningfully change the toxicity of insecticides from safe to toxic." [7] For example, pesticide tank mixtures can be over 1,000 times more toxic than active ingredients on their own.[8]

5. Despite these risks, EPA's assessment of pesticides in the pesticide registration process focuses almost entirely on the individual pesticide active ingredients and not the inert ingredients, nor the synergistic effects of interactions amongst different ingredients. As EPA itself

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[3] EPA, *Inert Ingredient Frequently Asked Questions* (May 6, 2014), *available at* https://www.epa.gov/sites/default/files/2014-05/documents/faqs.pdf.

[4] Genrong *et al.*, *Research Status of Toxicity and Residue Detection of High-Risk Pesticide Adjuvants*, 10 (4) Plant Diseases and Pests 26-30 (2019).

[5] Caroline Cox and Michael Surgan, *Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health*, Environmental Health Perspectives, Vol. 114, No. 12, 1803-06, 1804 (Dec. 2006); Holly Knight, *Worst Kept Secrets: Toxic Inert Ingredients in Pesticides* (1998).

[6] Edward Straw & Mark Brown, *Co-formulant in a Commercial Fungicide Product Causes Lethal and Sub-Lethal Effects in Bumblebees*, 11 Nature Scientific Reports 21653 (2021).

[7] Straw *et al.*, *'Inert' Ingredients are Understudied, Potentially Dangerous to Bees and Deserve More Research Attention*. 289 Proceedings Royal Soc. B, at 4 (2022), https://doi.org/10.1098/rspb.2021.2353.

[8] Mesnage, R *et al.*, *Major Pesticides are More Toxic to Human Cells than their Declared Active Principles*, 2014 Biomedical Res. Int'l (Feb. 2014).

admits, "[u]nlike active ingredients, inert ingredients do not have a 'required' data set[.]"[9] Nearly all of EPA's data requirements for pesticide registrations test only the "technical grade active ingredient" or a "typical end-use product," neither of which capture the actual pesticide formulations that are being registered and then used in the real world. As a result, "[m]ost of the tests required to register a pesticide are performed with the active ingredient alone, and not the full pesticide formulation."[10]

6. Accordingly on July 10, 2017, CFS filed the Petition with EPA requesting formal rulemaking to cure EPA's lack of assessment of the potential human health and environmental effects of pesticide whole formulations and tank mixtures. The Petition was a comprehensive, 22-page scientific and legal document detailing the numerous environmental and health impacts that whole formulations have compared to active ingredients alone, outlining EPA's authority under FIFRA, and explaining why EPA's current rules do not prevent "unreasonable adverse effects on the environment" from pesticides as required by FIFRA. *See* Ex. A. The Petition was supported by 147 citations and supporting documents. The Petition more than sufficiently provided both the legal and scientific basis for EPA to (1) revise its pesticide regulations setting data requirements for pesticide registration and review to comprehensively test whole pesticide formulations and tank mixtures for unreasonable adverse effects on the environment, and (2) to require EPA to comply with the Endangered Species Act (ESA) on the effects of whole pesticide formulations and tank mixtures on threatened and endangered species in its pesticide registration actions. To date, EPA has not issued a formal response to the Petition.

7. EPA's failure to respond to the Petition 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). More than five years have passed since EPA first received the Petition.

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[9] EPA, *Inert Ingredient Frequently Asked Questions*, *supra* note 3.

[10] Cox & Surgan, *supra* note 5.

As a result of EPA's inaction, pesticide formulations and tank mixtures continued to be used without any adequate assessment of their human health and environmental impacts.

8. The interests of Plaintiffs and their members are continuing to be harmed by EPA's failure to respond to the Petition. EPA's failure to answer the petition alone is sufficient cognizable injury in this context. Plaintiffs are public interest nonprofit organizations with dedicated programs addressing and reducing the harms of pesticides to human health and our environment and have a statutory right to a response. Further, many of Plaintiffs' individual members reside, work, and/or recreate in areas where the pesticide formulations and tank mixtures are sprayed. Some are concerned about the health risks of pesticide formulations and tank mixtures to them and their families. Some of Plaintiffs' members who farm or garden are concerned about the potential increased toxicity of pesticide whole formulations or tank mixtures to their property. And others of Plaintiffs' members have dedicated interests in the observation and protection of sensitive wildlife, including federally protected endangered species, species and habitat at risk from the potential increased toxicity of pesticide whole formulations and tank mixtures.

9. 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 the Petition by a Court-ordered date certain and without further unlawful delay.

JURISDICTION

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

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

12. 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

13. 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

14. 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, with many thousands of conservationists, gardeners, farmers, and beekeepers. CFS and its members are being, and will be, adversely affected by EPA's continued failure to answer CFS's legal petition and research the impacts that inert ingredients and whole formulations of pesticides have on human health and environmental health.

15. CFS combines a myriad of 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.

16. 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 pesticides in a manner that minimizes negative impacts, such as wildlife mortality and human health risks. This advocacy has specifically included closing regulatory loopholes in the pesticide registration process, such as the whole formula loophole at issue here. CFS has commented on

numerous agency actions for pesticides, submitted petitions to agencies, and litigated various cases to prevent environmental harm.

17. 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 where pesticides and tank mixtures are applied, and thus have a strong interest in ensuring that EPA protect public health and the environment from the potential increased toxicity of pesticide whole formulations and tank mixtures. PANNA's members are highly concerned by the lack of assessment of actual pesticide formulations and their effects 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.

18. Plaintiff **Center for Environmental Health (CEH)** is a tax-exempt, nonprofit corporation with an office in Oakland, California. Founded in 1996, CEH is a nonprofit organization dedicated to protecting the public from environmental and public health hazards, including harmful pesticides. CEH achieves its mission by working with communities, consumers, workers, government, and the private sector to demand and support business and agricultural practices that are safe for public health and the environment.

19. As part of its mission, CEH and its staff have long been involved in efforts to combat the negative human health and environmental effects of pesticides and other harmful contaminants in our food system. For example, CEH is a member of co-plaintiff Californians for Pesticide Reform, an organization whose mission is to protect public health, improve

environmental quality, and expand a sustainable and just agriculture system by seeking to change state and local pesticide policies and practices. When necessary, CEH also engages in public interest litigation to address the concerns of pesticide safety raised by the current regulatory framework and the negative impacts of unsafe products. The interests of CEH and its members in reducing the harmful impacts stemming from pesticide use are being, and will be, adversely affected by EPA's ongoing failure to assess the effects of whole pesticide formulations.

20. Plaintiff **Californians for Pesticide Reform (CPR)** is an unincorporated statewide coalition, headquartered in Lindsay, California, whose mission is to protect public health, improve environmental quality and support a sustainable and just agricultural system by building a diverse movement across California to change statewide and local pesticide policies and practices. Founded in 1996, CPR is made up of more than 210 member organizations across California, including public health, children's health, educational and environmental advocates, clean air and water organizations, health practitioners, environmental justice groups, labor organizations, farmers, and sustainable agriculture advocates, all interested in shifting the way pesticides are used in California. When necessary, CPR engages in both state and federal public interest litigation to address the concerns of pesticide safety raised by the current regulatory framework. The interests of CPR and its coalition members in protecting public health and improving environmental quality are being, and will be, adverse affected by EPA's ongoing failure to require testing and data on whole pesticide formulations.

Defendants

21. Under FIFRA, Defendant EPA is charged with the registration of pesticides.

22. 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.

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

LEGAL AUTHORITY

I. ADMINISTRATIVE PROCEDURE ACT

24. 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).

25. 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).

26. 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" 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.

27. 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

28. FIFRA controls the registration, 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).

29. 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).

30. 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).

31. When deciding if there are unreasonable adverse effects on the environment, EPA must take into account "the economic, social and environmental costs and benefits of the use of [the] pesticide." *Id* § 136(bb). "Environment" "includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these." *Id.* § 136(j). For pesticides used on food products, EPA must also consider the "human dietary risk from residues." *Id.* § 136(bb).

32. Congress tasked EPA with setting forth the necessary support data for pesticide registrations. *Id.* § 136a(c)(2). Congress specified that the data collected should reflect a pesticide's use in its entirety. *Id.* § 136a(c)(5); *see also* § 136a(c)(2)(A).

33. An application for registration is incomplete if it contains insufficient information for EPA to determine if a pesticide is safe. 40 C.F.R. § 152.104. Registration of a pesticide—conditional or otherwise—cannot continue on the basis of an incomplete application. *Id.* § 152.105. Once a pesticide is registered, FIFRA provides EPA with ongoing oversight authority, and EPA may at any time propose cancellation if it appears a pesticide does not meet FIFRA's safety standard. 7 U.S.C. § 136d(b).

34. EPA has promulgated regulations that detail the data requirements for pesticide registrations. *See* 40 C.F.R. Part 158.

35. EPA's regulations define and direct what particular pesticide component or formulation are required in studies to generate the necessary data.

36. According to the regulations, studies can be conducted using one of the following: the end use product (EP), the manufacturing use product (MP), the technical grade active ingredient (TGAI), the pure active ingredient (PAI), or a typical end-use product (TEP). *See, e.g.*, 40 C.F.R. § 158.500; *id.* § 158.630.

37. If the EP is used, the data will reflect the effects of the combination of the active and inert ingredients. If the MP is used, the data may or may not reflect the effects of inert ingredients. If the TGAI or PAI is used, inert ingredients will not be factored into the testing at all. *See* 40 C.F.R. § 158.300.

38. Most EPA regulations require registrants to submit toxicity data on active ingredients in isolation. *See* 40 C.F.R. § 158. While acute toxicological effects tests use the EP, chronic toxicological effects tests require only the TGAI or the PAI. *See* 40 C.F.R. § 158.500. Tests for toxicological effects on wildlife (both terrestrial and aquatic non-target organisms) or sediment do not require the EP or the MP. *Id.* § 158.630. Tests for degradation effects and other tests only use the TGAI or the PAI. *Id.* § 158.1300.

STATEMENT OF FACTS

The Toxicity of So-Called "Inert" Ingredients

39. Even though inert ingredients are not the active component in a pesticide formulation designed to control the target pest, they are by no means biologically nor chemically inactive. As EPA explains, "inert" does not mean non-toxic,[11] acknowledging that these chemicals can be harmful.[12] The potential harm of inert ingredients is clear in that hundreds of these chemicals have also been registered for use as active ingredients, and over half of inert ingredients are considered hazardous air and water pollutants of at least moderate risk.[13] This cross-listing of the same chemicals had led scholars to conclude that the distinction between inert and active ingredients is related more to regulation than the toxic potential of the chemical.[14]

[11] EPA, *Inert Ingredients Overview and* Guidance, http://www2.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance (last updated May 24, 2017).

[12] Office of Pesticide Programs, EPA, *Methodology for Determining the Data Needed and the Types of Assessments Necessary to Make FFDCA Section 408 Safety Determinations for Lower Toxicity Pesticide Chemicals* 6 (June 7, 2002), *available at* https://web.archive.org/web/20030413194437/http://www.epa.gov/oppfead1/cb/csb_page/updates/lowertox.pdf.

[13] Cox & Surgan, *supra* note 5, at 1804; Knight, *supra* note 5.

[14] Cox & Surgan, *supra* note 5, at 1804.

40. Inert ingredients "are not ecotoxicologically benign." [15] In fact, research shows that so-called 'inert' ingredients on their own can be *more* toxic than active ingredients.[16] This is problematic because inert ingredient are used in much higher quantities than active ingredients.[17] This means that pollinators, amphibians, birds, listed species, and humans have vastly higher exposure to inert ingredients than active ingredients.[18]

41. For example, organosilicones, a class of inert ingredients, have been found to impair honey bees' learning ability and increase mortality in the absence of active ingredients.[19] Yet, organosilicones are used as adjuvants—additions in pesticide tank mixtures—then sprayed directly on flowering almond trees in California, where 80% of the nation's honey bees pollinate, eating pollen and ingesting organosilicones in the process.[20]

42. A 2022 meta-study covering all studies on the effect of inert ingredients on bees concluded that inert ingredients "urgently require[] research attention and funding" and that "a well-funded and systematic approach to [inert] residue monitoring [] is something *only* a regulatorily mandated process can offer."[21] (emphasis added.)

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[15] Straw *et al.*, *supra* note 7, at 7.

[16] Edward Straw & Mark Brown, *supra* note 6.

[17] Genrong, *supra* note 4, at 26.

[18] Straw *et al.*, *supra* note 7, at 6.

[19] Ciarlo TJ, Mullin CA, Frazier JL, Schmehl DR, *Learning Impairment in Honey Bees Caused by Agricultural Spray Adjuvants*, 7 PLoS ONE 1 (July 16 2012), http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0040848.

[20] Fine, J. D. *et al.*, *An Inert Pesticide Adjuvant Synergizes Viral Pathogenicity and Mortality in Honey Bee Larvae*, *Sci. Rep.* 7, 40499; doi: 10.1038/srep40499 (2017). *See also* Mullin *et al.*, *The formulation makes the honey bee poison*, Pesticide Biochemistry and Physiology (2015), doi: 10.1016/j.pestbp.2014.12.026.

[21] Straw *et al.*, *supra* note 7, at 6.

EPA's Acknowledgment of the Potential Harms of Inert Ingredients

43. EPA recognizes the potential harms of inert ingredients, and it has repeatedly indicated that reassessing their evaluation and testing requirements is necessary.

44. In 1987, EPA created lists that divided inert ingredients into four categories. The purpose of these lists was to establish priorities for regulatory activities related to inert ingredients of highest concern. Of primary concern were "List 1" inert ingredients, inert ingredients of toxicological concern. "The criteria used to place chemicals on List 1 were carcinogenicity, adverse reproductive effects, neurotoxicity or other chronic effects, [] developmental toxicity (birth defects)[,] documented ecological effects[,] and the potential for bioaccumulation."[22] EPA required registrants to submit additional safety data on List 1 inert ingredients, and, ultimately, nearly all of these inert ingredients disappeared from pesticide formulations due to cancellation or voluntary removal.

45. Despite recognizing the potential effects of inert ingredients, EPA's evaluation of inert ingredients remains cursory. The 1987 policy also required that any new inert ingredients go through a new registration process. In this new process, however, "[t]he minimal data generally required to evaluate the risks posed by the presence of a new inert ingredient in a pesticide product [was] a subset of the kinds of data typically required for active ingredients under 40 CFR Part 158."[23]

46. As a result of an ongoing review of inert ingredients, in 1999, EPA published a notice that it had removed certain chemicals from its approved inert ingredient lists.[24] EPA emphasized that these unapproved inert ingredients would not be registered until a "registrant satisfies all 10 data requirements as identified by [EPA], and [EPA] is able to make a determination

[22] Inert Ingredient in Pesticide Products Policy Statement (IIPS), 52 Fed. Reg. 13,305 (Apr. 22, 1987).

[23] *Id.*

[24] Inert Ingredients No Longer Used in Pesticide Products, 64 Fed Reg. 31,575, 31,575 (June 11, 1999).

that the use of the inert ingredient will not pose unreasonable risk to human health or the environment."[25]

47. In 2006, Congress passed the Food Quality Protection Act (FQPA), which "required the reassessment of inert ingredient tolerances and tolerance exemptions [for pesticides used on food] that were in place before August 3, 1996." Pub. L. No. 104-170 (1996). EPA completed this review, but to date has not reassessed inert ingredients used in pesticide formulations not used on food.

48. In 2009, EPA proposed disclosing inert ingredients on pesticide labels, but in 2014 revoked that proposal.[26] Explaining its decision not to mandate inert ingredient labeling, EPA resolved to further categorize and prioritize inert ingredients for review and regulatory efforts; EPA also specified that non-food use inert ingredients were top priority, since they did not benefit from the reassessment conducted for food use inerts, and about 230 non-food-use inert ingredients remained for further consideration of potential risks.[27]

49. Despite these repeated acknowledgments of the potential harm of inert ingredients and the need to reassess them, EPA has not taken action to strengthen its review of inert ingredients by requiring more stringent consideration of their potential effects in its pesticide review process.

The Synergistic Effects of Pesticide Ingredients

50. Synergy is the interaction of two or more ingredients in a mixture in such a way as to enhance their toxic effects beyond the effects of each individual ingredient.[28] Research suggests

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[25] *Id.*

[26] Public Availability of Identities of Inert Ingredients in Pesticides, 74 Fed. Reg. 68,215, 68,216-17 (Dec. 23, 2009) (citing 7 U.S.C. § 136a(c)(5)(C)).

[27] EPA Office of Chemical Safety and Pollution Prevention Letter to Attorney General of California, Northwest Coalition for Alternatives to Pesticides, and Western Environmental Law Center (May 22, 2014), EPA-HQ-OPP-2014-0558-0003.

[28] Press Release, EPA, *EPA Seeks Comment on Process for Evaluating Pesticide Synergy for Ecological Risk Assessments* (Sept. 9, 2019).

that the synergistic effects of multiple active ingredients, or a pesticide formulation's active and inert ingredients, can boost a pesticide's toxicity, ecotoxicity, and exposure to both target and non-target organisms by a factor of up to100.[29]

51. Scientific findings from the past decade have consistently found that inert ingredients synergistically interact with active ingredients to make pesticides more hazardous. A 2020 meta-study found that 24 of 36 of scientific studies found the toxicity of whole formulations to be greater than the toxicity of the active ingredient alone.[30] One of these studies found that 8 out of 9 pesticide formulations were "several hundred times more toxic than their active principle."[31] Indeed, it is well documented that pesticide "[f]ormulations are generally more toxic than active ingredients, particularly fungicides, by up to 26,000-fold[.]"[32]

52. Additionally, inert ingredients can meaningfully increase the half-life of an active ingredient, resulting in active ingredients existing in the ecosystem for longer amounts of time than EPA's active-ingredient-only tests considered.[33] Both the National Marine Fisheries Service and the Fish and Wildlife Service express substantial concern for these potential synergistic effects in their Biological Opinions (BiOp).[34]

53. In bees, for example, data has demonstrated "incredibly high variation in the toxicity of [different] formulations with the same active ingredients."[35] A 2022 study found that

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[29] NRC, *supra* note 1 at 112 (citing Sahay & Agarwall 1997).

[30] Nagy *et al.*, *Systematic Review of Comparative Studies Assessing the Toxicity of Pesticide Active Ingredients and Their Product Formulations*, 181 Env't Rsch. 108926, at 17 (Nov. 2020).

[31] Mesnage, R *et al.*, *Major Pesticides are More Toxic to Human Cells than their Declared Active Principles*, 2014 Biomedical Res. Int'l (Feb. 2014).

[32] Mullin *et al.*, *Toxicological Risks of Agrochemical Spray Adjuvants: Organosilicone Surfactants May Not Be Safe*, 4 Frontiers in Pub. Health 92 (2016), http://journal.frontiersin.org/article/10.3389/fpubh.2016.00092/full.

[33] Genrong, *supra* note 2, at 26.

[34] NRC, *supra*, note 1, at 118-19.

[35] Straw, *supra* note 7, at 4.

50% of adjuvant-active ingredient combinations significantly increased honey bee mortality compared to active ingredients alone.[36] The adjuvants tested were not toxic on their own, so this increased mortality was due exclusively to the synergistic effects between the adjuvant and the active ingredient.

54. Amphibians are another group threatened by synergistic effects of inert ingredients. Both inert and active ingredients in pesticides eventually runoff into wetlands, where amphibians live. Inert ingredients can increase the toxicity of pesticides to amphibians, many of which are listed as endangered or threatened under the Endangered Species Act.

55. For example, amphibians are particularly susceptible to the pesticide glyphosate. Studies done on the different formulations of glyphosate and its various adjuvants found that these varying formulations are highly toxic to amphibians.[37] However, EPA's current mitigation measures on glyphosate applications, such as the size of a buffer to prevent spraying near wetlands, are made based on consideration of the toxicity of the active ingredient glyphosate alone.[38] By failing to consider the synergistic effects of inert and active ingredients, these buffers may be too small to adequately protect sensitive amphibians.

56. Such synergistic effects are not accidental. Inerts are often specifically "designed to affect the behavior of an active ingredient after application."[39] Adjuvants are intentionally added to

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[36] Wernecke *et al.*, *Inert Agric. Spray Adjuvants May Increase the Adverse Effects of Selected Insecticides on Honey Bees (Apis mellifera L.) under Laboratory Conditions*, 129 J. of Plant Diseases and Protection 93, 93 (July 2022).

[37] Relyea, R.A.,2006. Response to Thompson *et al.* Letter to the editor, "The impact of insecticides and herbicides on the biodiversity and productivity of aquatic communities." Ecological Applications 16:2027-2034; Relyea, R.A. and D.K. Jones, *The toxicity of Roundup Original MAX® to 13 species of larval amphibians,* Environmental Toxicology and Chemistry 28: 2004-2008 (2009); Relyea, R.A., *Amphibians Are Not Ready for Roundup*, *in* J.E. Elliott et al. (eds.), Wildlife Ecotoxicology: Forensic Approaches, pp. 267 – 300 (2011). Emerging Topics in Ecotoxicology 3, DOI 10.1007/978-0-387-89432-4_9, © Springer Science+Business Media, LLC 2011.

[38] Norman Wagner, Hendrik Müller & Bruno Viertel, *Effects of a commonly used glyphosate-based herbicide formulation on early developmental stages of two anuran species*, 24 Envtl. Sci. and Pollution Res. Int'l 1496-1508 (2016).

[39] Mullin, *supra* note 32, at 5-6.

pesticides for their powerful ability to enhance absorption and efficacy, leading scientists to conclude that adjuvants can "meaningfully change the toxicity of insecticides from safe to toxic."[40]

57. Consequently, it is essential to consider the synergistic effects among the cocktail of chemicals contained in a pesticide formulation or tank mixture when assessing whether a pesticide poses unreasonable adverse effects to the environment. As a recent literature review concluded, "relevant pesticide risk assessment for pollinators and other non-target species cannot be addressed solely by evaluating the active ingredients[.]"[41]

58. Nonetheless, despite the safety hazards of inerts and the potential synergistic effect of multiple ingredients, most EPA regulations require registrants to submit toxicity data on active ingredients in isolation. *See* 40 C.F.R. § 158.

EPA's Failure to Account for Synergistic Effects of Ingredients in Pesticide Risk Assessments

59. EPA is also aware that its existing pesticide regulations and data requirements do not capture the potential synergistic effects of interactions amongst individual pesticide ingredients, yet the agency still does not require data on synergistic effects of pesticide ingredients as a necessary part of its pesticide assessment.

60. In 2015, amid litigation brought by Plaintiffs and other farming and consumer protection groups challenging EPA's registration of Enlist Duo, a pesticide formulation containing the active ingredients 2,4-D and glyphosate, EPA voluntarily revoked the pesticide registration, citing synergistic effects of the ingredients that made the Enlist Duo pesticide formulation more toxic than EPA had initially found based on review of the individual active ingredients. EPA uncovered the potential for synergy not from any of its registration data, but from a patent claim filed by the pesticide's registrant Dow AgroSciences (now Corteva).

61. In 2019, EPA sought public comment on an interim process for reviewing synergy data for mixtures of pesticide active ingredients.[42] EPA admitted that its current ecological risk

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[40] Straw *et al.*, *supra* note 7, at 4.

[41] Mullin, *supra* note 32, at 5-6.

[42] Press Release, EPA, *supra* note 28.

assessment is "based on toxicity information from studies conducted with single active ingredients."[43] Yet rather than requiring toxicity studies on the whole pesticide formulation, which would then capture any synergistic effects, EPA instead proposed to rely data provided in patent claims concerning synergy effects of pesticide ingredients as the only source of information on synergistic toxicity.

62. EPA received 626 comments on its interim process. Many of the commentors stressed that data submitted for patent claims are insufficient to assess synergistic effects of pesticide formulations and urged EPA to require data on whole formulations of pesticides in order to assess chemical interactions of the different ingredients as part of its pesticide registration process.

63. To date, EPA has not taken any formal action to require whole formula testing that would capture any synergistic effects of the ingredient combinations.

Harm to Threatened and Endangered Species

64. In addition to failing to comply with FIFRA by declining to test whole pesticide formulas, EPA has so far also failed to comply with mandates in the ESA that prevent EPA from registering pesticides that may harm endangered species.

65. Pursuant to the ESA, EPA has a duty to consult with the expert federal wildlife agencies to ensure that pesticide uses authorized by EPA will not likely jeopardize any threatened or endangered species and their critical habitats. 16 U.S.C. § 1536(a)(2). EPA regulations specify that upon determining that its actions "may affect" any listed species or any designated critical habitat, it must consult the designated expert wildlife agencies before acting. 50 C.F.R. § 402.14(a). Effects determinations include the "direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action." *Id.* § 402.02.

66. By not fully testing whole pesticide formulations and tank mixtures, EPA cannot properly determine whether a pesticide as used "may affect" endangered species or critical habitat

[43] *Id.*

or whether it should consult with expert federal agencies on a pesticide's impact on endangered species' survival.[44]

Plaintiff Center for Food Safety's 2017 Petition

67. 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 will not be used in ways that have "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C)). Nevertheless, EPA continues to register pesticides with little more than a cursory look at the toxicity of pesticide mixtures as they are intended to be used in the field.

68. Accordingly, on July 10, 2017, CFS submitted a legal petition for rulemaking to EPA urging the agency to remedy the above failures. The 2017 Petition detailed the existing research on the dangers of inert ingredients and the potential for synergistic effects in pesticide mixtures. The 2017 Petition emphasized that pesticide formulations that act differently may have different effects on the environment (including humans).

69. The 2017 Petition also pointed out that by failing to account for the effects of inert ingredients and for synergistic effects in pesticide mixtures, EPA's current assessment of pesticides focusing solely on single active ingredients violates FIFRA, which defines the term "pesticide" broadly to include "mixture of substances,"[45] rather than the narrower term "active ingredient."

70. The 2017 Petition noted that under FIFRA, EPA cannot register a pesticide use unless EPA determines that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."[46] Because pesticides are commonly used in their existing formulations and/or tank mixtures, EPA's failure to assess whole pesticide formulations and/or tank mixtures violates FIFRA.

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[44] NRC, *supra* n. 1, at 13-14, 65-70, 112-116, 118-128.

[45] 7 U.S.C. § 136(u).

[46] 7 U.S.C. § 136a(c)(5)(D).

71. The 2017 Petition explained that as a result, EPA's pesticide registration decisions based on assessments of single active ingredients cannot be supported by substantial evidence, in violation of FIFRA.[47]

72. The 2017 Petition urged EPA to require enough testing data for every whole pesticide formulation and tank mixture to capture all synergistic effects and potential unreasonable effects on the environment.

73. Specifically, the 2017 Petition requested EPA take the following actions:

> (1) Revise pesticide registration regulations to take into account all pesticide ingredients (active, inert and adjuvant) and their effects on the environment.
>
> (2) Revise pesticide registration regulations to require whole pesticide formulation and tank mixture testing to take into account synergistic effects.
>
> (3) Revise pesticide registration regulations to require inert ingredients and whole pesticide formulations testing for chronic toxicological effects and degradation.
>
> (4) Revise pesticide registration regulations to require Endangered Species Act (ESA) consultation on the effects of whole pesticide formulations and tank mixtures on threatened and endangered species.
>
> (5) Comply with the above requirements in conducting statutorily mandated registration reviews of pesticides.

74. Specifically, to implement requests (1) through (4), the 2017 Petition requested EPA to make specific amendments to its existing pesticide regulations.

75. The 2017 Petition requested that EPA amend the definition of "end-use product" as used in its existing pesticide regulations, 40 C.F.R. § 152.3 and 40 C.F.R. § 158.300, by adding the language in italics:

> End-use product means a pesticide product *being registered, including all active and inert ingredients (including adjuvants and surfactants) in the formulation,* whose labeling:
>
> (1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating or regulating growth of plants, or as a nitrogen stabilizer, and

[47] 7 U.S.C. § 136n.

(2) does not state that the product may be used to manufacture or formulate other pesticide products

76. The 2017 Petition requested that EPA amend the test substance requirements in Part 158, Subpart C, 40 C.F.R. §§ 158.200 to .270, from technical grade active ingredient (TGAI) or typical end-use product (TEP) to End-use product (EP).

77. The 2017 Petition requested that EPA amend the test substance requirements in Part 158, Subpart F, 40 C.F.R. § 158.500, from TGAI or TEP to EP, or End-use product.

78. The 2017 Petition requested that EPA expand the required data for pesticide registration by replacing the phrase "active ingredient" with "end-use product" in Part 158, subpart F, 40 C.F.R. § 158.510(a), concerning tiered testing options for non-food pesticides. The amended provision would read in full (proposed change in itatlics):

> Acute, subchronic, chronic, and other toxicological studies on the *end-use product* must be submitted together. The specific makeup of the set of toxicology study requirements is based on the anticipated exposure to the pesticide as determined by the Agency. If hazards are identified based upon review of these studies, specific exposure data will be required to evaluate risk.

79. The 2017 Petition requested that EPA amend the test substance requirements in Part 158, Subpart G, 40 C.F.R. § 158.630(d), from TGAI or TEP to EP, or End-use product.

80. The 2017 Petition requested EPA add a testing requirement for "Combination and tank mixtures" to Part 158, Subparts C, F, and G as "conditionally required" for all categories, with the following testing note:

> This test is required if, as recommended by the pesticide manufacturer, indicated by the pesticide label, or in common practice, 1) the pesticide product will be mixed prior to application with any recommended vehicles or adjuvants or 2) if the pesticide product will be mixed prior to application with any other approved pesticide product or active ingredient.

81. On December 21, 2018, EPA opened a ninety-day public comment period in response to Plaintiffs' 2017 Petition. EPA, *Petition Seeking Revised Testing Requirements of Pesticides Prior to Registration; Request for Comment*, 83 Fed. Reg. 65672 (Dec. 21, 2018). The comment period ran until March 21, 2019.

82. EPA received more than 500 comments on the 2017 Petition. Many commenters were concerned that EPA's failure to sufficiently test inert ingredients and whole formulas has already caused and will continue to result in devastating impact on bees, other pollinators, and human health.[48] Commenters agreed that testing active ingredients in isolation from how the pesticide is actually used does not adequately illuminate the potential risks of that pesticide's application.

83. In the approximately five years since Plaintiffs filed the 2017 Petition, the agency still has not issued a response or answer to the 2017 Petition in whole or in part.

CLAIM FOR RELIEF

VIOLATION OF THE APA

84. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 83 *supra*.

85. 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, 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. *See id.* §§ 551, 553(e).

86. 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.

87. 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.

[48] 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).

88. 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.

89. 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

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

Respectfully submitted this 12th day of October, 2022, in San Francisco, California.

/s/Sylvia Shih-Yau Wu

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