JENNIFER LODA (CA Bar No. 284889)
PEGGA MOSAVI (*Pro Hac Vice* Pending)
Center for Food Safety
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
Phone: (415) 826-2770
Emails: jloda@centerforfoodsafety.org
pmosavi@centerforfoodsafety.org

Counsel for Plaintiffs

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ALIANZA NACIONAL DE CAMPESINAS, PESTICIDE ACTION NETWORK NORTH AMERICA, RURAL COALITION, CENTER FOR ENVIRONMENTAL HEALTH, ORGANIZACIÓN EN CALIFORNIA DE LÍDERES CAMPESINAS, AND CENTER FOR FOOD SAFETY, *Plaintiffs*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY and MICHAEL REGAN, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *Defendants*.	Case No. 22-cv-9030 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** Administrative Procedure Act Case

TABLE OF CONTENTS

INTRODUCTION 1
JURISDICTION 4
VENUE 4
DIVISIONAL ASSIGNMENT 4
PARTIES 4
STATUTORY BACKGROUND 10
STATEMENT OF THE FACTS 12
CAUSE OF ACTION 49
PRAYER OF RELIEF 50

GLOSSARY

APA - Administrative Procedure Act

EDSP - Endocrine Disruptor Screening Program

EDSTAC - Endocrine Disruptor Screening and Testing Advisory Committee

EPA - Environmental Protection Agency

FFDCA - Federal, Food, Drug, and Cosmetic Act

FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act

FQPA - Food Quality Protection Act

IG - Inspector General

Plaintiffs Alianza Nacional de Campesinas, Pesticide Action Network North America, Rural Coalition, Center for Environmental Health, Organización en California de Líderes Campesinas, and Center for Food Safety (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 agency) to implement the Endocrine Disruptor Screening Program (EDSP) by the statutory deadline of August 3, 1999, and to test all pesticide chemicals for possible endocrine effects as the agency is required to do in accordance with the Food Quality Protection Act (FQPA).[1]

2. Congress unanimously enacted the FQPA in 1996. The Act, an overhaul of federal pesticide and food safety policy, responded to scientific advancements revealing the dangers posed by many pesticides used in the United States, particularly to children.

3. The science of endocrine disruption grew substantially between the late 1980s and mid-1990s, with contributions from scientific disciplines ranging from conservation biology to endocrinology to toxicology.[2] Various scientists discovered that certain chemicals were disrupting the endocrine systems of both humans and wildlife, impairing development and reproduction.[3] Scientific studies have since linked endocrine disruption to additional adverse human health outcomes, including but not limited to altered nervous system function, disrupted

---

[1] Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996) (codified as amended in scattered sections of 21 U.S.C. § 301 et seq.).

[2] Maricel V. Maffini & Laura N. Vandenberg, *Failure to Launch: The Endocrine Disruptor Screening Program at the U.S. Environmental Protection Agency*, FRONTIERS IN TOXICOLOGY, May 2022, at 2.

[3] *Id.*

immune function, cancer, respiratory issues, metabolic abnormalities, diabetes, obesity, cardiovascular problems, and neurological and learning disabilities.[4]

4. In response to scientific and broader public concern that certain chemicals interfere with the endocrine system and adversely affect human health, Congress included provisions in the FQPA requiring EPA develop and implement a program investigating the potential endocrine effects posed by all pesticide chemicals and do it within established timelines.

5. Congress mandated EPA implement an endocrine disruptor screening program no later than August 1999 and tasked EPA with reviewing *every* registered pesticide chemical for potential human endocrine disruption. Congress also required EPA to use this information and its legal authority to take action to safeguard humans from chemicals that have endocrine effects. However, EPA can only take such actions to protect public health by complying with the FQPA's mandates, starting with implementing the EDSP and completing the testing of all registered pesticide chemicals for possible endocrine effects. EPA's failure to implement the EDSP leaves all humans and wildlife vulnerable to the health harms of endocrine disruptors.

6. As of the time of this filing, more than twenty-five years after the passage of the FQPA, EPA has yet to implement the EDSP it created and further, has failed to even initiate endocrine testing for approximately 96% of registered pesticides. Of the few pesticide chemicals that EPA has begun the screening process for, almost half remain unfinished, with more screening necessary to definitively

---

[4] *Endocrine-Disrupting Chemicals (EDCs)*, ENDOCRINE SOC'Y (Jan. 24, 2022), https://www.endocrine.org/patient-engagement/endocrine-library/edcs [hereinafter Endocrine Society]; *see generally* A.C. Gore et al., *EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine Disrupting Chemicals*, ENDOCRINE REV. Dec 2015, at E1, https://academic.oup.com/edrv/article/36/6/E1/2354691.

determine endocrine effects. This continuing failure is despite reviews of the EDSP by the Office of Inspector General, drawing attention to the program's failings and making recommendations to promote progress.

7. Further, EPA also missed its own timelines for implementation of the EDSP, timelines set by Congress upon appropriation of additional funds, and court-imposed timelines set pursuant to a prior litigation settlement agreement. EPA failed to even complete endocrine screening of a small subset of pesticides that the agency itself flagged as potential endocrine disruptors over seven years ago.

8. All these failings are indications of EPA's lack of commitment to implement the EDSP and to achieve its congressional purpose of safeguarding public health, in violation of Congress's commands.

9. EPA's failure to abide by their statutory mandates to "implement" the EDSP by August 3, 1999, and to test all pesticide chemicals for possible endocrine effects violates the Administrative Procedure Act (APA), because EPA cannot "unlawfully withhold" or "unreasonably delay" agency action. 5 U.S.C. § 706. And as a result of EPA's inaction on the EDSP, EPA continues to approve the use of pesticides in vast quantities without adequately considering their potential to impact endocrine systems, with the associated risks that Congress decades ago commanded the agency to address still going unabated.

10. Accordingly, this Court should hold that EPA's failure to implement the EDSP and test all pesticide chemicals for possible endocrine effects violates the FQPA and APA, and order EPA to implement the EDSP and test all pesticide chemicals by a Court-ordered date(s) 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 28 U.S.C. § 1346 (United States as Defendant).

12. Plaintiffs have a right to bring this action pursuant to the Administrative Procedure Act (APA). 5 U.S.C. § 702.

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.

DIVISIONAL ASSIGNMENT

15. The action arises outside of the district, but venue is proper due to Plaintiffs' residency. Center for Food Safety maintains an office in San Francisco County. Thus, pursuant to Civil L.R. 3-2(c), it is appropriate to request intradistrict assignment in San Francisco.

PARTIES

Plaintiffs

16. Plaintiffs are public interest nonprofit organizations with dedicated programs addressing and reducing the harms of pesticides to human health and our environment. They include Alianza Nacional de Campesinas, Pesticide Action Network North America, Rural Coalition, Center for Environmental Health, Organización en California de Líderes Campesinas, and Center for Food Safety.

17. Plaintiff **Alianza Nacional de Campesinas** (Alianza Nacional) is a tax-exempt, nonprofit organization of farmworker women, comprised of fifteen member organizations based across ten states and Washington D.C. Its members

include Plaintiffs Líderes Campesinas and Rural Coalition. Alianza Nacional addresses a wide range of topics affecting farmworker women (campesinas), including the effects of pesticide exposure on farmworker women and their families. Alianza maintains a campaign, the Satchel (Moralitos), dedicated to creating public awareness about the health risks posed by pesticide exposure to farmworker women and their families. Alianza members hold community events where they teach women how to protect themselves from pesticide exposure, what to do in the event of an exposure, and what the current EPA policies are on legal pesticide use. Alianza is actively working to strengthen pesticide protections for farmworkers, by pushing for more protective legislation, and as here, engaging in public interest litigation to protect the interests of farmworker women and their families. The interests of Alianza Nacional and its members in the health and wellbeing of farmworker women are being, and will be, adversely affected by EPA's continuing failure to complete testing of all pesticide chemicals for endocrine effects.

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 where pesticides are applied, and thus have a strong interest in ensuring that EPA

protect public health and the environment from the potential pesticide chemicals that are endocrine disruptors. PANNA's members are highly concerned by EPA's lack of testing of pesticide chemicals for possible endocrine effects on humans and wildlife.

19. Plaintiff **Rural Coalition** is a tax-exempt, nonprofit membership organization located in Washington, D.C. that represents fifty grassroots and community based organizational members. Rural Coalition seeks just and sustainable food systems that bring fair returns to diverse small farmers and ranchers, tribal and other small communities; fair and safe working conditions and dignity for farmworkers and food chain workers; protection of mother earth; and safe, adequate, and healthy food for all, especially the elders, youth, and most vulnerable among us. Rural Coalition addresses the needs and concerns of historically underserved minority family farming communities and the issue of worker protection, including protection of farmworkers. Rural Coalition submits comments to regulatory agencies, provides action alerts to its members to encourage effective participation in the administrative rule making process, and when necessary, and as here, engages in public interest litigation to address the impacts of the current industrial food production model and its impacts on farmworkers and rural communities. Rural Coalition and its members are injured by EPA's failure to complete testing of all pesticide chemicals for endocrine effects. Many of Rural Coalition's members are farmers and farmworkers who live in rural areas where excessive amounts of pesticides are applied to crops. Rural Coalition's member groups also represent workers in the nursery industry, and those who maintain golf courses and other landscapes where pesticides are routinely applied. Rural Coalition and its members are concerned about the detrimental impacts on farmers, farmworkers, and on the public health of rural farm communities that will result

from the continued failure to complete testing of all pesticide chemicals for endocrine effects.

20. 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.

21. 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 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 implement the EDSP and test all pesticide chemicals for endocrine effects.

22. Plaintiff **Organización en California de Líderes Campesinas** (Líderes Campesinas) is a tax-exempt, nonprofit membership organization of farmworker women and girls located in Oxnard, California and has organized its Chapters around rural regions in California, including: Salinas, Greenfield, Soledad, Madera, Huron, Merced, Fresno, Ventura County, Coachella Valley, Northern Santa Barbara, Sonoma, Napa, and Kern. Líderes Campesinas represents

a culmination of decades of work by farm working women (campesinas). Farmworker women have been the leaders of many grassroots and mobilizing efforts to improve the lives of farmworker communities. Líderes Campesinas provides these long-time leaders and activists with the opportunity to coordinate their work statewide and has built collectives so that campesinas may become agents of change and be a more effective unified voice. Líderes Campesinas addresses a wide range of topics affecting campesinas, including the effects of pesticides on farmworkers and rural agricultural communities. Líderes Campesinas has educated farmworkers and created brochures in Spanish to provide written information for campesinas, including brochures on how to prevent pesticide poisoning. Líderes Campesinas has also worked with federal and state agencies and other organizations and public service providers to achieve better results on rural health issues. When necessary, and as here, Líderes Campesinas also engages in public interest litigation to protect the interests of rural farmworkers and communities. Líderes Campesinas and its members are being, and will be, adversely affected by EPA's continued failure to complete testing of all pesticide chemicals for endocrine effects.

23. Plaintiff **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, consumers, and farmers. CFS and its members are being, and will be, adversely affected by EPA's failure to implement the EDSP by the August 1999 statutory deadline and by EPA's continuing failure to test all pesticide chemicals for possible endocrine effects despite being required by law to do so.

24. 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.

25. Since its inception twenty-five years ago CFS has had a flagship program on pesticides and their impacts on humans and other wildlife, 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 pesticide product uses, including timely review of the possible health risks posed by pesticides. CFS has commented on numerous agency actions for pesticides, submitted petitions to agencies, and when necessary litigated myriad public interest cases to prevent harm to the environment and human health.

26. Plaintiffs' members are farmworkers and farmers that work with crops sprayed with pesticides EPA has identified as possible endocrine disruptors, rural residents who live in areas with heavy pesticide use, and consumers who routinely ingest such crops. Many are concerned about the health risks posed to them and their families by the pesticides EPA has already recognized as potential endocrine disruptors and those EPA will one day recognize as endocrine disruptors. Other members have dedicated interests in observing and protecting sensitive wildlife, including species exposed to the pesticides EPA has recognized as having potential endocrine effects on wildlife. The interests of Plaintiffs and their members are

continuing to be harmed by EPA's failure to implement the EDSP and complete endocrine testing of all pesticide chemicals.

Defendants

27. Under the FQPA, Defendant EPA is charged with the implementation of the EDSP and the testing of all pesticide chemicals for endocrine effects.

28. 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.

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

STATUTORY BACKGROUND

Administrative Procedure Act

30. Pursuant to the APA, "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . is entitled to judicial review thereof." 5 U.S.C. § 702.

31. "Agency action" is defined to include not just affirmative agency action but also—as the case here—the "failure to act," *Id.* § 551(13).

32. Pursuant to the APA, a reviewing court "shall compel agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1).

Food Quality Protection Act

33. The FQPA aims to regulate pesticides more robustly to safeguard human health, particularly the health of children and infants. The EDSP and other endocrine disruptor provisions of the FQPA contribute to this objective by screening pesticide chemicals for possible endocrine impacts and mandating protective action when such impacts exist.

34. The FQPA requires EPA to develop the endocrine disruptor screening program "using appropriate validated test systems and other scientifically relevant

information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen" no later than August 3, 1998. 21 U.S.C. § 346a(p)(1).

35. Pursuant to the FQPA, EPA "shall implement the [endocrine disruptor screening] program" no later than August 3, 1999. *Id.* § 346a(p)(2).

36. The FQPA dictates that in carrying out the EDSP, EPA "shall provide for the testing of all pesticide chemicals" and "may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if [EPA] determines that a substantial population may be exposed to such substance." *Id.* § 346a(p)(3).

37. The FQPA, also requires EPA submit a report to congress no later than August 3, 2000, including EPA's "findings . . . from the [EDSP][,]" "recommendations for further testing[,]" and "recommendations for any further action." *Id.* § 346a(p)(7).

38. Per the FQPA, EPA "shall issue" orders "to conduct testing in accordance with the [EDSP]" to registrants, manufacturers, or importers of chemicals for which testing is required. These people will then "submit [the] information obtained from the testing to the [EPA]" within a time period that EPA determines to be reasonable. *Id.* § 346a(p)(5)(A).

39. Finally, when any substance is found to have an endocrine effect on humans, the FQPA requires that EPA "as appropriate, take action under such statutory authority as is available to [it] . . . as is necessary to ensure the protection of public health." *Id.* § 346a(p)(6).

STATEMENT OF THE FACTS

The Science of Endocrine Disruption

40. The endocrine system, also known as the hormone system, regulates the biological processes underpinning the growth, development and normal functioning of humans and other higher organisms, from conception to old age.[5]

41. The endocrine system is composed of hormones, chemical messengers that instruct the body what to do and when to do it; glands located throughout the body that produce the hormones and release them into the bloodstream; and receptors in organs that recognize hormones and carry out their instructions.[6]

42. Roughly thirty glands, including the hypothalamus, pituitary, thyroid, and adrenals, produce hormones that control and regulate nearly every process in the human body, including metabolism, growth and development, emotions and mood, fertility and sexual function, sleep, blood sugar levels, and blood pressure.[7]

43. For example, hormones known as androgens, produced by the testicles, and estrogens, created by the ovaries, are responsible for male and female sexual characteristics and development. The thyroid gland secretes thyroxine and triiodothyronine, hormones that regulate metabolism, the process of extracting energy from the foods we eat, and also help regulate growth and development. The pancreas produces the hormones insulin and glucagon, which work to maintain a constant level of sugar in the bloodstream.[8]

---

[5] *What is the Endocrine System?*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/endocrine-disruption/what-endocrine-system (last visited Dec. 19, 2022) [hereinafter EPA Endocrine System]; *Endocrine System*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/articles/21201-endocrine-system (last visited Dec. 19, 2022) [hereinafter Cleveland ED].

[6] EPA Endocrine System, supra note 5.

[7] Mary Sue Marty et al., *Endocrine Disruption: Historical Perspectives and Its Impact on the Future of Toxicology Testing*, 120 TOXICOLOGICAL SCIENCES 93, 93 (2011); Cleveland ED, *supra* note 5.

[8] EPA Endocrine System, supra note 5.

44. Endocrine disruptors are chemicals that interfere with the operation of the endocrine system, and they can do this in various ways. Some chemicals mimic a natural hormone and thus cause the body to overreact or react at the wrong time. Others block a hormone from binding to its intended receptor, resulting in a lack of the desired response. Still other endocrine disruptors stimulate or inhibit the endocrine system, causing over or under production of particular hormones.[9]

45. As the EPA acknowledges, scientific research has linked chemical disruption of the endocrine system to adverse health consequences in humans, domestic animals, and fish and wildlife species.[10]

46. These effects include "developmental malformations, interference with reproduction, increased cancer risk, and disturbances in immune and nervous system function."[11]

47. The Endocrine Society, a global community of physicians and scientists at the forefront of hormone science, has published two exhaustive reviews of studies on endocrine-disrupting chemicals. The 2015 review, which is 150 pages, discusses over 1,300 studies that collectively have linked endocrine disrupting chemicals to numerous adverse human health outcomes including, but not limited to, alterations in sperm quality and fertility, abnormalities in sex organs, endometriosis, early puberty, altered nervous system function, disrupted immune function, different

---

[9] *What is Endocrine Disruption?*, U.S. Env't Prot. Agency, https://www.epa.gov/endocrine-disruption/what-endocrine-disruption (last visited Dec. 19, 2022) [hereinafter EPA Endocrine Disruption].

[10] *Id.* ("Growing scientific evidence shows that humans, domestic animals, and fish and wildlife species have exhibited adverse health consequences from exposure to environmental chemicals that interact with the endocrine system."); EPA Endocrine System, *supra* note 5.

[11] EPA Endocrine Disruption, *supra* note 9.

kinds of cancers, respiratory issues, metabolic abnormalities, diabetes, obesity, cardiovascular problems, and growth, neurological and learning disabilities.[12]

48. Research also demonstrates that exposure to endocrine disrupting chemicals is particularly detrimental at critical developmental windows, such as fetal development and infancy.[13]

49. Further, both natural hormones and endocrine-disrupting chemicals are extraordinarily potent, with infinitesimal amounts capable of either triggering the desired response, or disrupting it, respectively. In fact, scientists find that endocrine disruptors exert their effects at levels far below the amounts tested in traditional toxicology studies, levels that approximate the amounts to which people are exposed.[14]

50. People are exposed to endocrine disruptors through drinking contaminated water, breathing contaminated air, ingesting contaminated food, or contacting contaminated soils. Those working with endocrine-disrupting pesticides and other industrial chemicals, as well as those working and/or living in areas sprayed with endocrine-disrupting pesticides, generally bear the most risk, given their high level of potential exposures.[15]

---

[12] Endocrine Society, *supra* note 4; *see also* Gore, *supra* note 4.

[13] *Endocrine-Disrupting Chemicals: An Endocrine Society Position Statement*, ENDOCRINE SOC'Y (May 1, 2018), https://www.endocrine.org/advocacy/position-statements/endocrine-disrupting-chemicals#:~:text=The%20Endocrine%20Society%20is%20concerned,protect%20populations%20from%20EDC%20exposures [hereinafter ES Position Statement].

[14] *See generally* Laura N. Vandenberg et al., *Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*, 33 ENDOCRINE REV. 378 (2012), https://academic.oup.com/edrv/article/33/3/378/2354852.

[15] Evanthia Diamanti-Kandarakis et al., *Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement*, 30 ENDOCRINE REV. 293 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726844/; *see also* Thomas P. van der Meer et al., *Exposure to Endocrine Disrupting Chemicals in the Dutch general population is associated with adiposity-related traits,* SCIENTIFIC REPORTS (June 9, 2020), https://www.nature.com/articles/s41598-020-66284-3.

51. DDT, chlorpyrifos, atrazine, 2,4-D, and glyphosate are among the pesticides recognized as endocrine disruptors.[16]

52. Growing evidence suggests that exposure to endocrine disrupting chemicals is linked to an increase over the past few decades in the incidence of neurodevelopmental, reproductive, and metabolic disorders, as well as certain cancers.[17]

53. Congress's willingness to mandate the creation of the EDSP and the testing of all pesticide chemicals for possible endocrine effects back in 1996 was based on firm scientific evidence of the serious threats endocrine disruptors pose to public health; and the evidence has only grown stronger over the past quarter century.

54. The endocrine disrupting capabilities of pesticides and other chemicals are also recognized as threats to a wide variety of wildlife, potentially contributing to species declines.[18] Similar to humans, endocrine disrupting pesticides can

---

[16] Heather Patisaul, *Hormones and Endocrine Disrupting Chemicals: What You Need To Know*, ENDOCRINE SOC'Y, https://www.endocrine.org/-/media/endocrine/files/patient-engagement/hormones-and-series/hormones_and_edcs_what_you_need_to_know.pdf (last visited Dec. 19, 2022).

[17] ES Position Statement, *supra* note 13.

[18] *See, e.g.*, Vance L. Trudeau et al., *Agrochemicals disrupt multiple endocrine axes in amphibians*, 513 MOLECULAR & CELLULAR ENDOCRINOLOGY 1 (2020), https://digital.csic.es/bitstream/10261/214982/1/Agrochemicals%20disrupt%20multiple%20endocrine%20axes%20in%20amphibians.pdf; *see generally* Zaheer Khan & Francis Law, *Adverse effects of pesticides and related chemicals on enzyme and hormone systems of fish, amphibians, and reptiles: A review*. 42 PROC. PAKISTAN ACAD. SCI. 315 (2005), https://www.researchgate.net/profile/Francis-Law/publication/241312982_Adverse_effects_of_pesticides_and_related_chemicals_on_enzyme_and_hormone_systems_of_fish_amphibians_and_reptiles_A_review/links/544681c20cf22b3c14de358b/Adverse-effects-of-pesticides-and-related-chemicals-on-enzyme-and-hormone-systems-of-fish-amphibians-and-reptiles-A-review.pdf.

interfere with an animal's hormones, causing a wide range adverse effects including, but not limited to: abnormal sexual development, including feminization seen in fish and amphibians, behavioral impacts, development impacts, disruption of immune function and neurological functions, and physical deformities. While aquatic animals appear to be at particularly high risk of exposure to and impacts from endocrine disrupting pesticides, terrestrial animals, including insects such as bees, may also be harmed by endocrine disruption of pesticides.[19]

55. All in all, endocrine disrupting chemicals pose enormous risks to the health of both humans and wildlife and the chemicals posing such risks must be promptly identified and mitigated.

The Food Quality Protection Act

56. The Federal, Food, Drug, and Cosmetic Act (FFDCA) requires federal agencies to regulate foods, drugs, and cosmetics to ensure their safety.[20] For pesticides registered for use in food production, the Act directs the EPA to establish allowable pesticide residue levels, referred to as tolerances, in food and animal feed.[21]

57. In 1996, Congress amended the FFDCA via the Food Quality Protection Act (FQPA).[22] The FQPA enacted sweeping changes to both the FFDCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

---

[19] *See, e.g.*, Danica Baines et al., *Neonicotinoids act like endocrine disrupting chemicals in newly-emerged bees and winter bees*, SCIENTIFIC REPORTS, Sept. 2017, at 1, https://www.nature.com/articles/s41598-017-10489-6; *see generally* Peter L deFur, *Use and Role of Invertebrate Models in Endocrine Disruptor Research and Testing*, 45 INST. LABORATORY ANIMAL RES. J. 484 (2004), https://academic.oup.com/ilarjournal/article/45/4/484/661247.

[20] Federal Food Drug and Cosmetic Act, 21 U.S.C. § 301–399.

[21] *Id.* § 346a.

[22] Food Quality Protection Act of 1996, P.L. 104-170, 110 Stat. 1533 (1996) (codified as amended in scattered sections of 21 U.S.C. § 301 et seq.).

58. The FQPA was designed to standardize the way EPA managed pesticides and to update the U.S. laws to protect public health in accordance with the most recent scientific evidence. It mandated a single, health-based safety standard for pesticide residue in all foods; provided special protections for infants and children via an additional safety factor that accounts for children's special sensitivity to pesticide chemicals; and required periodic re-evaluation of pesticide registrations and tolerances to ensure pesticide registrations continue to meet federal safety standards, amongst other things.

FQPA Provisions Specific to Endocrine Disruption

59. In response to the growing body of science showing that exposure to pesticides adversely affects the health of humans and wildlife via endocrine disruption, as well as a number of other events, including but not limited to a National Academy of Science report examining pesticides in children's diets, the BBC documentary, "Assault on the Male", explaining causes of reduced male fertility, and the newly published *Our Stolen Future*, chronicling how certain synthetic chemicals interfere with hormones, Congress also included provisions regarding estrogenic substances in the FQPA.[23] Congress explicitly stated "scientific reports indicat[e] that some pesticides may imitate, enhance, or block the activity of hormones in humans and wildlife . . . Since hormones govern fundamental biological functions such as reproduction, growth, and metabolism in humans and other species, the Committee believes that it is important for EPA to obtain data about the potential hormone-disrupting effects of pesticides in order to make informed regulatory decisions under FIFRA." [24]

[23] *Id.*; Maffini & Vandenberg, *supra* note 2, at 1–2.
[24] H.R. REP. 104-669, pt. 1, at 56 (1996).

60. These provisions require EPA to take several steps in order to evaluate the link between pesticide chemicals and possible endocrine disruption.[25]

61. First, by no later than August 3, 1998, the FQPA required EPA to "develop a[n] [endocrine disruptor] screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by naturally occurring estrogen, or such other endocrine effect as the [EPA] may designate." *See* 21 U.S.C. § 346a(p)(1).

62. Second, EPA must then "implement the [endocrine disruptor screening] program" no later than August 3, 1999. *Id.* § 346a(p)(2).

63. Third, the FQPA mandates that in carrying out the EDSP, EPA "provide for the testing of all pesticide chemicals." *Id.* § 346a(p)(3)(a).

64. Finally, the FQPA requires that EPA "as appropriate, take action under such statutory authority as is available to [it] . . . as is necessary to ensure the protection of public health" when any substance is found to have endocrine effects on humans." *Id.* § 346a(p)(6).

EPA's Endocrine Disruptor Screening Program

65. Following the enactment of the FQPA, EPA initially took some action with regard to the Congressional mandates; however, as will be discussed in detail below, such action was short lived, and the agency has otherwise failed for over two decades to comply with Congress's commands.

66. In October of 1996, the EPA created the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), a group of representatives from industry, government, environmental and public health groups, worker safety groups, and academia, to advise EPA on developing an endocrine disruptor

[25] *See* 21 U.S.C. § 346a(p).

screening program. EDSTAC was "charged with developing consensus-based recommendations for a scientifically defensible screening program that would provide EPA the necessary information to make regulatory decisions about the endocrine effects of chemicals."[26]

67. For two years EDSTAC members reviewed scientific information, sought the opinions of outside experts, and consulted members of the public. Ultimately, the committee recommended that EPA's endocrine disruptor screening program should evaluate ecological effects in addition to human effects; initially test for disruption of just the three most-studied hormone systems (estrogen, androgen, and thyroid), but later incorporate tests for effects on more of the fifty hormone systems; evaluate non-pesticide chemicals (commercial chemicals, ingredients in cosmetics, nutritional supplements, and food additives) in addition to pesticide chemicals; screen six distinct mixtures representative of two or more chemicals to determine whether they cause endocrine effects different than the component chemicals; and implement a tiered approach.[27]

68. EPA adopted EDSTAC's recommendations and created the EDSP in August of 1998.[28]

69. On EDSTAC's recommendation, EPA separated the EDSP into several stages. The first is a priority setting stage: a stage in which EPA must decide, based on existing information, which chemicals most urgently need testing based on their

---

[26] *Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) Final Report*, ENV'T PROT. AGENCY, https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-and-testing-advisory-committee-edstac-final (last visited Dec. 19, 2022).

[27] *Id.*; Endocrine Disruptor Screening Program, 63 Fed. Reg. 7152, 71545 (Dec. 28, 1998); *see also* ENDOCRINE DISRUPTOR SCREENING AND TESTING ADVISORY COMMITTEE (EDSTAC) FINAL REPORT ES-3 (AUG. 1998) [hereinafter EDSTAC Final Report].

[28] Endocrine Disruptor Screening Program, 63 Fed. Reg. 42852 (Aug. 11, 1998).

likelihood to affect the endocrine system. Following priority setting, chemicals undergo a screening stage. The screening stage consists of two tiers of testing and evaluates each chemical to determine whether it is an endocrine disruptor.[29]

70. Per the EDSP, Tier 1 testing is an initial screen, through which EPA determines whether a chemical is a potential endocrine disruptor. If EPA finds a chemical potentially disrupts the endocrine system—more specifically the estrogen, androgen, or thyroid signaling pathways—the chemical must then be tested under the more rigorous Tier 2 testing.[30]

71. Tier 2 testing is intended to identify the adverse effects caused by the substance and establish "a quantitative relationship between the dose and the adverse effect[,]" essentially conducting a risk assessment for chemicals determined to be endocrine disruptors.[31]

72. In practice, however, EPA will often both identify a pesticide as an endocrine disruptor, and establish a quantitative dose-effect relationship, based on Tier 1 tests, but still eschew the more rigorous and definitive Tier 2 testing altogether.[32] For instance, EPA found the pesticide atrazine exerted effects on both estrogen and androgen systems at particular doses based on Tier 1 screening tests, but nevertheless decided against Tier 2 tests. This approach raises even more questions about the efficacy of the EDSP.

73. As is noted above, per the FQPA, in the event a chemical is found to be an endocrine disruptor, EPA is required to take appropriate action to ensure the protection of public health. *See* 21 U.S.C. § 346a(p)(6).

---

[29] Endocrine Disruptor Screening Program, 63 Fed. Reg. at 71544.
[30] *Id.*
[31] *Id.* at 71543; 71545.
[32] ENV'T PROT. AGENCY, ATRAZINE WEIGHT OF EVIDENCE ANALYSIS (JUL. 2015), https://www.regulations.gov/document/EPA-HQ-OPP-2013-0266-0313.

74. Also key to the EDSP is the screen (or assay) validation process. Assay validation establishes a test's reliability, ensuring it can achieve its intended purpose and be performed consistently across different laboratories.[33] The FQPA mandates that all tests and screens be validated prior to use. *See* 21 U.S.C. § 346a(p)(1). While the EPA's 1998 published EDSP included specific assays, none were validated at the time of the program's publication, thus creating another required step before testing could begin.

75. Shortly following EPA's creation of the EDSP, EPA released an overview of how it planned to implement the EDSP moving forward, estimating Tier 1 testing for select chemicals would begin in 2003, following validation of assays used for Tier 1 testing.[34] This proved to be just the beginning of EPA's empty promises and failures regarding the EDSP.

EPA's Progress (or lack thereof) to Date

76. Since the creation of the EDSP in 1998, EPA's steps towards implementing the EDSP have been few and far between, with a complete failure to act on the EDSP program since August of 2015.

77. EPA has repeatedly made empty promises and proposed timelines with regard to accomplishing various aspects of EDSP development and implementation, including assay validation, Tier 1 and 2 testing, and more. EPA failed to keep most of these promises, and those it has managed to keep have often been years late.

78. EPA provided their own timeline for beginning implementation in a Federal Register notice in December of 1998, shortly after creation of the EDSP. It

---

[33] ENV'T PROT. AGENCY, ENVIRONMENTAL PROTECTION AGENCY ENDOCRINE DISRUPTOR SCREENING PROGRAM: REPORT TO CONGRESS 1 (2000), https://www.epa.gov/sites/default/files/2015-12/documents/reporttocongress0800.pdf.

[34] Endocrine Disruptor Screening Program, 63 Fed. Reg. at 71559.

estimated Tier 1 testing for the first batch of chemicals would begin in 2003, following priority setting and validation of assays. [35]

79. Despite consultation with the FIFRA scientific advisory board in 1999 and a recommendation by the board that EPA start implementation by reviewing data for 50 to 100 pesticides using Tier 1 assays, EPA took no significant action in the years that followed.[36] In fact, it took a lawsuit by Natural Resources Defense Council (NRDC) and a subsequent settlement agreement with agreed upon deadlines for EPA to begin any real progress in developing the EDSP.[37]

80. In August of 1999, NRDC sued EPA for failing to meet their August 1999 statutory deadline to implement the EDSP.[38] The lawsuit ended in a settlement agreement in 2001, in which NRDC agreed to dismiss their cause of action and EPA committed to use best efforts to implement the EDSP in a number of ways by several new deadlines, as well as to submit progress reports directly to NRDC.[39]

81. EPA committed to publishing a list of initial chemicals to evaluate by 2002. Instead, EPA released a draft list of chemicals for evaluation in 2007 and a final list of 67 chemicals (referred to as List 1) in 2009, seven years after their original promise.[40]

---

[35] *Id.*

[36] Maffini & Vandenberg, s*upra* note 2, at 4.

[37] *Endocrine Disruptor Screening Program* Timeline, ENV'T PROT. AGENCY, https://www.epa.gov/sites/default/files/2016-04/documents/edsp-timeline-042016.pdf (last visited Nov. 7, 2022) [hereinafter EDSP Timeline]

[38] Natural Resources Defense Council v. Whitman, 2001 WL 1221774 (N.D. Cal. Sept. 24, 2001).

[39] Settlement Agreement, Natural Resources Defense Council v. Whitman, 2001 WL 1221774 (N.D. Cali Sept. 24, 2001) (No. C-99-3701) [hereinafter NRDC-EPA Settlement Agreement].

[40] *Id.*; EDSP Timeline, *supra* note 37.

82. EPA promised to validate all but one of the Tier 1 assays and begin Tier 1 testing by 2003. However, EPA did not complete validation of Tier 1 assays and did not issue Tier 1 test orders for List 1 chemicals until 2009, six years later than originally promised. Further, it was not until 2015 that EPA released screening results of these Tier 1 test orders, but—despite a finding that eighteen of the List 1 chemicals necessitated Tier 2 testing—to date no such testing has occurred.[41]

83. EPA additionally committed to validating the mammalian 2-generation Tier 2 assay and beginning Tier 2 testing of the List 1 chemicals by 2004, with validation of all other Tier 2 assays to be completed by 2005. But EPA did not validate and finalize Tier 2 assays until 2015, 10 years late.[42]

84. In addition to failing to meet the court-imposed deadlines with regard to development and implementation of the EDSP over the past two decades, EPA also failed to meet deadlines imposed by the House Appropriations Committee (the Committee), as well as those the agency itself laid out in EDSP comprehensive management plans and in response to Office of the Inspector General Reports criticizing EPA's progress on the EDSP.

85. Specifically, when Congress appropriated additional funding to the EDSP in 2008 and 2010, it directed EPA to take specific actions for the EDSP by dates certain. These appropriations further show Congress's plain and continuing intent that EPA actually implement this important program, yet nonetheless EPA has still failed to so act.

---

[41] EDSP Timeline, *supra* note 37; NRDC-EPA Settlement Agreement, *supra* note 39.

[42] EDSP Timeline, *supra* note 37; NRDC-EPA Settlement Agreement, *supra* note 39.

86. In the 2008 appropriations report, the Committee required EPA to report annually to Congress on its progress in implementing the EDSP. Specifically, EPA was to update Congress on: the number of pesticides EPA conducted or required testing for; the number EPA has made a determination for; the number and identity of screening and testing assays EPA has and has not validated; and the reason why for those EPA has not validated.[43] EPA submitted reports to Congress in 2008, 2009, and 2010; however, EPA has not formally reported to Congress since 2010.[44]

87. Additionally, the Committee's 2010 appropriations report "direct[ed] EPA to . . .[p]ublish [by June 2011] a second list of no less than 100 chemicals for screening. . . and issue 25 orders per year for the testing of [List 2] chemicals."[45] But EPA did not publish a second list of chemicals (referred to as List 2) until two years after the deadline and to date, EPA has not issued a single test order for any of the List 2 chemicals, despite appearing to have been ready and able to so act.[46] Government documents received through the Freedom of Information Act reveal that EPA employees stated "EDSP was ready to go with List 2, but [EPA] lacked the institutional will to follow through with issuing test orders for List 2 – Tier 1."[47] Further, EPA staff attest that EPA likely will not issue test orders for List 2 now as the list has become "stale" given the delay.[48] They explained that the list was meant

---

[43] H.R. REP. NO. 110-187, pt. 1, at 108–09 (2008) [hereinafter *2008 Appropriations Report*].

[44] *See Endocrine Disruptor Screening Program Reports to Congress*, ENV'T PROT. AGENCY, https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-reports-congress (last visited Dec. 19, 2022).

[45] H.R. REP. NO. 111-180, at 105–06 (2010) [hereinafter *2010 Appropriations Report*].

[46] EDSP Timeline, *supra* note 37.

[47] Interviews Conducted in Preparation of the 2021 OIG Report, at 13 (received via a FOIA request, attached as Exhibit A).

[48] *Id.* at 16.

to line up with registration review for the pesticides on the list, and that now is no longer possible given the testing delay.[49]

Inspector General Investigations and Reports

88. The Office of Inspector General, an independent unit within the EPA, reviewed the EDSP in 2011 and 2021, both times finding EPA had made little progress with the EDSP.[50]

89. With the first report, EPA's Inspector General (IG) aimed to gauge whether EPA "ha[d] planned and conducted the requisite research and testing to evaluate and regulate" endocrine disrupting chemicals. The report's conclusions were harshly critical, grimly concluding the EDSP had made little progress in identifying endocrine disruptors, due in large part to EPA's lack of management and that the protection of human health would not be achieved until the establishment of program control and accountability.[51]

90. The IG recommended that EPA establish the scope of chemicals included in the EDSP, develop standardized methods to prioritize the chemicals for screening and testing, finalize criteria for evaluation of Tier 1 and Tier 2 screening results, develop outcome performance measures, develop a comprehensive management plan to cover a 5-year period for the EDSP, and finally, complete annual internal reviews of EDSP progress.[52]

---

[49] Plaintiffs dispute this conclusion by EPA because registration review for nearly all pesticides remains incomplete. Such excuse should not allow EPA to avoid completing Tier 1 and 2 testing for List 2.

[50] EPA's ENDOCRINE DISRUPTOR SCREENING PROGRAM SHOULD ESTABLISH MANAGEMENT CONTROLS TO ENSURE MORE TIMELY RESULTS, OFF. OF INSPECTOR GEN., ENV'T PROT. AGENCY (May 2011) [hereinafter *2011 OIG Report*]; EPA's ENDOCRINE DISRUPTOR SCREENING PROGRAM HAS MADE LIMITED PROGRESS IN ASSESSING PESTICIDES, OFF. OF INSPECTOR GEN., ENV'T PROT. AGENCY (July 2021) [hereinafter *2021 OIG Report*].

[51] *See generally 2011 OIG Report*, *supra* note 50.

[52] *Id.* at 19–20.

91. EPA dismissed some of the recommendations as having already been implemented, or as irrelevant until further assay validation, and failed to respond to others. However, EPA agreed to develop a comprehensive management plan by 2012 per the IG's recommendations.[53] While EPA followed through on this promise by publishing comprehensive management plans in 2012 and 2014, it entirely flouted the IG's intended purpose of the comprehensive management plans by failing to actually adhere to the targets outlined within those plans.[54]

92. The 2014 comprehensive management plan superseded the 2012 plan, with many of the goals outlined in the 2012 comprehensive management plan simply being restated with drawn out target dates in the 2014 plan. Despite having already allowed itself more time to complete various tasks, the EPA still failed to adhere to those drawn-out timelines set in the 2014 comprehensive management plan.[55]

93. Within the 2014 comprehensive management plan, EPA outlined milestones for the EDSP that it planned to meet between 2014 and 2023.[56] EPA planned to conduct Tier 2 testing of List 1 chemicals between 2014-2015 and complete risk assessments for List 1 in 2020. EPA planned to conduct Tier 1 tests of List 2 chemicals between 2014-2016 and complete scientific review of those tests between 2017-2019. EPA also planned to create List 3 and to complete Tier 1

---

[53] *Id.* at 23–26.

[54] OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION & THE OFF. OF WATER, EPA, ENDOCRINE DISRUPTOR SCREENING PROGRAM COMPREHENSIVE MGMT. PLAN (2012) [hereinafter *2012 CMP*]; OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION & THE OFF. OF WATER, EPA, ENDOCRINE DISRUPTOR SCREENING PROGRAM COMPREHENSIVE MGMT. PLAN 13 (2014) [hereinafter *2014 CMP*].

[55] *See 2012 CMP*, *supra* note 54, at 4–5; *see 2014 CMP*, *supra* note 54, at 6.

[56] *See 2014 CMP*, *supra* note 54, at 6.

testing for List 3 between 2018-2020.[57] Yet EPA has failed to meet *even a single one* of these self-imposed targets and does not seem close to finishing any of these tasks.

94. While EPA was adamant that the 2014 comprehensive management plan be a "living document" to be "evaluated on an annual basis," EPA never amended the original 2014 plan to account for delays; rather EPA simply failed to meet all of their projected deadlines.[58] The 2014 comprehensive management plan was only for use between FY 2014-2019, so EPA currently has no guiding plan for the EDSP.

95. The IG's second report findings were equally grim, noting EPA's continued lack of progress and concluding the program in its current state cannot achieve the statutory requirement of safeguarding human health and the environment against endocrine risks. Specifically, it found EPA "has not implemented Section 408(p)(3)(A) of the [FFDCA] to test all pesticide chemicals for endocrine disruption activity." Further, it found EPA 's failure to complete testing for the seventeen pesticides recommended for Tier 2 testing based on possible wildlife endocrine effects was inconsistent with the FFDCA. It additionally concluded EPA does not have adequate controls in place to effectively implement the EDSP, has not conducted internal reviews to gauge progress, and has not effectively communicated with internal and external stakeholders. Finally, it found EPA had in large part failed to follow through the corrective actions it had promised in response to the 2011 OIG recommendations.[59]

96. In addition to its conclusions regarding EPA's stalled progress with the EDSP, the IG's 2021 report included the shocking discovery that some EPA staff were instructed to function as if the EDSP had been eliminated from the EPA's

---

[57] *Id.*
[58] *Id.* at 3.
[59] *See 2021 OIG Report*, *supra* note 50, at 8.

budget, despite a $7.5 million allocation to the EDSP in 2021, when the program had only four full-time staff members. One employee stated, "on multiple occasions, I was directly instructed to adhere to the reality of zero funding in the President's budget even though we were fully funded by Congress."[60] Such instruction demonstrates an intentional flouting by the agency of its statutory duties.[61]

97. EPA agreed to certain actions in response to the IG's 2021 report, as with the 2011 report. The IG recommended EPA issue Tier 1 test orders for each of the List 2 chemicals and EPA committed to doing so by September of 2024. The IG recommended EPA issue Tier 2 test orders for the eighteen List 1 pesticides deemed worthy of Tier 2 testing, EPA committed to doing so by December of 2023. The IG further recommended EPA develop and implement an updated comprehensive management plan by September of 2022, among other things.[62] EPA committed to publishing a new plan by September 30, 2022; however, no such comprehensive management plan has been published as of the filing of this complaint.[63]

98. In summary, over the course of two decades the IG has published two different reports on EPA's failure to implement the program, to which EPA has responded and promised to take action. Yet the program still sits without implementation and testing, and thus fails to meet its statutory purpose.

---

[60] Interviews Conducted in Preparation of the 2021 OIG Report, *supra* note 47, at 6.
[61] *See 2021 OIG Report*, *supra* note 50, at 12–13.
[62] See Maffini & Vandenberg, *supra* note 2, at 6 for a complete list of the IG's 2021 recommendations to EPA; *see also 2021 OIG Report*, *supra* note 50, at 15–16.
[63] *See 2021 OIG Report*, *supra* note 50, at 23; *see also Endocrine Disruptor Screening Program (EDSP) Comprehensive Management Plans*, ENV'T PROT. AGENCY (last visited Dec. 19, 2022), https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-comprehensive-management-plans.

The Assay Validation Roadblock

99. EPA's general failure to meet timelines—whether imposed by Congress, a court, the Congressional Appropriations Committee, the IG, or self-imposed—is not the only cause for concern as to EPA's duty to implement and carry out the EDSP. The agency's preoccupation with focusing exclusively on developing new screening assays also seems to all but guarantee a lack of progress in actually *testing* chemicals. Congress has repeatedly urged EPA to adopt more efficient screens to hasten the process of testing chemicals for possible endocrine effects. In the 2010 report, the House Appropriations Committee "direct[ed] EPA to . . . [e]ngage in a timely re-evaluation of the battery of screening" to adopt more efficient screens.[64] Again, in 2012, the Committee "continue[d] to have concerns with the . . . [EDSP]'s slow progress and believe[d] it need[ed] additional guidance." "In order to spur the agency to action," the committee directed EPA to change their chemical screening tests in various ways to make them more efficient.[65] After more than a decade of such urging, EPA is still in the process of assessing and adopting these new screening tests.[66]

100. In 2015 EPA published a notice in the Federal Register describing a more efficient way to screen chemicals, called ToxCast.[67] But EPA has yet to utilize this new screening technique for even a single chemical, as EPA has not conducted any testing since 2015. Further, in response to the 2021 OIG report, EPA announced that it would publish its acceptance of New Approach Methodologies, a

---

[64] *See 2010 Appropriations Report*, *supra* note 45, at 106.
[65] H.R. REP. NO. 112-151, at 71 (2012) [hereinafter *2012 Appropriations Report*].
[66] *See Use of High Throughput Assays and Computational Tools in the Endocrine Disruptor Screening Program*, ENV'T PROT. AGENCY, https://www.epa.gov/endocrine-disruption/use-high-throughput-assays-and-computational-tools-endocrine-disruptor#screening (last visited Dec. 21, 2022).
[67] Use of High Throughput Assays and Computational Tools, 80 Fed. Reg. 35350 (June 19, 2015).

newer collection of screens focused on not using vertebrates as test animals, in 2021.[68] But yet again, this date passed with no such action from EPA, and to date EPA still has not published the promised New Approach Methodologies.

101. Despite EPA's lack of progress in validating and implementing new screens, the agency has leaned on its directive from Congress to create and validate such screens as an excuse to halt testing of chemicals and to work only on the development of assays. In fact, EPA's website and former EPA employees readily admit as much. The website states "[w]hile EPA has discretionary authority to issue, at any time, testing orders requiring manufacturers to conduct Tier 1 assays, the Agency plans to assess the performance of the Tier 1 battery based on the test data received for the initial list (List 1) of chemicals before beginning to routinely issue orders to test additional chemicals."[69] The former EDSP Director confirmed this as EPA's stance in his interview for the 2021 OIG report, stating, "since 2015, the EDSP performance plan was just about the development and validation of the HTP assays and computation toxicity methods."[70] This is despite the explicit direction from the IG in its 2011 report that EPA should *not* wait until new methods are validated to continue Tier 1 testing with proven, validated tests.[71]

---

[68] *See 2021 OIG Report*, *supra* note 50, at 20; *see also* ENV'T PROT. AGENCY, *EPA Releases Updated New Approach Methodologies (NAMs) Work Plan* (Jan. 19, 2022), https://www.epa.gov/sciencematters/epa-releases-updated-new-approach-methodologies-nams-work-plan (illustrating that a work plan for the NAMs exists but no actual NAMs are anticipated until 2024, despite EPA's previous promise to release such methodologies in 2021).

[69] *Endocrine Disruptor Screening Program Overview*, ENV'T PROT. AGENCY, https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-overview (last visited Dec. 19, 2022).

[70] Interviews Conducted in Preparation of the 2021 OIG Report, *supra* note 47, at 40.

[71] *2011 OIG Report*, *supra* note 50, at 27.

EPA's Failure to Act From 2015 to Present

102. Most alarming with regard to EPA's commitment to carrying out the EDSP is the complete *lack of action on the program since 2015*. And the amount of activity from EDSP of late appears to be diminishing, rather than increasing. EPA reported to Congress in 2008, 2009, and 2010, but has not provided a single report since then.[72] And historically, EPA published notices in the Federal Register with updates on the EDSP, even if just for minor advancements in the program like assay validation.[73] Between 2000 and 2015 EPA published more than 50 Federal Register notices about the EDSP. But then it came to a halt and since 2015 EPA has not published a single Federal Register notice about the EDSP.

103. The 2021 OIG report's statements of EPA instructing staff members to ignore the FQPA's endocrine disruption legal requirements seems only to affirm EPA's blatant disregard for their statutorily mandated duty to implement the EDSP and test all pesticide chemicals.[74]

104. Further, EPA's failure to even complete testing for the eighteen chemicals the agency themselves identified as possible endocrine disruptors, despite having had *seven years* to do so, demonstrates a complete failure on the part of EPA to honor the FQPA's purpose to safeguard public health.

105. Such failure is perhaps explained by EPA's apparent attitude toward the EDSP of late. Former EDSP employees attested that many within the EPA do not believe EDSP testing is necessary. [75] One employee stated that "[i]n [EPA Office

---

[72] *Endocrine Disruptor Screening Program Reports to Congress*, ENV'T PROT. AGENCY, https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-reports-congress (last visited Dec. 19, 2022).

[73] *Endocrine Disruptor Screening Program Federal Register Notices*, ENV'T PROT. AGENCY, https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-federal-register-notices (last visited Dec. 19, 2022).

[74] *See 2021 OIG Report*, *supra* note 50, at 13.

[75] Interviews Conducted in Preparation of the 2021 OIG Report, *supra* note 47, at

of Pesticide Program]'s opinion, endocrine disruption can be elucidated by the normal toxicity studies already generated and collected for a pesticide registration" and thus, EPA "has adequately evaluated the endocrine disruption potential of about 95% of the active ingredients."[76] Even if such sentiment was accurate scientifically—and it is not, because it flies in the face of the consensus view of endocrinologists—it is not within EPA's discretion to act accordingly and fail to carry out the program that Congress required it to carry out.[77]

Litigation to Date

106. Plaintiffs are not the first to recognize EPA's failings with reference to the EDSP. As is discussed above, in 1999 NRDC sued over EPA's failure to implement the EDSP, a suit that ultimately ended in a settlement. *See infra* ¶79-80.

107. Directly on the heels of that, in 2005, nonprofit organizations Physicians Committee for Responsible Medicine and People for the Ethical Treatment of Animals also sued over EPA's shortcomings with reference to the EDSP.[78] Like NRDC, they alleged EPA failed to implement the EDSP by the statutory deadline, amongst other unrelated claims. In 2006 the court dismissed that case on standing grounds, namely due to the plaintiffs' failure to allege a concrete and particularized and actual and imminent injury.[79] The plaintiffs failed

---

37.

[76] *Id.* at 19.

[77] ENDOCRINE SOC'Y, *Comments to EPA on Strategic Plan for the Environmental Protection Agency* (Nov. 12, 2021), https://www.endocrine.org/-/media/endocrine/files/advocacy/society-letters/2021/november-2021/endocrine-society-comments-epa-strategic-plan-2226.pdf.

[78] Physicians Committee for Responsible Medicine, *et al.* v. U.S. Env't Prot. Agency, No. C 05-04093, 2006 WL 3000657 (N.D. Cal. Oct. 20, 2006), *aff'd*, 292 Fed. Appx. 543 (2008).

[79] *Id.* at *5–*7.

to identify any pesticides with unreasonable endocrine effects and any foods on which such pesticides were sprayed.

108. Plaintiffs here do not suffer from these standing deficiencies. As is discussed *infra,* Plaintiffs have identified multiple pesticides with possible endocrine effects, pesticides EPA recognized as having such effects, and a myriad of uses and products on which they are sprayed to which Plaintiffs are routinely exposed. The court in *Physicians Committee* explicitly stated their ruling did not stand for the proposition that "no consumers have standing to challenge the EPA's alleged failure to implement the [EDSP]." It clarified the "ruling is not nearly so broad."[80] This lawsuit involves not just consumer exposure but direct exposure to farmers and farmworkers. And finally, the prior case was over fifteen years ago, and in the interim, EPA has *still* not complied with Congress's directives, making its violations all the more egregious.

EPA Identified Possible Endocrine Disruptors But Has Taken No Further Steps to Protect Public Health and Implement the Program

109. As discussed above, EPA found eighteen chemicals to be possible endocrine disruptors after Tier 1 testing, thus necessitating Tier 2 testing. Of these eighteen chemicals, seventeen have been deemed to be possible wildlife endocrine disruptors, and five have been deemed to be possible human endocrine disruptors.

110. The chemicals include carbaryl, chlorothalonil, cypermethrin, DCPA, dichlobenil, dimethoate, flutolanil, folpet, iprodione, linuron, metalaxyl, metribuzin, myclobutanil, o-phenylphenol, PCNB, propargite, propiconazole, and tebuconazole.[81]

---

[80] Memorandum and Order at 11, Physicians Committee for Responsible Medicine, *et al.* v. U.S. Envt'l Prot. Agency, 2006 WL 3000657 (N.D. Cal. Oct. 20, 2006) (C 05-04093).

[81] *Endocrine Disruptor Screening Program (EDSP) Tier 1 Assessments*, ENV'T PROT. AGENCY, https://www.epa.gov/endocrine-disruption/endocrine-disruptor-

111. The five deemed to be possible human endocrine disruptors are cypermethrin, DCPA (also known as chlorthal-dimethyl or propanil), dimethoate, linuron, and metribuzin. Of the eighteen, only dimethoate was deemed to not be a possible wildlife endocrine disruptor.[82]

112. All five of the possible human endocrine disruptors are still registered for use throughout the U.S., despite EPA's recognition, over seven years ago, that they pose a possible human health risk.

113. While the federal government lacks a comprehensive pesticide reporting system, well-kept pesticide use records in California reveal each of these five pesticides are used heavily throughout California. Further, EPA records reflect more than one million pounds of each of the five pesticides are used annually, for varied uses including on food and feed crops, non-crop, commercial, industrial, and residential sites, ornamentals, and recreational areas.[83] Thus, there is little doubt that enormous quantities of each of the five are being sprayed beyond California.

114. For example, cypermethrin is registered for use by EPA "on food and feed crops including cotton, pecans, peanuts, broccoli and other Brassicas, and sweet corn."[84] It can also be applied to livestock and is "registered for use on industrial, commercial, and residential sites."[85] Total cypermethrin use per year is over 2.0 million pounds.[86] In California specifically, it is sprayed on a variety of food

---

screening-program-edsp-tier-1-assessments#results-mean (last visited Nov. 7, 2022).

[82] *Id.*

[83] *See infra* notes 84–103 and accompanying text.

[84] ENV'T PROT. AGENCY, CYPERMETHRIN SUMMARY DOCUMENT REGISTRATION REVIEW 15 (Mar. 2012), https://www.regulations.gov/document/EPA-HQ-OPP-2012-0167-0002; ENV'T PROT. AGENCY, CYPERMETHRINS INTERIM REGISTRATION REVIEW DECISION 17 (Mar. 2021), https://www.regulations.gov/document/EPA-HQ-OPP-2012-0167-0168 [hereinafter Cypermethrins IRRD].

[85] Cypermethrins IRRD, *supra* note 84, at 5.

[86] *Id.* at 17.

crops, including but not limited to rapini, pistachio, onion, lettuce heads, kale, garlic, Chinese cabbage, cauliflower, broccoli, and bok choy. It is also heavily used for landscape maintenance. California state pesticide use data shows that annually, enormous quantities are sprayed in Fresno, Imperial, Kern, L.A., Riverside, and Tulare counties in California.[87] Cypermethrin mimics estrogen and can cause changes in female genital organs.[88] In the environment, cypermethrin breaks down into chemical metabolites that have stronger estrogenic effects than their parent compound and thus are more likely to interfere with the endocrine system.[89]

115. DCPA is an herbicide registered for use by EPA "on a variety of crop and non-crop sites, including corn, soybeans, cole crops, cucurbits, onions, tomatoes, peppers, herbs, and non-residential turf and ornamentals."[90] Use is estimated at somewhere between 1.0 and 1.8 million pounds per year.[91] In California, DCPA is sprayed most heavily on food crops, particularly Bok-choy, broccoli, brussels sprouts, cabbage, cauliflower, Chinese cabbage, radish, and rapini. However, it is also used on other crops, as well as for landscaping purposes. California state pesticide use data shows heavy application in Ventura, Fresno, Imperial, Kern,

---

[87] *Pesticide Use Reporting*, CALI. DEP'T OF PESTICIDE REGULATION, https://www.cdpr.ca.gov/docs/pur/purmain.htm (last visited Nov. 4, 2022) (based on 2020 data) [hereinafter *Pesticide Use Reporting*].

[88] Elena Marettova et al., *Effect of pyrethroids on female genital system, review*, 184 ANIMAL REPRODUCTION SCIENCE 132 (2017), https://www.sciencedirect.com/science/article/abs/pii/S0378432017302075; Wissem Mnif et al., *Effect of Endocrine Disruptor Pesticides: A Review*, 8 INT'L J. ENV'T RES. PUB. HEALTH 2265, 2274 (2011), https://www.mdpi.com/1660-4601/8/6/2265.

[89] Marettova, *supra* note 88.

[90] ENV'T PROT. AGENCY, DCPA SUMMARY DOCUMENT REGISTRATION REVIEW INITIAL DOCKET 11 (June 2011), https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0002.

[91] *Id.*

Monterrey, Riverside, San Benito, San Luis Obispo, Santa Barbara, and Stanislaus counties.[92]

116. In addition to being a flagged as a possible endocrine disruptor for which EPA has not completed screening, DCPA's registration also may be facing suspension due to a failure of the retailer to provide many of the studies necessary for evaluating health impacts during registration review.[93] Nevertheless, products containing DCPA continue to be sold and sprayed as of the filing of this complaint. DCPA can keep androgens (male sex hormones) from binding with androgen receptors and has been demonstrated to alter the immune system, including altering antibody production.[94]

117. Dimethoate is registered for use by EPA "to control a variety of insect pests on fruit, vegetable, grain, and field crops, as well as ornamentals and non-cropland adjacent to agricultural fields."[95] EPA estimates 1.8 million pounds are used annually, with the highest uses being on alfalfa, wheat, cotton, and corn.[96] Dimethoate is also used significantly throughout California, on food crops and for

---

[92] *Pesticide Use Reporting*, *supra* note 87.

[93] *EPA Issues Notice of Intent to Suspend the Herbicide* DCPA, ENV'T PROT. AGENCY, (April 28, 2022), https://www.epa.gov/pesticides/epa-issues-notice-intent-suspend-herbicide-dcpa#:~:text=Released%20on%20April%2028%2C%202022,pesticide%20dimethyl%20tetrachloroterephthalate%20(DCPA).

[94] Corsini et al., *Immune System Toxicology*, 11 COMPREHENSIVE TOXICOLOGY 761 (2018), https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/propanil#:~:text=3%2C4%2DDichloroproprioanilide%20(DCPA,Wham%20DF%2C%20and%20Wham%20EZ.; Hiroyuki Kojima et al., *Screening for Estrogen and Androgen Receptor Activities in 200 pesticides by In Vitro Reporter Gene Assays Using Chinese Hamster Ovary Cells*, 112 ENVIRONMENTAL HEALTH PERSPECTIVES 524 (2004), https://ehp.niehs.nih.gov/doi/pdf/10.1289/ehp.6649.

[95] ENV'T PROT. AGENCY, DIMETHOATE SUMMARY DOCUMENT REGISTRATION REVIEW 10 (Mar. 2009), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0059-0006.

[96] *Id.*

landscape maintenance, but most prevalently on commodity crops such as alfalfa and cotton. For example, its application exceeds 1000 pounds per year in Ventura, Yolo, Fresno, Imperial, Kern, Kings, L.A., Merced, Monterey, Riverside, Sacramento, San Joaquin, Solano, Stanislaus, and Tulare counties.[97] Dimethoate disrupts thyroid hormones, increases insulin blood concentration, and decreases the blood's concentration of luteinizing hormone, a hormone that plays a pivotal role in sexual development and functioning.[98]

118. Linuron is registered by EPA for use on agricultural crops including asparagus, carrots, celery, corn, cotton, potato, sorghum, soybeans, and wheat, and for uses on non-cropland (roadsides, fencerows, etc.) and ornamental bulbs.[99] In California, Linuron is used most prevalently on food crops, specifically carrots, celery, and cilantro, throughout Ventura, Fresno, Imperial, Kern, Monterey, Riverside, San Luis Obispo, and Santa Barbara counties.[100] Linuron mimics androgen and thyroid hormones, disrupting reproduction, heartrate, metabolism, and development.[101]

119. Metribuzin is registered for use by EPA "on terrestrial food and feed crops, grasses grown for seed, recreational areas, ornamental lawns and turf."[102] Annually, approximately 1.4 million pounds are used, with sugarcane, potatoes, soybeans, and alfalfa accounting for a large portion of the application.[103] Throughout California, Metribuzin also incurs widespread use on food crops,

---

[97] *Pesticide Use Reporting*, *supra* note 87.
[98] Mnif, *supra* note 88, at 2274.
[99] ENV'T PROT. AGENCY, LINURON INTERIM REGISTRATION REVIEW DECISION 11, 18 (June 2020), https://www.regulations.gov/document/EPA-HQ-OPP-2010-0228-0073.
[100] *Pesticide Use Reporting*, *supra* note 87.
[101] Mnif, *supra* note 88, at 2279.
[102] ENV'T PROT. AGENCY, METRIBUZIN PRELIMINARY WORK PLAN 6 (Sept. 2012), https://www.regulations.gov/document/EPA-HQ-OPP-2012-0487-0008.
[103] *Id.*

including potatoes and tomatoes, as well as significant use on alfalfa crops. Its use is most prevalent in Yolo, Colusa, Lassen, Modoc, San Joaquín, Siskiyou, and Solano counties.[104] Metribuzin results in a hyperactive thyroid, as well as disrupted levels of growth hormone.[105]

120. EPA determined in its Tier 1 tests that four of the five pesticides discussed above, as well as thirteen additional pesticides, are possible wildlife endocrine disruptors.[106] For example, the insecticide cypermethrin, discussed above,[107] is recognized as acting as an endocrine disrupting compound in mammals and fish.[108]

121. Carbaryl is one of the most widely used broad spectrum insecticides.[109] EPA authorized its use on fruit and nut trees and many other fruits and vegetables and grain crops, as well as professional turf management and ornamental production, and in residential lawn and garden markets.[110] Approximately one million pounds of carbaryl are used in the U.S. each year.[111] Carbaryl is sprayed

---

[104] *Pesticide Use Reporting*, *supra* note 87.
[105] Mnif, *supra* note 88, at 2281.
[106] *See* ¶ 109.
[107] *See* ¶ 114.
[108] Susanne Brander et al., *Pyrethroid pesticides as endocrine disruptors: molecular mechanisms in vertebrates with a focus on fishes*, 50 ENV'T SCI. & TECH. 17 (2016), https://www.researchgate.net/profile/Susanne-Brander/publication/305690104_Pyrethroid_Pesticides_as_Endocrine_Disruptors_Molecular_Mechanisms_in_Vertebrates_with_a_Focus_on_Fishes/links/5a0affda458515e48274418d/Pyrethroid-Pesticides-as-Endocrine-Disruptors-Molecular-Mechanisms-in-Vertebrates-with-a-Focus-on-Fishes.pdf.
[109] Ann M. Blacker et al., *Toxicological Profile of Carbaryl*, *in* HAYES' HANDBOOK OF PESTICIDE TOXICOLOGY 1607 (3rd ed. 2010), https://www.sciencedirect.com/science/article/pii/B9780123743671000744.
[110] ENV'T PROT. AGENCY, CARBARYL PROPOSED INTERIM REGISTRATION REVIEW DECISION 15 (Nov. 2022), https://www.regulations.gov/document/EPA-HQ-OPP-2010-0230-0120 [hereinafter Carbaryl IRRD].
[111] *Id.* at 15–17.

widely in California, with use reported in 41 counties across California in 2018.[112] Carbaryl acts as an endocrine disruptor to impact metamorphosis and immune function in amphibians, among other potential harms to wildlife.[113] EPA indicated that it did not make "any human health or environmental safety findings associated with the Endocrine Disruptor Screening Program (EDSP) screening of carbaryl" in its recently published proposed interim registration decision for the pesticide.[114]

122. Chlorothalonil is a broad spectrum, protectant fungicide used on a wide variety of agricultural crops, as well as home garden use on fruits and vegetables.[115] It is also approved by EPA for non-agricultural uses, such as on golf courses, residential and commercial lawns and other turfgrass.[116] About 12 million pounds of chlorothalonil are sprayed annually, with the biggest use on golf courses, followed by use on peanuts, potatoes, almonds, tomatoes, and cherries.[117] Chlorothalonil is also used in significant quantities for residential use and in nurseries and greenhouses.[118] Chlorothalonil is a likely endocrine disruptor in mammals, fish, and amphibians.[119]

---

[112] *Pesticide Use Reporting*, *supra* note 87.

[113] Francisco De Jesus Andino et al., *Long term effects of carbaryl exposure on antiviral immune responses in Xenopus laevis*, 170 CHEMOSPHERE 169 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5205582/; Michelle D. Boone et al., *Specific time of exposure during tadpole development influences biological effects of the insecticide carbaryl in green frogs (Lithobates clamitans)*, 130–131 AQUATIC TOXICOLOGY 139 (2013), https://www.sciencedirect.com/science/article/abs/pii/S0166445X12003591?via%3Dihub; Trudeau, *supra* note 18.

[114] Carbaryl IRRD, *supra* note 110.

[115] ENV'T PROT. AGENCY, CHLOROTHALONIL: DRAFT ECOLOGICAL RISK ASSESSMENT FOR REGISTRATION REVIEW 4 (2020), https://www.regulations.gov/document/EPA-HQ-OPP-2011-0840-0036.

[116] *Id.*

[117] *Id.* at 22.

[118] *Id.*

[119] ZhiChao Dang et al., *Fish toxicity testing for identification of thyroid disrupting chemicals*, 284 ENV'T POLLUTION 1 (2021),

123. Propiconazole is a broad-spectrum triazole fungicide that is used in agricultural and non-agricultural settings, such as turfgrass, ornamentals, fruit and nut trees, and several food crops.[120] More than 2 million pounds of propiconazole are applied annually on agricultural crops, with major uses on wheat, corn, soybeans, and rice.[121] Propiconazole has been observed to cause endocrine disruption in mammals, fish, and amphibians.[122]

EPA's Failure to Implement the EDSP and Test All Pesticide Chemicals

124. As discussed above, one of the critical purposes of the FQPA is the protection of public health, and at issue here, the specific intent to protect against adverse human health effects caused by endocrine disruption.

---

https://www.sciencedirect.com/science/article/pii/S0269749121009568; Yanan Hao et al., *Chlorothalonil inhibits mouse ovarian development through endocrine disruption*, 303 TOXICOLOGY LETTERS 38 (2019), https://www.sciencedirect.com/science/article/abs/pii/S037842741832068X; Taegan A. McMahon et al., *The Fungicide Chlorothalonil Is Nonlinearly Associated with Corticosterone Levels, Immunity, and Mortality in Amphibians,* 119 ENV'T HEALTH PERSPECTIVES 1098 (2011), https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.1002956.

[120] ENV'T PROT. AGENCY, PROPICONAZOLE PROPOSED INTERIM REGISTRATION REVIEW DECISION 5 (Mar. 2022), https://www.regulations.gov/document/EPA-HQ-OPP-2015-0459-0072.

[121] *Id.* at 13.

[122] Sofia Svanholm et al., *Developmental reproductive toxicity and endocrine activity of propiconazole in the Xenopus tropicalis model*, 753 SCI.TOTAL ENV'T 1 (2020), https://www.researchgate.net/profile/Cecilia-Berg/publication/343844062_Developmental_reproductive_toxicity_and_endocrine_activity_of_propiconazole_in_the_Xenopus_tropicalis_model/; Miaomiao Teng et al., *Life cycle exposure to propiconazole reduces fecundity by disrupting the steroidogenic pathway and altering DNA methylation in zebrafish (Danio rerio),* 135 ENV'T INT'L 1 (2020), https://www.sciencedirect.com/science/article/pii/S0160412019331551; Nathalia Orlandini Costa et al., *Evaluation of the reproductive toxicity of fungicide propiconazole in male rats*, 335 TOXICOLOGY 55 (2015), https://core.ac.uk/reader/82434630.

125. As such, Congress required EPA to develop and implement the EDSP in relatively short order and to be thorough in carrying out the EDSP. Congress mandated that the EDSP be implemented no later than August 3, 1999, 21 U.S.C. § 346a(p)(2), and required testing of *all* pesticide chemicals for possible endocrine effects in carrying out the EDSP. *Id.* § 346a(p)(3)(A). EPA, on the Endocrine Disruptor Screening and Testing Advisory Committee's recommendation, expanded the scope of the EDSP to encompass even more chemicals, not just those present in pesticides.[123]

126. EPA has failed to meet their deadlines and take Congressionally required action. In the more than twenty-five years since the enactment of the FQPA, EPA has failed to finalize validation of assays for testing and has only succeeded in making complete endocrine effect determinations for approximately *2%* of pesticide chemicals.

127. Specifically, EPA has published only two lists of chemicals to date: List 1 consisting of sixty-seven pesticides (although it was reduced to fifty-two) and List 2 consisting of 109 pesticides. EPA has only completed Tier 1 testing for List 1 chemicals and has not completed any Tier 2 testing for List 1 despite a finding by EPA, more than seven years ago, that eighteen of the chemicals are possible endocrine disruptors. EPA has completed no testing for List 2.

128. At the same time as EPA only managed to complete Tier 1 testing for fifty-two pesticides, EPA completed registration for 425 new pesticides *without consideration* of their potential endocrine effects—flouting the whole point of Congress's FQPA mandates—bringing the total number of registered pesticides from 890 in 1990 to 1315 in 2020.[124]

---

[123] *See supra* note 27 and accompanying text.
[124] *See 2021 OIG Report*, *supra* note 50, at 10.

129. Because the EDSP has not tested any pesticides since 2015, yet has continued to register hundreds of new ones, EPA has fallen further and further behind with the EDSP, as the percentage of pesticides screened for Tier 1 testing has steadily diminished from 2015 to 2022.

130. Multiple former EPA employees cautioned the agency against such approach, encouraging the agency to require Tier 1 screening data for all registration applications for new active ingredients.[125] Nevertheless, the agency disregarded the advice of EDSP employees and simply registered more pesticides necessitating future endocrine screening.

131. Further, pesticide chemicals are not the only chemicals slated to be tested under the EDSP adopted by EPA. EPA themselves estimated over 87,000 chemicals are subject to testing under the EDSP.[126] If current trends hold and testing continues to happen at this (at best) languid pace, the percentage of screened pesticides will only continue to diminish, and EPA will never meet their statutory mandates.

132. Still less will EPA's current approach permit it to ever assess the impacts of pesticides or other chemicals on the over forty additional hormone systems–beyond estrogen, androgen, and thyroid–that EDSTAC deemed "essential" to test.[127]

133. In sum, EPA is not complying with the Congressional mandates of the FQPA's EDSP provisions. EPA failed and continues to fail to implement the EDSP as required by Section 346a(p)(2).[128] EPA also failed to test all pesticide chemicals, and its minimal previous action and complete lack of action in recent years indicate

---

[125] Interviews Conducted in Preparation of the 2021 OIG Report, *supra* note 47, at 13.
[126] Endocrine Disruptor Screening Program, 63 Fed. Reg. at 71545.
[127] EDSTAC Final Report, *supra* note 27.
[128] 21 U.S.C. § 346a(p)(2).

that EPA is not on track to "provide for the testing of all pesticide chemicals" anytime in the near future, if at all.[129]

Harm to Plaintiffs

134. The interests of Plaintiffs, organizationally and through their hundreds of thousands of members, are being and will be adversely affected by Defendants' continued failure to implement the EDSP and complete testing of all pesticides.

135. Defendant's unlawful withholding and unreasonable delay of FQPA pursuant to 21 U.S.C. § 346a(p), regarding implementing the EDSP and testing all pesticides for endocrine effects, injures Plaintiffs by putting their members' health and safety in increased jeopardy, through the continuing risk of exposure to endocrine disrupting chemicals. Without the FQPA-required EDSP determining which chemicals are endocrine disruptors and thus prompting action to safeguard against adverse health impacts, Congress's will is thwarted and Plaintiffs' members are put at a greater risk of suffering adverse health impacts as a result of exposure to endocrine disruptors. Endocrine disruption affects members' health, well-being, and conservation interests.

136. Plaintiffs' members are farmers, farmworkers, landscapers, consumers, and conservationists. They live and work in, landscape, and eat food produced in the above recognized areas of California that are sprayed with pesticides EPA has identified as being possible human endocrine disruptors, and in other areas of the U.S. where crops are grown with the aid of possible human endocrine disrupting pesticides. Further, they recreate with the purpose of enjoying wildlife in areas sprayed with pesticides EPA has recognized as possible wildlife endocrine disruptors.

---

[129] *Id.* § 346a(p)(3)(A).

Farmworkers, Landscapers, and Consumers

137. The failure to test all pesticides for possible endocrine effects injures Plaintiffs' members' health, to the detriment of their economic, vocational, health, and personal interests.

138. As is noted above, EPA recognized cypermethrin, DCPA, dimethoate, linuron, and metribuzin as possible human endocrine disruptors.[130]

139. Plaintiffs' have farmer and farmworker members who work with crops, such as alfalfa and cotton, crops dimethoate is readily sprayed on, among other pesticides that EPA has found are possible endocrine disrupters.

140. Plaintiffs' have members who live and work in areas that utilize cypermethrin in conducting landscape maintenance, among other pesticides that EPA has found are possible endocrine disrupters.

141. Plaintiffs' farmworker and landscaper members continue their work with no real certainty as to whether the chemicals they are exposed to everyday are disrupting their hormone systems and potentially inducing adverse health impacts such as cancer, thyroid conditions, diminished fertility, and more. Those farmworker and landscaper members who wish to err on the side of caution given EPA's failure to provide definitive findings on the question of endocrine disruption will have to take extra, potentially costly, precautions to prevent exposure to the pesticides during their jobs or quit their jobs entirely to avoid exposure to pesticides that potentially pose adverse health effects.

142. Many of the Plaintiffs' members consume vegetables grown in states, like California and Florida, where endocrine disrupting pesticides such as metribuzin and linuron are readily used on food crops, including but not limited to carrots, celery, cilantro, potatoes, tomatoes, and corn.

---

[130] *See* ¶ 111.

143. Plaintiffs' consumer members continue to purchase and consume produce. While many of Plaintiffs' members try to avoid pesticide use on their produce by purchasing organic options, organic produce is not always available and for other members it is financially unattainable. As such, many members must purchase and consume produce they fear is adversely impacting their health. Those that are able to purchase organic produce in order to avoid consuming produce sprayed with possible endocrine disruptors are incurring an additional expense as a result of EPA's failure to complete endocrine testing.

144. The livelihood and economic interests of Plaintiffs' members are injured by EPA's failure to implement the EDSP.

145. There is little doubt that EPA's failure to complete screening of all pesticide chemicals for possible endocrine effects has caused damage to Plaintiffs' members health. A wealth of scientific studies conclude that many chemicals in use today are endocrine disruptors capable of devasting adverse health impacts.[131] Plaintiffs' members are routinely exposed to a myriad of pesticides, including the five EPA has flagged as possible endocrine disruptors, via their livelihoods and food consumption. EPA's continued failure to implement the EDSP and complete testing of all pesticides for possible endocrine effects compounds Plaintiffs' members' exposure.

146. Plaintiffs' members are deeply concerned that EPA's failure to complete testing for all pesticides, but particularly those EPA has already acknowledged as being possible endocrine disruptors, will result in their continued exposure to chemicals at levels that are causing harm to their health and that of their children and future children.

[131] *See supra* notes 10–14 and accompanying text.

147. Plaintiffs' members with young children, and those hoping to one day welcome children, are concerned about the long-term impacts of likely repetitive exposure to endocrine disrupting chemicals. Many fear developmental delays in their young children and others fear possible fertility struggles, well recognized health consequences of endocrine disruption.

148. All in all, EPA's failure to implement the EDSP and test all pesticides for possible endocrine effects has, and will continue to, injure Plaintiffs' members interests and their ability to freely select what they eat and how and where they work, as well as cost them additional money to take precautions to mitigate possible exposure to endocrine disrupting chemicals.

149. One of plaintiff CEH's members is concerned about the effects of endocrine disruptors on her health and that of her children. She began attempting to avoid endocrine disrupting chemicals at the direction of her doctor after experiencing infertility. She has since spent extra time and money attempting to minimize hers and her children's exposure to endocrine disrupting chemicals. She does this by buying organic produce whenever possible, incurring a larger expense as a result, and going through the labor-intensive process of cooking, blending, and freezing her own organic baby food. Despite her best efforts, she knows her children are inevitably exposed to endocrine disrupting chemicals via the foods they consume at school, restaurants, and friends' houses, and during the occasional fast-food outing. Her children, like many others, enjoy french fries, a potato product that in all likelihood is being sprayed with at least one of the above five mentioned pesticides. She fears the developmental impacts that her children may face as a result of such exposure.

Conservationists

150. The failure to test all pesticides for possible endocrine effects injures Plaintiffs member's environmental interests.

151. Plaintiffs' members are also conservationists with aesthetic, recreational, vocational, and personal interests in the protection of the environment, more specifically wildlife, from the adverse impacts of endocrine disruption. Members are heavily involved with protecting species and ensuring the environment safeguards wildlife health, for recreational, and personal reasons. The use of chemicals flagged as possible endocrine disruptors poses a real threat of harm to the health of wildlife, injuring Plaintiff's members' recreational interest in maintaining biodiversity and protecting sensitive species.

152. EPA's continued failure to test all pesticide chemicals, but especially its failure to complete Tier 2 testing for those that EPA recognizes as possible endocrine disruptors, will result in the continued use of these likely damaging pesticide chemicals. Consequently, species may face developmental malformations, interference with reproduction, increased cancer risk, and disturbances in immune and nervous system function. Such realities will diminish members' abilities to enjoy wildlife.

153. One of Plaintiff Center for Food Safety's members is an environmentalist and wildlife enthusiast, with a bachelor's degree in natural resources, who is concerned about the impacts of endocrine disrupting pesticides on wildlife. She enjoys searching for and observing wildlife and is concerned about how endocrine disrupting pesticides may be contributing to wildlife declines. Both the knowledge of these losses and the fact that such losses are making it more difficult for her to observe wildlife harms her. She is also the mother of a four-year-old child and is concerned about the impacts of exposures to endocrine disrupting pesticides on her child's development. Because of this she spends extra money to primarily buy organic foods in an attempt to reduce potential exposures and protect both her family's health and wildlife.

154. The requested relief will redress this harm by compelling EPA to implement the EDSP and resume testing of all pesticide chemicals as required by law for the safety of all Americans, and Plaintiffs' members in particular.

Organizational Injury

155. In addition to the injury to its individual members, the EPA's failure to act also injures Plaintiffs' organizational interests. Each organization has a mission dedicated to protecting the environment and/or farmers and farmworkers from the adverse impacts of industrial agriculture, specifically pesticides. EPA's continued failure to implement the EDSP and test all pesticide chemicals causes Plaintiff organizations to divert resources from addressing other pesticides to focus on the harms and injuries caused by endocrine disrupting pesticides.

CAUSE OF ACTION

[Violation of the FQPA and the APA – Against EPA]

[By All Plaintiffs]

156. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 155 *supra*.

157. The FQPA requires EPA to implement the EDSP by August 3, 1999. The Act also requires the EPA test all pesticide chemicals for possible endocrine effects in carrying out the EDSP. EPA's failure to take either of these mandatory actions constitutes unlawfully withheld and unreasonably delayed agency action within the meaning of the APA.

158. 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." 5 U.S.C. § 702.

159. The definition of "agency action" includes a "failure to act." 5 U.S.C. § 551(13).

160. Plaintiffs and their members are adversely affected by EPA's past and continued failure to complete the actions required by Congress in the FQPA. *See id.*

161. The APA states that a reviewing court shall interpret statutes and "shall compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

162. EPA's failure to implement the EDSP and test all pesticide chemicals for possible endocrine effects constitutes both unlawfully withheld agency action and unreasonably delayed agency action that this Court shall compel. *See id.*

PRAYER OF RELIEF

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

163. Declaring the EPA has violated the FQPA and the APA by failing to implement the EDSP by August 3, 1999;

164. Declaring the EPA continues to be in violation of the FQPA and the APA by failing to implement the EDSP;

165. Declaring the EPA has violated the FQPA and the APA by failing to timely complete the testing of all pesticide chemicals for possible endocrine effects;

166. Declaring that EPA continues to be in violation of the FQPA and the APA by failing to complete the testing of all pesticide chemicals for possible endocrine effects;

167. Ordering EPA to complete all actions required under the FQPA at issue in this case as soon as reasonably practicable, according to a Court-ordered timeline;

168. Retaining jurisdiction of this action to ensure compliance with its decree;

169. Awarding Plaintiffs attorney's fees and all other reasonable expenses incurred in pursuit of this action; and

170. Granting such other relief as the Court deems just and proper.

Dated this 20th day of December, 2022.

/s/ Jennifer Loda

Jennifer Loda (Ca Bar No. 284889)
Pegga Mosavi (*Pro Hac Vice* Pending)
Center for Food Safety
303 Sacramento Street, 2nd Floor
Emails: jloda@centerforfoodsafety.org
pmosavi@centerforfoodsafety.org

Counsel for Plaintiffs