LEGAL RULEMAKING PETITION TO THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AMERICAN BIRD CONSERVANCY; BEYOND PESTICIDES; MASSACHUSETTS POLLINATOR NETWORK; MAINE ORGANIC FARMERS AND GARDENERS ASSOCIATION; NORWALK RIVER WATERSHED ASSOCIATION; PESTICIDE ACTION NETWORK NORTH AMERICA; NORTHEAST ORGANIC FARMING ASSOCIATION; NORTHEAST ORGANIC FARMING ASSOCIATION OF VERMONT; NORTHWEST CENTER FOR ALTERNATIVES TO PESTICIDES; RURAL VERMONT; TOXIC FREE NC;; and **TOM NELTNER** including and represented by **CENTER FOR FOOD SAFETY** 600 California Street, Suite 12-013 San Francisco, CA 94108; *Petitioners,* ***Filed With:*** **MICHAEL REGAN, ADMINISTRATOR** Environmental Protection Agency Office of the Administrator, Mail Code: 1101A 1200 Pennsylvania Ave., NW Washington, D.C. 20004	Docket Number _____

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GLOSSARY

Administrative Procedure Act	**APA**
Clean Air Act	**CAA**
Clean Water Act	**CWA**
Emergency Planning and Community Right-to-Know Act	**EPCRA**
Endangered Species Act	**ESA**
Environmental Protection Agency	**EPA**
Federal Insecticide, Fungicide, Rodenticide Act	**FIFRA**
Hexafluoropropylene oxide dimer acid	**HFPO-DA**
High-density polyethylene	**HDPE**
Maximum Contaminant Level	**MCL**
Maximum Contaminant Level Goal	**MCLG**
Per- and polyfluoroalkyl substances	**PFAS**
Perfluorooctanoic acid	**PFOA**
Perfluorooctane sulfonic acid	**PFOS**
Perfluorobutanoic acid	**PFBA**
Perfluoropentanoic acid	**PFPeA**
Perfluorohexanoic acid	**PFHxA**
Perfluoroheptanoic acid	**PFHpA**
Perfluorononanoic acid	**PFNA**
Perfluorodecanoic acid	**PFDA**
Perfluoroundecanoic acid	**PFUdA**

Perfluorohexane sulfonate	**PFHxS**
Resource Conservation and Recovery Act	**RCRA**
Safe Drinking Water Act	**SDWA**
Significant New Use Rule	**SNUR**
Toxic Substances Control Act	**TSCA**
United States Department of Agriculture	**USDA**
United States Geological Survey	**USGS**

CITIZEN PETITION TO THE U.S. ENVIRONMENTAL PROTECTION AGENCY SEEKING CANCELLATION AND SUSPENSION OF SEVERAL EXISTING REGISTRATIONS OF PESTICIDE INGREDIENTS THAT ARE PFAS CHEMCIALS AND REQUIRING RULEMAKING REGARDING PFAS CHEMICAL ASSESSMENT AND PFAS IN PESTICIDE CONTAINERS

INTRODUCTION AND SUMMARY

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136 *et seq.*, mandates that the Environmental Protection Agency (EPA) regulate pesticide use in the United States to ensure no "unreasonable adverse effects on the environment."[1] But despite referring to perfluoroalkyl and polyfluoroalkyl substances, or PFAS chemicals, as an "urgent public health and environmental issue facing communities across the United States,"[2] and, in some instances, "highly toxic and present[ing] unreasonable risks,"[3] EPA has failed to take any significant action on these chemicals' use in pesticides under FIFRA.

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[1] 7 U.S.C. § 136a(c)(5).

[2] U.S. Env't Prot. Agency, *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024* (Oct. 2021), https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf [hereinafter PFAS Strategic Roadmap].

[3] U.S. Env't Prot. Agency, *EPA Orders Issued to Inhance Technologies Related to Long-Chain PFAS Significant New Use Notices*, Reviewing New Chemicals Under the Toxic Substances Control Act (TSCA) (updated December 14, 2023), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epa-orders-issued-inhance [hereinafter EPA Orders to Inhance]; *see also* U.S. Env't Prot. Agency, *Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs),* Public Webinar (September 6, 2023), https://www.epa.gov/system/files/documents/2023-09/13313_PFAS%20Framework%20Webinar_9-12-2023_508.pdf at 14 (describing a "Not Likely" determination for PFAS) [hereinafter Framework for TSCA].

Instead, EPA has continued *registering* active ingredients that qualify as PFAS,[4] is maintaining other registrations of PFAS active and inert ingredients,[5] and is allowing the use of fluorinated high-density polyethylene (HDPE) and polypropylene storage containers that leach PFAS into pesticides.[6] This cannot stand under FIFRA: EPA itself has stated it "must leverage the full range of statutory authorities to confront the human health and ecological risks of PFAS."[7] Accordingly, this Petition requests that EPA do just that: cancel existing registrations for inert and active ingredients that qualify as PFAS, amend FIFRA regulations to prohibit PFAS in pesticide formulations and containers, or alternatively, require assessment of PFAS chemicals' unique environmental impacts.

Numerous studies have found high PFAS levels in widely used pesticides in the United States.[8] PFAS chemicals are a subset of fluorinated chemicals, which

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[4] *See* Notice of Pesticide Registration, EPA Reg. Number 86203-28 (Jan. 14, 2021) (unconditional registration of new active ingredient broflanilide by EPA).

[5] Jeff Dawson and Anne Overstreet, Presentation at NPIRS & ALSTAR Spring Conference, U.S. Env't Prot. Agency (Apr. 12, 2023), https://www.npirs.org/ref/conference/2023_Washington_DC_Presentation_on_PFAS_(EPA-Dawson-Overstreet).pdf [hereinafter Dawson].

[6] BERLIN PACKAGING, *Fluorination* (Oct. 20, 2019), https://www.berlinpackaging.com/fluorination/; Tom Neltner, *Beyond Paper: PFAS Linked to Common Plastic Packaging Used for Food, Cosmetics, and Much More,* Env't Defense Fund (updated Aug. 11, 2021), https://blogs.edf.org/health/2021/07/07/beyond-paper-pfas/.

[7] PFAS Strategic Roadmap, *supra* n.2, at 5.

[8] *See, e.g.*, Tom Perkins, *Toxic 'Forever Chemicals' Detected in Commonly Used Insecticides in US, Study Finds,* The Guardian (Oct. 7, 2022), https://www.theguardian.com/environment/2022/oct/07/forever-chemicals-found-insecticides-study; Steven Lasee, et al., *Targeted Analysis and Total Oxidizable Precursor Assay of Several Insecticides for PFAS,* J. HAZARDOUS MATERIALS LETTERS

possess strong carbon-fluorine bonds.[9] That means such chemicals are both highly stable and useful in pesticide products to extend shelf life and provide an even coating, as well as in pesticide containers to reduce permeation.[10] But it also means they do not readily biodegrade; rather, their strong molecular bonds can take hundreds of years to break down, with certain PFAS linked to public health and environmental concerns nationwide, leaching into soil and groundwater, and increasing risks of testicular and kidney cancers, reproductive disorders, thyroid disease, high cholesterol levels, reduced immune response, and increased susceptibility to COVID-19.[11]

As a result, EPA has committed to addressing PFAS contamination in the environment. Specifically, EPA Administrator Regan recently assured the public that EPA is "laser focused on protecting people from [PFAS] pollution and holding polluters accountable."[12] But EPA's only actions under FIFRA have been its December 2022 decision to remove twelve PFAS chemicals and its February 2024

(2022), https://www.sciencedirect.com/science/article/pii/S266691102200020X#tbl0005.

[9] Meg Wilcox, *Pesticides are Spreading Toxic 'Forever Chemicals,' Scientists Warn*, Scientific American (June 15, 2022), https://www.scientificamerican.com/article/pesticides-are-spreading-toxic-lsquo-forever-chemicals-rsquo-scientists-warn/.

[10] Monica Amarelo, *Maine Data Unveils Troubling Trend: 55 PFAS-related Chemicals in over 1,400 Pesticides*, EWG (Jun. 6, 2023), https://www.ewg.org/news-insights/news-release/2023/06/maine-data-unveils-troubling-trend-55-pfas-related-chemicals.

[11] Wilcox, *supra* n.9.

[12] U.S. Env't Prot. Agency, *EPA Administrator Regan Announces Comprehensive National Strategy to Confront PFAS Pollution* (Oct. 18, 2021), https://www.epa.gov/newsreleases/epa-administrator-regan-announces-comprehensive-national-strategy-confront-pfas.

proposal to remove another from its list of approved inert ingredients, none of which were even *in use.*[13] EPA's actions and inactions have led to ongoing PFAS contamination and public health impacts as a result, harming Petitioners' interests.

PETITION REQUESTS

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,[14] the Administrative Procedure Act (APA),[15] and FIFRA § 136d(b),[16] Petitioners request the Administrator of EPA to take the following actions:[17]

1. **Cancel registrations for all active and inert ingredients that meet the definition of PFAS pursuant to FIFRA § 136d(b), in accordance with the United States Geological Survey (USGS) definition, *see* 15 U.S.C. § 8931(2)(B), and state-based definitions of PFAS as "a class of fluorinated organic chemicals that contain at least one fully fluorinated carbon atom," and cease registering any more.**

2. **Suspend the registrations for active and inert ingredients that qualify as PFAS under the 15 U.S.C. § 8931(2)(B) definition, pending completion of cancellation proceedings pursuant to FIFRA § 136d(c)(1).**

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[13] 87 Fed. Reg. 76,488 (Dec. 14, 2022); 89 Fed. Reg. 14, 646 (Feb. 28, 2024).

[14] U.S. CONST. amend. I.

[15] 5 U.S.C. § 553(e).

[16] This section provides authority for EPA to cancel a pesticide registration "if it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." 7 U.S.C. § 136d(b).

[17] EPA lacks regulations for handling public petitions related to pesticides, a problem it has been urged by its Inspector General to cure. *See* U.S. Env't Prot. Agency, *EPA Needs Policies and Procedures to Manage Public Pesticide Petitions in a Transparent and Efficient Manner,* IG Report No. 16-P-0019 (Oct. 27, 2015), www.epa.gov/sites/production/files/2015-10/documents/20151027-16-p-0019.pdf.

3. **Alternatively, clarify pesticide registration regulations at 40 C.F.R. § 152.112 to explicitly require EPA to consider PFAS chemicals' unique long-term impacts on human health and the environment, as EPA has required in other contexts.**

Amend 40 C.F.R. 152.112 to add the following underlined paragraph:

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).
EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:
(a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part;
(b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);
(c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application;
(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted for the product by part 158 or part 161 of this chapter, as applicable.
(e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;
(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;
(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, and
(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

(i) In accordance with paragraph (e) of this section, the Agency must identify PFAS ingredients in pesticides and account for their persistence in the environment and bioaccumulation potential in its assessment.

4. **As an alternative to cancellation, amend data requirements under 40 C.F.R. 158.630(d) to require registrants to submit data on PFAS ingredient persistence in the environment, as well as environmental fate/bioaccumulation, toxicokinetic, and human health and/or environmental toxicity data specific to PFAS chemicals.**

5. **Amend the definitions in 40 C.F.R. § 158.300 to include the USGS and state-based definitions of PFAS at 15 U.S.C. § 8931(2)(B).**

   Amend 40 C.F.R. § 158.300 to add the following underlined paragraph:

   PFAS means "a class of fluorinated organic chemicals that contain at least one fully fluorinated carbon atom."

6. **Alternatively, create a PFAS in Pesticides Guidance Document.** This petition proposes the creation of a guidance document similar to previous guidelines the agency has developed, for example EPA's 2014 Bee Guidance.[18] This guidance document will recommend reporting under FIFRA section 6(a)(2) for any PFAS contamination in pesticides. It will specify that EPA finds PFAS contamination "toxicologically significant," requiring registrants to report contamination to EPA immediately under 40 C.F.R. § 159.179(b). If action is not immediately taken by the registrant to remove the contaminated, adulterated product from the market, EPA will issue a "stop sale, use, or removal" order.

   Additionally, should EPA refuse cancellation of all PFAS ingredients, these guidelines will further direct the agency in the practices required to incorporate the analysis and data required in the above amended regulations (along with the broader scientific literature) into the risk assessment process. This guidance document should provide guidance to risk assessors for evaluating the potential risk of PFAS in pesticides to the environment and public health. This includes information on the phases of the assessment (i.e., analysis and risk characterization) and specifics on a tiered approach by which additional information can be requested from the registrant. Importantly, this guidance document should outline an approach that

[18] U.S. Env't Prot. Agency, Office of Pesticide Programs, *Guidance for Assessing Pesticide Risks to Bees* (June 19, 2014), https://www.epa.gov/sites/default/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf.

effectively incorporates studies in the published literature and does not arbitrarily discount those studies. Specifically, this guidance document should discuss and implement a methodology that the EPA can use to ensure incorporation of all available science, not just registrant studies.

7. **Amend nonrefillable container standard regulations to prohibit use of fluorinated HDPE containers, as well as polyethylene and polypropylene containers.**

Amend 40 C.F.R. § 165.25 to add the following underlined paragraph:

§ 165.25 Nonrefillable container standards.

(a) ***What Department of Transportation (DOT) standards do my nonrefillable containers have to meet under this part if my pesticide product is not a DOT hazardous material?*** A pesticide product that does not meet the definition of a hazardous material in 49 CFR 171.8 must be packaged in a nonrefillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178, and part 180 that are applicable to a Packing Group III material, or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.

(b) ***What DOT standards do my nonrefillable containers have to meet under this part if my pesticide product is a DOT hazardous material?***

(1) If your pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the DOT requires your pesticide product to be packaged according to 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B.

(2) For the purposes of these regulations, a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a nonrefillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.

(c) ***What will EPA do if DOT proposes to change any of the cross-referenced regulations?*** If the DOT proposes to change any of the regulations that are incorporated in paragraphs (a) and (b) of this

section, EPA will provide notice of the proposed changes and an opportunity to comment in the Federal Register. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such revision will correspond with revised DOT regulations.

(d) ***What standards for closures do my nonrefillable containers have to meet?*** If your nonrefillable container is a rigid container with a capacity equal to or greater than 3.0 liters (0.79 gallons), if the container is not an aerosol container or a pressurized container, and if the container is used to distribute or sell a liquid agricultural pesticide, each nonrefillable container must have at least one of the following standard closures:

(1) Bung, 2-inch pipe size (2.375 inches in diameter), external threading, 11.5 threads per inch, National Pipe Straight (NPS) standard.

(2) Bung, 2-inch pipe size (2.375 inches in diameter), external threading, 5 threads per inch, buttress threads.

(3) Screw cap, 63 millimeters, at least one thread revolution at 6 threads per inch.

(4) Screw cap, 38 millimeters, at least one thread revolution at 6 threads per inch. The cap may fit on a separate rigid spout or on a flexible pull-out plastic spout.

(e) ***What standards for dispensing do my nonrefillable containers have to meet?*** If your nonrefillable container has a capacity of 5 gallons (18.9 liters) or less, if the container is not an aerosol container, a pressurized container, or a spray bottle, and if the container holds a liquid pesticide, your nonrefillable container must do both of the following:

(1) Allow the contents of the nonrefillable container to pour in a continuous, coherent stream.

(2) Allow the contents of the nonrefillable container to be poured with a minimum amount of dripping down the outside of the container.

(f) ***What standards for residue removal do my nonrefillable containers have to meet?*** Each nonrefillable container and pesticide formulation combination must meet the applicable residue removal standard of this section.

(1) If the nonrefillable container is rigid and has a capacity less than or equal to 5 gallons (18.9 liters) for liquid formulations or 50 pounds (22.7 kilograms) for solid formulations and if the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application (that is, if the pesticide is dilutable), each container/formulation combination must be capable of attaining at least 99.99 percent removal of each active ingredient when tested using the EPA test procedure "Rinsing Procedures for Dilutable Pesticide Products in Rigid Containers."

(2) The test must be conducted only if the pesticide product is a suspension concentrate or if EPA specifically requests the records on a case by case basis.

(3) For the rigid container/dilutable product standard in paragraph (f)(1) of this section, percent removal represents the percent of the original concentration of the active ingredient in the pesticide product when compared to the concentration of that active ingredient in the fourth rinse. Percent removal is calculated by the formula:

percent removal = [1.0 - RR] x 100.0, where RR = rinsate ratio = Active ingredient concentration in fourth rinsate/Original concentration of active ingredient in the product.

(g) ***Can I obtain a waiver from or a modification to any of the nonrefillable container standards?*** Yes, it is possible for you to obtain a waiver from or a modification to the nonrefillable container standards, as follows:

(1) EPA may waive or modify the requirements of paragraph (a) of this section regarding the DOT standards for pesticide products that are not DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (a) of this section.

(2) EPA may waive or modify the requirements of paragraph (b) of this section regarding the DOT standards for pesticide products that are DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (b) of this section. EPA will modify or waive the requirements of paragraph (b) of this section only after consulting with DOT to ensure consistency with DOT regulations and exemptions.

(3) EPA may approve a non-standard closure (that is, a closure not listed in paragraph (d) of this section) if EPA determines that both of the following conditions are satisfied:

(i) The non-standard closure is necessary for the proper mixing, loading, or application of the pesticide product.

(ii) The non-standard closure offers exposure protection to handlers during mixing and loading that is the same or greater than that provided by the standard closures.

(4) EPA may waive or modify the container dispensing capability standards in paragraph (e) of this section if EPA determines that at least one of the following conditions is satisfied:

(i) The product is typically removed from the container by a method other than pouring.

(ii) Compliance with the container dispensing capability standards would increase exposure to the pesticide container handler.

(5) EPA may waive or modify the requirements of paragraph (f) of this section regarding the residue removal standard if EPA determines that both of the following conditions are satisfied:

(i) The residue remaining in the container would not cause an unreasonable adverse effect on the environment; and

(ii) The product offers significant benefits and cannot be economically reformulated or repackaged.

(h) ***How do I obtain a waiver from or a modification to any of the nonrefillable container standards?*** To obtain a waiver from or a modification to any of the nonrefillable container standards, you must submit a written request for a waiver or a modification to the EPA to the following address: Office of Pesticide Programs (7504P); U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. You cannot distribute or sell the pesticide product in a nonrefillable container that does not comply with all of the nonrefillable container standards unless and until EPA approves the request for the waiver or modification in writing. You must include two copies of the following information (which may be part of an application for registration or amended registration) with your written request:

(1) The name and address of the registrant; the date; and the name, title, signature, and phone number of the company official making the request.

(2) The name and EPA registration number of the pesticide product for which the waiver or modification is requested.

(3) A statement specifying the requirement or requirements from which you are requesting a waiver or a modification.

(4) A description of the nonrefillable container or containers for which the waiver or modification is requested.

(5) Documentation or justification to demonstrate that the applicable waiver or modification criteria in paragraph (g) of this section are satisfied.

(g) ***What materials are prohibited for use in all nonrefillable containers?*** Nonrefillable containers may not be fluorinated HDPE or polypropylene containers or any material that contains PFAS chemicals.

Failure by the Administrator to take the requested actions would severely harm Petitioners' interests. It would also violate FIFRA's mandates and constitute arbitrary and capricious agency action. In view of the severity of the impacts the

Petitioners are suffering, EPA must act on the requests in this Petition within **180 days** of its filing date.

PETITIONERS

Petitioner Center for Food Safety (CFS) is a nonprofit membership organization of over one million farmer and consumer members with a mission to empower people, support farmers, and protect the environment from the harmful impacts of industrial agriculture. Through legal, scientific, and grassroots action, CFS serves to protect and promote the right to safe food and the environment. Accordingly, since its inception over 25 years ago, one of CFS's flagship programs has focused on pesticides, combining multiple tools in support of its mission including public and policymaker education, outreach, and campaigning. CFS disseminates a wide array of informational materials to government agencies, lawmakers, nonprofits, and the public regarding the effects of pesticides on human health and the environment. These educational and informational materials include, but are not limited to news articles, policy reports, white papers, legal briefs, press releases, newsletters, product guides, action alerts, and fact sheets. CFS often has provided expert testimony to policymakers on the potentially harmful agrichemical impacts associated with industrial monoculture cropping systems, including the increased use of pesticides and chemical fertilizers. When necessary, CFS also engages in public interest litigation to address the impacts of industrial food production and pesticides on its members, the environment, and the public interest.

Petitioner American Bird Conservancy (ABC) is a 501(c)(3) dedicated to conserving birds and their habitat across the Americas. ABC restores bird habitat, performs original research, works cooperatively with federal and state agencies, and leads coalitions of stakeholders to reverse the 3 billion bird decline North America is currently experiencing. ABC also seeks legal, regulatory, and legislative solutions to the issues of lethal and sublethal pesticide poisoning on birds.

Petitioner Beyond Pesticides is a Washington, D.C. based, nonprofit organization that works to protect public health and the environment from the adverse effects of pesticide production, transportation, use, storage, and disposal. Beyond Pesticides has members in fifty states and the District of Columbia. Beyond Pesticides promotes safe air, water, land, and food and works to protect public health and the environment by encouraging a transition away from the use of toxic pesticides, including chemicals like PFAS that are at issue in this petition. To achieve its goals, Beyond Pesticides provides the public with resources and information on the hazards associated with pesticides, including PFAS. Beyond Pesticides' Gateway on Pesticide Hazards and Safe Pest Management provides the public with easy access to current and historical information on pesticide hazards, and safe and organic pest management; drawing on and linking to numerous independent and governmental sources and organizations that provide pesticide-related science and policy information. Beyond Pesticides' Pesticide-Induced Disease Database (PIDD), with over 1,400 studies, facilitates access to epidemiologic and laboratory studies based on real world exposure scenarios that

link pesticides to public health effects, including asthma, autism and learning disabilities, birth defects and reproductive dysfunction, endocrine system disruption, diabetes, Parkinson's and Alzheimer's diseases, and several types of cancer. When necessary, Beyond Pesticides also engages in public interest litigation to address the impacts of pesticides on the environment, its members, and the public interest. Many of the members of Beyond Pesticides are adversely affected by PFAS; members have purchased products or live, work, and recreate where pesticides with PFAS have and/or are being used, or will be, applied.

Petitioner Massachusetts Pollinator Network's (MAPN) mission is to expand pollinator habitat and reduce the use of pesticides through the creation of a statewide network that connects and supports the growing number of individuals, communities, organizations, and research groups working to protect pollination systems across the Commonwealth.

Petitioner Maine Organic Farmers and Gardeners Association (MOFGA) is a 501(c)(3) nonprofit headquartered in Unity, Maine. MOFGA is a broad-based community working to build a food system that is healthy and fair for all. Through education, training and advocacy, MOFGA is helping farmers thrive, making more local, organic food available, and building sustainable communities. The organization's wholly owned subsidiary, MOFGA Certification Services, LLC, certifies 525 organic farmers and processing operations, representing roughly $120 million in sales. MOFGA has been deeply engaged in advocacy efforts to address the escalating problem of PFAS contamination on farmland in Maine and across the

country. One successful state policy that MOFGA strongly supports is Maine PFAS pesticides law, which requires pesticide manufacturers to disclose the presence of PFAS in their products, report whether their products have been stored in fluorinated containers and eliminate PFAS from their formulations by 2030. The threat of PFAS-contamination of farmland is of highest importance to the MOFGA community. Several MOFGA-certified organic farms have been at the center of an ongoing crisis caused by PFAS-contaminated wastewater treatment sludge designated "biosolids" and used as soil amendments. Since 2016, when PFAS was first found to have contaminated soil, water and subsequently milk at a Maine dairy farm, the state has been at the forefront investigating and remediating PFAS contamination of farmland. Administrators in Maine's Department of Environmental Protection (DEP); Department of Agriculture, Conservation and Forestry (DACF); and Department of Health and Human Services (DHHS) have responded to widespread PFAS contamination with broad, non-partisan support from the Maine Legislature. Since 2021, the DEP and DACF have been systematically testing soil and water in locations known to have been permitted for sludge or septage application, and DHHS has been testing food and drinking water and providing alternative drinking water or filtration for contaminated residential wells. MOFGA has provided extensive technical, financial and emotional support to farmers across the management spectrum (i.e., conventional and organic) who are navigating this unprecedented challenge. MOFGA believes that the U.S.

government agencies must take swift action to eliminate PFAS from the U.S. food and agriculture system.

Petitioner Norwalk River Watershed Association is a nonprofit membership organization that accomplishes its mission by engaging community volunteers to help restore native trees, shrubs, wildflowers and grasses to the riverbanks, meadows, parks, and forests of the watershed; working to expand community access to the river, the surrounding open space, and its trails; supporting research and legislative policy that protects biodiversity, clean air, and water; and promoting education, cooperation, and action on the part of the stakeholders in the seven watershed towns in CT (Ridgefield, Redding, Wilton, New Canaan, Weston, and Norwalk) and NY (Lewisboro).

Petitioner Pesticide Action Network North America (PANNA) is a non-profit organization that uses grassroots science, strategic communications and coalition organizing to build power with communities across the U.S. and around the world to confront the harms of industrial agriculture and build solutions. PANNA's mission is to end reliance on hazardous pesticides and achieve health, resilience and justice in food and farming. PANNA has over 65,000 members and supporters and was founded in 1984. It is one of five regional centers who cooperate to transform systems of food and farming across the globe.

Petitioner Northeast Organic Farming Association (NOFA) is a regional federation of seven independent state Chapters in NY, VT, NH, MA, CT, RI and NJ. Beyond their work on state initiatives, the Chapters work together regionally,

nationally and internationally via the NOFA Interstate Council (NOFA-IC), which is a separate 501(c)(3) organization. Further, under the auspices of NOFA-IC the Interstate NOFA Policy Program coordinates and carries out joint initiatives under the auspices of NOFA-IC. Founded in 1971, NOFA is one of the oldest organic farming education and advocacy groups in the country.

Petitioner Northwest Center for Alternatives to Pesticides (NCAP) is the leading Northwest voice for non-toxic pest and weed solutions. We promote safe pest and weed alternatives for the health of people and the environment. NCAP has been at the forefront of advocating for disclosure and review of inert ingredients in pesticide formulations and supports this effort in hopes that it helps the EPA prioritize meaningfully addressing this timely issue.

Petitioners Rural Vermont is a nearly 40 year old member-based organization which organizes, educates and advocates in collaboration with local and global movements to strengthen the social, ecological and economic health of the agrarian communities that connect us all. Rural Vermont envisions a just and equitable world rooted in reverence for the earth and dignity for all. This abundant and generous way of life celebrates our diversity and interdependence, in which communities of microorganisms, animals, plants, and humans tend one another and nurture generations to come.

Petitioner Toxic Free NC's mission is to engage North Carolina in initiatives that advance environmental health and justice by advocating for safe alternatives to harmful pesticides and chemicals. Established in 1986 in response to a

community pesticide poisoning in rural Gorgas, NC, Toxic Free NC has steadfastly been the leading pesticide education and outreach organization in North Carolina for almost four decades.

Petitioner Tom Neltner is a chemical policy expert with experience in industry, academia, government, and advocacy. He has coauthored three petitions to the Food and Drug Administration (FDA) regarding PFAS, including the food additive petition that prompted FDA to revoke its rules in 2016 that allowed use of PFOA as a food contact substance in paper. He has also coauthored the pending citizen petition asking FDA to revoke its food contact authorizations for PFAS where the chemicals may bioaccumulate in people and the environment.

LEGAL BACKGROUND

FIFRA is the primary statute under which EPA regulates the distribution, sale, and use of pesticides. FIFRA defines a "pesticide" as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest[.]"[19] When a pesticide is sold or distributed, it is generally referred to as a "pesticide product." FIFRA generally prohibits the sale or distribution of a pesticide product unless it has first been "registered" under FIFRA Section 3.[20]

FIFRA authorizes EPA to register a pesticide only upon determining that it "will perform its intended function without unreasonable adverse effects on the environment," and that "when used in accordance with widespread and commonly

[19] 7 U.S.C. § 136(u).
[20] *Id.* § 136a(a).

recognized practice it will not generally cause unreasonable adverse effects on the environment."[21] The statute defines "unreasonable adverse effects on the environment" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[22] "Environment" "includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these."[23] When EPA applies this risk-benefit balancing test, it may only register a pesticide if it finds that the risks associated with the use of a pesticide are justified by the benefits of such use.[24]

FIFRA tasks EPA with dictating what information applicants must submit to support pesticide registrations and assessing that data to determine whether the pesticide will perform its intended function while meeting the safety standard.[25] A pesticide registration application must include, among other things, "the complete formula of the pesticide" and "a full description of the tests made and the results thereof upon which [safety and efficacy] claims are based, or alternatively a citation to [relevant safety and efficacy] data."[26] EPA requires a "confidential statement of

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[21] *Id.* § 136a(c)(5)(C), (D); 40 C.F.R. § 152.112(e).

[22] 7 U.S.C. § 136(bb).

[23] 7 U.S.C. § 136(j).

[24] *Wa. Toxics Coal. v. Env't Prot. Agency*, 413 F.3d 1024, 1032 (9th Cir. 2005) (explaining that FIFRA uses a "cost-benefit analysis to ensure that there is no unreasonable risk created for people or the environment from a pesticide.").

[25] 7 U.S.C. § 136a(c)(2); *Id.* § 136a(c)(5)(C).

[26] *Id.* § 136a(c)(1)(D, F); *see also* U.S. Env't Prot. Agency, *Pesticide Registration Manual*, Ch. 2, https://www.epa.gov/system/files/documents/2021-08/pesticide-registration-manual-chapter-2.pdf ("The purpose of these data

formula" that includes all active and inert ingredients and impurities in a given pesticide formula or formulation.[27] EPA has broad discretion to require supporting data for pesticide applications and to require additional data for registered pesticides to maintain registration.[28] An application for registration is incomplete if it contains insufficient information for EPA to determine if a pesticide is safe.[29] Registration of a pesticide—conditional or otherwise—cannot continue on the basis of an incomplete application.[30]

EPA's regulations provide a myriad of data requirements and specific considerations. For example, EPA must consider the "human dietary risk from residues"[31] for pesticides used on food products. EPA must also use "studies ... pertain[ing] to leaching" to assess "potential environmental hazards related to ... habitat loss of wildlife resulting from pesticide residue movement or transport in the environment"[32]; "mutagenicity studies" to assess "hazards to ... domestic animals"[33]; and "aerobic ... metabolism studies" to assess "the persistence of [the] pesticide" in the environment.[34] Data requirements for applicants also include testing on residue chemistry to estimate human exposure to pesticides, acute

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requirements is to demonstrate that the product will not cause unreasonable adverse effects.").

[27] *Pesticide Registration Manual*, *supra* n.26, at ch. 2 (citing 7 U.S.C. § 136a(c)(1)(D)).

[28] 7 U.S.C. § 136a(c)(2)(A)-(B).

[29] 40 C.F.R. § 152.104.

[30] *See id.* § 152.105.

[31] 7 U.S.C. § 136(bb).

[32] *See* 40 C.F.R. § 158.130(h)(4).

[33] *See id.* § 158.130(d).

[34] *See id.* § 158.130(h)(3).

human hazard, sub chronic human hazard, chronic human hazard, reentry hazard, and spray drift evaluation, as well as oncogenicity, teratogenicity, neurotoxicity, and reproductive effects in humans.[35]

In order for EPA to register a pesticide, its entire formulation must meet FIFRA's registration standard.[36] In enacting FIFRA, Congress understood that pesticides are generally comprised of active ingredients[37] that "will prevent, destroy, repel, or mitigate any pest,"[38] as well as inert ingredients "which [are] not active."[39] EPA maintains a list of approved inert ingredients for use in pesticide products.[40] A pesticide formulation is a mixture of one or more active ingredients—the pesticide formula, along with other chemicals, statutorily defined and commonly known as inert ingredients.[41] The mixture of the pesticide formula and inert ingredients is often referred to simply as the pesticide or the pesticide formulation.[42] Though inert ingredients may or may not have a direct effect on the target species, they can be toxic, biologically active and potentially hazardous.[43]

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[35] *See id.* § 158.130.

[36] 7 U.S.C. § 136(u) (defining "pesticide" as a "substance or mixture of substances"); *id.* § 136a(c)(5) (providing for "pesticide" registrations).

[37] *See* 40 C.F.R. § 158.300 (defining "formulation" to mean the process of mixing active and inert ingredients to create a final pesticide product).

[38] 7 U.S.C § 136(a)(1).

[39] *Id.* § 136(m); *see also* 40 C.F.R. §152.3 (defining an inert ingredient as "any substance ... other than an active ingredient, which is intentionally included in a pesticide product.").

[40] U.S. Env't Prot. Agency, InertFinder, https://ordspub.epa.gov/ords/pesticides/f?p=INERTFINDER:1:0::NO:1::.

[41] National Research Council, *Assessing Risks to Endangered and Threatened Species from Pesticides*, at 65 (National Academies Press, 2013).

[42] *Id.*

[43] *Id.* at 66.

To use a pesticide, the pesticide formulation is often added to a tank or other container containing adjuvants.[44] Adjuvants differ from inerts because applicators add them to a tank mixture in the field at the time they apply the pesticide, rather than when formulating the pesticide in the laboratory.[45] Both "[i]nerts and adjuvants are comprised of an extremely broad array of chemicals, including carriers, stabilizers, sticking agents, and other materials added to facilitate handling or application."[46] However, EPA's testing requirements for inerts and adjuvants remains elusive: EPA's guidance documents for developing new pesticide inerts do not contain a specific list or detail the required tests for approval; however, inerts and adjuvants can and should be subject to the same types of tests that are required for active ingredients.[47]

Once EPA registers a pesticide, FIFRA provides EPA with ongoing oversight authority, and EPA may at any time propose cancellation or suspension if it

[44] *Id.* at 65.
[45] *Id.* at 66.
[46] *Id.*
[47] *Id.* at 120.

appears a pesticide does not meet FIFRA's safety standard.[48] FIFRA also allows EPA to suspend registrations that cause an "imminent hazard."[49]

FIFRA also governs the storage, disposal, transportation, and recall of pesticides. Specifically, FIFRA mandates that "the Administrator shall … promulgate regulations for the design of pesticide containers that will promote the safe storage … of pesticides."[50] EPA may require applicants to submit data about transportation and storage methods and may require certain procedures be followed for storage or disposal of containers that used to contain pesticides, and can also require certain recycling procedures for containers.[51] FIFRA authorizes EPA to promulgate regulations for the design of pesticide containers to ensure safe disposal and reuse.[52] Pesticide manufacturers must monitor whether EPA uses these authorities to recall containers or products containing PFAS.[53]

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[48] *See* 7 U.S.C. § 136d ("If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either--(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or (2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.").

[49] *Id.* § 136d(c)(1) ("If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately.").

[50] 7 U.S.C. § 136q(e)(1).

[51] *Id.* § 136q(a).

[52] *Id.* § 136q(b), (e).

[53] *Id.* § 136q(b).

FACTUAL BACKGROUND

I. Characteristics of PFAS.

PFAS are a series of man-made chemical compounds that persist in the environment for long periods of time. Commonly referred to as "forever chemicals," PFAS chemicals possess strong carbon-fluorine bonds, rendering them highly stable and resistant to heat, oil, grease, stains, and water.[54] As a result, manufacturers often use these chemicals in clothing, furniture, food packaging, cookware, cleaning products, insulation, paint, and even cosmetics.[55]

Despite their commercial usefulness, PFAS chemicals pose numerous well-documented risks to human health and the environment. Because of their molecular structure, PFAS do not break down naturally, instead traveling through soils and waterways and building up, or bioaccumulating, in plants, wildlife, and soils.[56] For humans, the pathways to PFAS exposure are numerous, including via consumer products, contaminated air or drinking water, or food grown in PFAS-contaminated soil, also referred to as dietary exposure.[57] PFAS chemicals' persistence in the

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[54] U.S. Food and Drug Administration, Per- and Polyfluoroalkyl Substances (PFAS) (Apr. 29, 2024), https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas.

[55] *Per- and Polyfluoroalkyl Substances (PFAS) and Your Health: How can I be exposed?*, Agency For Toxic Substances And Disease Registry (ATSDR) (last reviewed Nov. 1, 2022), https://www.atsdr.cdc.gov/pfas/health-effects/exposure.html [hereinafter *ATSDR Exposure*].

[56] U.S. Env't Prot. Agency, *Our Current Understanding of the Human Health and Environmental Risks of PFAS*, https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas [hereinafter *Our Current Understanding*]; U.S. Food and Drug Administration, *supra* n.54.

[57] *ATSDR Exposure*, *supra* n.55.

environment, along with dietary exposures due to food contact substances,[58] has resulted in 99% of Americans having certain PFAS chemicals in their blood.[59]

This exposure is harmful: Certain PFAS have been linked to adverse reproductive health effects, developmental effects in children, increased risk of certain cancers, and immunosuppression.[60] Among the thousands of chemicals in the PFAS class, PFOA and PFOS, remain two of the most studied PFAS compounds in various applications.[61] And as with other PFAS chemicals, PFOA and PFOS persist in the environment, and exposure can lead to high cholesterol, changes in liver enzymes, decreased immune response to vaccination, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and

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[58] *See* Katherine Bourzac, *Unexpected 'Forever Chemicals' Found in Food Packaging*, Scientific American (Mar. 19, 2024), https://www.scientificamerican.com/article/61-unexpected-pfas-forever-chemicals-found-in-food-packaging/.

[59] Env't Working Grp., *What Are PFAS Chemicals?,* https://www.ewg.org/pfaschemicals/what-are-forever-chemicals.html (last visited May 14, 2024); *see also Report: Up to 110 Million Americans Could Have PFAS-Contaminated Drinking Water*, Env't Working Grp. (May 22, 2018), https://www.ewg.org/research/report-110-million-americans-could-have-pfas-contaminated-drinking-water.

[60] *Our Current Understanding, supra* n.56; *see also* Economic Analysis for the Final Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation, U.S. Env't Prot. Agency, EPA-815-R-24-001, 6-27 (Apr. 2024), https://www.epa.gov/system/files/documents/2024-04/pfas-npdwr_final-rule_ea.pdf [hereinafter Economic Analysis] (noting health effects from numerous PFAS); Penelope Rice *et al.*, *Comparative analysis of the toxicological databases for 6:2 fluorotelomer alcohol (6:2 FTOH) and perfluorohexanoic acid (PFHxA)*, Food and Chemical Toxicology (Mar. 17, 2020), https://www.sciencedirect.com/science/article/pii/S027869152030137X/pdfft?md5=205a8a0a1a4dca9c29060c397408d2ba&pid=1-s2.0-S027869152030137X-main.pdf.

[61] U.S. Env't Prot. Agency, *Technical Fact Sheet—Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)* (Nov. 2017), https://19january2021snapshot.epa.gov/sites/static/files/2017-12/documents/ffrrofactsheet_contaminants_pfos_pfoa_11-20-17_508_0.pdf.

kidney for PFOA, liver and thyroid for PFOS).[62] Moreover, EPA has found PFOA and PFOS Likely to Be Carcinogenic to Humans.[63] These impacts can result from exposure to extremely low levels: any level above zero for PFOA and PFOS in drinking water, according to EPA itself,[64] posing "substantial danger to public health or welfare or the environment."[65]

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[62] 87 Fed. Reg. 54,417 (Sept. 6, 2022); PFOS (Perfluorooctane Sulfonate or Perfluorooctane Sulfonic Acid, Proposition 65: Your Right to Know(last visited May 16, 2024), https://www.p65warnings.ca.gov/fact-sheets/pfos-perfluorooctane-sulfonate-or-perfluorooctane-sulfonic-acid; *Per- and Polyfluoroalkyl Substances (PFAS) and Your Health: What are the health effects of PFAS?*, ATSDR (last reviewed Nov. 1, 2022), https://www.atsdr.cdc.gov/pfas/health-effects/index.html [hereinafter *ATSDR Health Effects*].

[63] U.S. Env't Prot. Agency, *Maximum Contaminant Level Goals for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water* (Apr. 2024), https://www.epa.gov/system/files/documents/2024-04/mclg-doc-for-pfoa-pfos_final-508.pdf.

[64] In June 2022, EPA released new data and draft analyses indicating that the levels at which negative health effects could occur are much lower than previously understood when EPA issued the 2016 health advisories for PFOA and PFOS (70 parts per trillion or ppt previously). *See* U.S. Env't Prot. Agency, *Drinking Water Health Advisories for PFAS* (last viewed May 16, 2024), https://www.epa.gov/system/files/documents/2022-06/drinking-water-ha-pfas-factsheet-communities.pdf. In June 2022, EPA's advisory levels were 0.004 ppt for PFOA and 0.02 ppt for PFOS. *Id.* EPA admitted that "negative health effects may occur with concentrations of PFOA or PFOS in water that are near zero and below EPA's ability to detect at this time." U.S. Env't Prot. Agency, *EPA Announces New Drinking Water Health Advisories for PFAS Chemicals, $1 Billion in Bipartisan Infrastructure Law Funding to Strengthen Health Protections* (June 15, 2022), https://www.epa.gov/newsreleases/epa-announces-new-drinking-water-health-advisories-pfas-chemicals-1-billion-bipartisan.

[65] 87 Fed. Reg. 54,417 (Sept. 6, 2022). In September 2022, EPA proposed designating these two chemicals as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) due to their "substantial danger to public health or welfare or the environment." 87 Fed. Reg. 54,417 (Sept. 6, 2022).

PFOA and PFOS exposure can also result in decreased fertility, increased risk of high blood pressure or pre-eclampsia in pregnant women, and decreased birth weight in infants.[66] Even low doses may cause developmental delays and other growth deficits, while the highest levels of exposure may be associated with birth defects and neonatal mortality.[67] Additionally, numerous studies provide evidence of associations between birth weight and/or other developmental effects and exposure to other PFAS such as PFBA, PFDA, PFHxS, PFHxA, HFPO-DA, PFNA, PFUnA, and PFBS.[68]

Numerous studies have also linked certain PFAS to increased risk of kidney, prostate, or testicular cancer, as well as increased risk of obesity, thyroid disease, liver damage, and endocrine disruption.[69] Further some PFAS can weaken the immune system, leading to reduced ability to fight off infection and decreased vaccine response.[70] Studies have shown higher mortality risk for COVID-19 in a population heavily exposed to PFAS (including PFOA, PFOS, PFHxS, PFBS, PFBA, PFPeA, PFHxA, and PFHpA) via drinking water, and other studies have indicated general immunosuppressive effects of PFBA in the lungs.[71] And EPA has also admitted PFOA, PFOS, PFNA, PFDA, and PFHxS may result in cardiovascular

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[66] *ATSDR Health Effects*, *supra* n.62.

[67] Joint Subcommittee On Environment, Innovation, And Public Health, Per- And Polyfluoroalkyl Substances Strategy Team Of The National Science And Technology Council, Per- And Polyfluoroalkyl Substances (PFAS) Report, at 33 (Mar. 14, 2023) [hereinafter White House Report].

[68] Economic Analysis, *supra* n.60.

[69] White House Report, *supra* n.67, at 32-34.

[70] *ATSDR Health Effects, supra* n.62.

[71] Economic Analysis, *supra* n.60, at 6-29.

effects, including high cholesterol, high blood pressure, and other cardiovascular disease.[72]

PFAS contamination poses similar risks to wildlife. Because PFAS can bioaccumulate in animal tissue, exposure can spread quickly between species, or "biomagnify."[73] For example, in one North Carolina river, researchers found fourteen PFAS chemicals throughout every level of the food chain, although there was no "known industrial input" of these chemicals along the river.[74] The effects of exposure to certain PFAS in both livestock and wildlife largely mirror the adverse health outcomes in humans, such as liver disease, thyroid disease, reproductive issues, and developmental barriers.[75]

Specifically, PFOS threatens avian species by significantly decreasing hatching success,[76] a significant threat considering researchers have recorded high levels of PFAS chemicals in migratory birds more than ninety miles from the

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[72] *Id.* at 6-17-18, 6-20, 6-27-28.

[73] White House Report, *supra* n.67, at 37-38.

[74] Greg Cope*, PFAS Present Throughout the Yadkin-Pee Dee River Food Chain*, NC STATE UNIVERSITY NEWS (June 5, 2020), https://news.ncsu.edu/2020/06/pfas-food-chain.

[75] *PFAS and Pets and Livestock Health*, MICHIGAN PFAS ACTION RESPONSE TEAM (last visited April 10, 2024), https://www.michigan.gov/pfasresponse/faq/categories/pfas-and-pets-and-livestock-health.

[76] Meg Sedlak et al., *San Francisco Estuary Institute, Per And Polyfluoroalkyl Substances (PFAS) in San Francisco Bay: Synthesis and Strategy*, RMP CONTRIBUTION NO. 867, at 37 (June 2018), https://www.sfei.org/sites/default/files/biblio_files/PFAS%20Synthesis%20and%20Strategy.pdf.

nearest source.[77] PFAS contamination also threatens plant species and soil health, as bioaccumulation of numerous PFAS chemicals can damage plant cell structure and disturb critical biochemical processes, such as photosynthesis and gene expression.[78] Further, some PFAS resist microbial degradation and linger in the soil, leading to a significant reduction in microbial biodiversity.[79]

It is worth noting that these myriad concerns regarding PFAS impacts are not new. For decades, scientists have raised concerns about the extensive and well-documented adverse effects of PFAS.[80] As far back as 1950, 3M's studies showed that PFAS chemicals could build up in the general public's blood.[81] And by the 1960s, 3M and DuPont's animal studies revealed that PFAS chemicals could pose health risks.[82] However, it was not until the 1990s that EPA began investigating

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[77] Univ. of R. I., *PFAS in seabirds: Narragansett Bay, Massachusetts Bay, Cape Fear*, SCIENCEDAILY (Sept. 23, 2020), https://www.sciencedaily.com/releases/2020/09/200923164617.htm.

[78] Juiyi Li et al., *Exposure routes, bioaccumulation and toxic effects of per- and polyfluoroalkyl substances (PFASs) on plants: A critical review*, 158 ENV'T INTL. 1, 11-13 (2022).

[79] Lifeng Cao et al., *Occurrence of PFASs and its effect on soil bacteria at a fire-training area using PFOS restricted aqueous film-forming*, 25 ISCIENCE (Apr. 15, 2022).

[80] Jeffrey Kluger, *Companies Knew the Dangers of PFAS 'Forever Chemicals'—and Kept Them Secret*, Time (June 1, 2023), https://time.com/6284266/pfas-forever-chemicals-manufacturers-kept-secret/.

[81] Jared Hayes, *For Decades, Polluters Knew PFAS Chemicals were dangerous but Hid Risks from Public*, EWG (Aug. 29, 2019), https://www.ewg.org/research/decades-polluters-knew-pfas-chemicals-were-dangerous-hid-risks-public.

[82] *Id.*

PFAS and the general public became aware of the health impacts PFAS pose, spurring EPA's work to reduce PFAS contamination today.[83]

II. PFAS in Pesticide Products.

PFAS presence in pesticides generally results from manufacturers introducing one or more trifluoromethyl (-CF3) group(s) in pesticides' molecular structures to boost their alleged efficacy.[84] The chemical engineering resulting in this fluorinated backbone with strong carbon-fluoride bonds, "improves both the hydrophobic (water repellent) and lipophobic (fat/oil repellent) properties of substances,[85] and therefore their stability."[86] The pesticide industry specifically lauds this latter property, as it results in longer periods of efficacy, allegedly diminishing spraying frequency. However, "stability" also equates to persistence: these chemicals linger in the environment far longer than other chemicals.

In the United States, independent testing has revealed high levels of certain PFAS chemicals in pesticides.[87] A 2022 study found seven out of ten insecticides contained PFAS chemicals, with one insecticide, Spiromesifen, containing PFOS at

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[83] U.S. Env't Prot. Agency, *Risk Management for Per and Polyfluoroalkyl Substances (PFAS) Under TSCA* (last visited May 21, 2024), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas.

[84] PAN Europe and Générations Futures, *Europe's Toxic Harvest: Unmasking PFAS Pesticides Authorized in Europe*, at 6 (Nov. 2023), https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/PFAS%20Pesticides%20report%20November%202023.pdf.

[85] *Id.*

[86] *Id.*; *see also* Wilcox, *supra* n.9.

[87] Perkins, *supra* n.8.

a level as high as 19m parts per trillion (ppt),[88] a sharp contrast to EPA's Maximum Contaminant Level Goal of zero.[89] EPA originally reported in May 2023 that it later evaluated the same ten pesticide products included in this study and found no PFAS.[90] However, internal documents revealed that EPA did find evidence of PFOS as well as other types of PFAS in the products.[91]

Other studies have found similarly high amounts of PFAS in pesticides: A May 2023 study found 510 ppt of PFOA in Malathion 5EC, an amount over 100,000 times higher than EPA's Maximum Contaminant Level for drinking water of four ppt,[92] as well as 680 ppt perfluoroheptanesulfonic acid (PFHpS).[93] The same study

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[88] Lasee, *supra* n.8.

[89] U.S. Env't Prot. Agency, *Per- and Polyfluoroalkyl Substances (PFAS): Final PFAS National Primary Drinking Water Regulation, Safe Drinking Water Act* (last viewed May 21, 2024), https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.

[90] U.S. Env't Prot. Agency, *EPA Completes Scientific Testing of Pesticide Products for PFAS* (May 30, 2023), https://www.epa.gov/pesticides/epa-completes-scientific-testing-pesticide-products-pfas#:~:text=Released%20on%20May%2030%2C%202023&text=EPA%20did%20not%20find%20any,the%20summary%20of%20its%20findings.

[91] Carey Gillam, *US regulator accused of "egregious" misconduct in PFAS testing of pesticides* (May 28, 2024), https://www.thenewlede.org/2024/05/us-regulator-accused-of-engaged-in-egregious-misconduct-in-pfas-testing-of-pesticides/; Letter from PEER to EPA (May 28, 2024), https://peer.org/wp-content/uploads/2024/05/5_28_24_Information-Quality-Act-Demand-for-Correction-final-Signed-TWSL.pdf; *see also* https://www.thenewlede.org/wp-content/uploads/2024/05/PFAS-in-pesticides-FOIA.pdf.

[92] Beyond Pesticides, *Report Adds to Evidence of Widespread PFAS Contamination Calls for Removal of Products* (May 4, 2023), https://beyondpesticides.org/dailynewsblog/2023/05/report-adds-to-evidence-of-widespread-pfas-contamination-calls-for-removal-of-products/.

[93] Eurofins Lancaster Laboratories Environment Testing LLC, Analytical Report: PFAS Pesticide Testing, Client: Biological Diversity, Job Number: 410-113812-1 (Mar. 28, 2023), https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/J113812-1-

also found 1,500 ppt perfluorobutanoic acid (PFBA) in Oberon 2SC,[94] as well as 350 ppt of perfluorobutanesulfonic acid (PFBS)[95] in Intrepid 2F, the most widely used insecticide in California, applied to over 1.3 million cumulative acres of California land per year.[96] Testing completed in 2020 also showed 250 ppt of PFOA in Anvil 10+10, sprayed on over 2.2 million acres the year prior in Massachusetts alone[97] and 3,500 ppt of PFOA in pesticide, Permanone 30-30, used statewide in Maryland for its mosquito control program.[98]

UDS-Level-2-Report-Final-Report.pdf. PFHpS can cause serious health effects, including cancer, endocrine disruption, accelerated puberty, liver and immune system damage, and thyroid changes. EWG, *Perfluoroheptane Sulfonic Acid (PFHpS), EWG's Tap Water Database—2021 Update* (last viewed May 21, 2024), https://www.ewg.org/tapwater/contaminant.php?contamcode=E312.

[94] *Id.* In laboratory animal studies, exposure to high levels of PFBA resulted in thyroid and liver effects, such as increased thyroid and liver weight, changes in thyroid hormones, decreased cholesterol, and cellular changes in both organs. Other effects of PFBA exposure included delayed development and decreased red blood cells and hemoglobin. Minnesota Dept. of Health, *Perfluorobutanoic Acid (PFBA) and Water* (Apr. 2022), https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfbainfo.pdf.

[95] Analytical Report: PFAS Pesticide Testing, *supra* n.93, at 8. EPA itself has admitted to numerous adverse health impacts of PFBS. Env't Prot. Agency, *Learn About the Human Health Toxicity Assessment for PFBS* (last visited May 21, 2024), https://www.epa.gov/chemical-research/learn-about-human-health-toxicity-assessment-pfbs.

[96] Center for Biological Diversity, *2021-top-100-pesticide-products-CA_acres-treated*, https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/2021-top-100-pesticide-products-CA_acres-treated.pdf (last visited Jun. 18, 2024).

[97] Public Employees for Environmental Responsibility, *Press Release: Aerially Sprayed Pesticide Contains PFAS* (Dec. 1, 2020), https://peer.org/aerially-sprayed-pesticide-contains-pfas/.

[98] Eurofins: Environment Testing America, Analytical Report, Client: PEER, Project/Site: Permanone 30-30, https://peer.org/wp-content/uploads/2021/03/3_24_21-Permanone-J31526-1-UDS-Level-2-Report-Final-Report.pdf.

In addition to pesticide ingredients, fluorinated HDPE containers used for storage contaminate pesticides with PFAS.[99] EPA has found eight different PFAS in HDPE containers in two separate studies, including PFOA, PFBA, PFPeA, PFHxA, PFHpA, PFNA, PFDA, and PFUdA.[100] These containers can also leach hexafluoropropylene oxide dimer acid, a replacement for PFOA.[101] EPA has concluded that, while PFAS were not intentionally added to the HDPE containers, the fluorination process produced PFAS[102]—the same process commonly used to treat polypropylene containers.[103]

As a result, the agricultural application of pesticides containing PFAS not only increases the risk of bioaccumulation in the crops and the soil and, in turn, dietary exposure for the public and wildlife, but also further contaminates the environment through aerial drift and runoff. The half-life of some fluorinated pesticides can reach up to *two years* for certain premium products, while EPA

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[99] Dawson, *supra* n.5, at 16, 19.

[100] Thuy Nguyen, U.S. Env't Prot. Agency, *Memorandum: EPA's Analytical Chemistry Branch PFAS Testing Rinses from Selected Fluorinated and Non-Fluorinated HDPE Containers* (Mar. 4, 2021), https://www.epa.gov/sites/default/files/2021-03/documents/results-of-rinsates-samples_03042021.pdf; Thuy Nguyen, *Memorandum: Results of EPA's Analytical Chemistry Branch Laboratory Study of PFAS Leaching from Fluorinated HDPE Containers* (Aug. 12, 2022), https://www.epa.gov/system/files/documents/2022-09/EPA%20PFAS%20Container%20Leaching%20Study%2008122022_0.pdf.

[101] PEER, *supra* n.97.

[102] *See* Env't Prot. Agency, Press Release: EPA Takes Action to Investigate PFAS Contamination (Jan. 14, 2021), https://www.epa.gov/newsreleases/epa-takes-action-investigate-pfas-contamination [hereinafter January 2021 EPA Press Release].

[103] BERLIN PACKAGING, *supra* n.6; Neltner, *supra* n.6.

defines pollutants with a half-life of only sixty days or more as "persistent."[104] PFAS-polluted groundwater can then travel far from the original application site, and contaminate soils long after application.[105] These attributes create massive potential to damage ecosystems as a result of recognized persistence, bioaccumulation potential, and ecotoxicological effects.[106] For example, a study found correlation between the bioaccumulation of fluorinated pesticides in honeybees and events of mass mortality of honeybee colonies in Italy.[107] There have also been examples of bioaccumulation in fish and shrimp.[108] Additionally, recent evidence of acute and chronic immunotoxicity has been reported for several

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[104] *Id.* Several recently registered fluorinated pesticides are very persistent, such as pydiflumetofen, registered in May 2018 (DT50 of 2416 days), *see* Diogo A. M. Alexandrino, et al., *Revisiting Pesticide Pollution: The Case of Fluorinated Pesticides*, 292 Env't Pollution 1, 4-5 (Jan. 1, 2022), https://www.sciencedirect.com/science/article/pii/S0269749121018972; *see also* https://www.regulations.gov/document/EPA-HQ-OPP-2015-0775-0029; bixafen registered in December 2018 (DT50 of 500 days), *see* Alexandrino, *supra* n.104, at 5; *see also* https://www.regulations.gov/document/EPA-HQ-OPP-2016-0538-0017; mefentrifluconazole registered in June 2019 (DT50 of 268 days), *see* Alexandrino, *supra* n.104, at 5; *see also* https://www.regulations.gov/document/EPA-HQ-OPP-2018-0002-0044; or fluxapyroxad registered in May 2012 (DT50 of 183 days), *see* Alexandrino, *supra* n.104, at 5; *see also* https://www.regulations.gov/document/EPA-HQ-OPP-2010-0421-0020.

[105] Sheena Scruggs, *PFAS—A Problem in North Carolina Drinking Water*, Environmental Factor, National Institute Of Environmental Health Sciences (Mar. 2019), https://factor.niehs.nih.gov/2019/3/feature/2-feature-pfas.

[106] Alexandrino, *supra* n.104.

[107] Marianna Martinello, *et al.*, *A survey from 2015 to 2019 to investigate the occurrence of pesticide residues in dead honeybees and other matrices related to honeybee mortality incidents in Italy*, 12 DIVERSITY 1, 15 (Dec. 2019), https://doi.org/10.3390/d12010015.

[108] Alexandrino, *supra* n.104, at 5.

fluorinated pesticides, including bifenthrin (included on EPA's PFAS Master List, discussed *infra*).[109]

This contamination finds its way into the food system, leading to the concerning health impacts described *supra*.[110] Multiple studies have established that crops uptake certain PFAS that the public can ingest.[111] The Food and Drug Administration began systematic testing of PFAS in food in 2019 and has detected

[109] Wilcox, *supra* n.9.

[110] Steven Lasee, et al., *The Effects of Soil Organic Carbon Content on Plant Uptake of Soil Perfluoro Alkyl Acids (PFAAs) and the Potential Regulatory Implications*, 40 Environmental Toxicology and Chemistry 832 (Mar. 2021), https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.4786; Irene Navarro, et al., *Uptake of perfluoroalkyl substances and halogenated flame retardants by crop plants grown in biosolids-amended soils*, 152 Env't Research 199 (Jan. 2017), https://www.sciencedirect.com/science/article/abs/pii/S0013935116308490.

[111] Lasee, *supra* n.110; Navarro, *supra* n.110; E. Bizkarguenaga, et al., *Uptake of perfluorooctanoic acid, perfluorooctane sulfonate and perfluorooctane sulfonamide by carrot and lettuce from compost amended soil*, Sci. Total Env't (Nov. 2016), https://www.sciencedirect.com/science/article/abs/pii/S004896971631453X?via%3Dihub; Steven Lasee, et al., *Plant uptake of PFAAs under a maximum bioavailability scenario*, Environmental Toxicology and Chemistry, at 1-6 (2019), https://setac.onlinelibrary.wiley.com/doi/full/10.1002/etc.4571; A. Blaine, et al., *Uptake of Perfluoroalkyl Acids Into Edible Crops via Land Applied Biosolids: Field and Greenhouse Studies*, 47 Env't Science and Technology (2013), https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NHEERL&dirEntryId=307369.

PFAS chemicals in fruits, vegetables, seafood, and dairy,[112] but has yet to set any limits to safeguard human health.[113]

III. EPA's Shifting PFAS Definition.

The number of pesticide ingredients classified as PFAS in the United States heavily depends on EPA's shifting definitions.[114] EPA's first working definition of PFAS appeared on its website in 2021, with no scientific antecedents or public review, and included chemicals that have "at least two adjacent carbon atoms, where one carbon is fully fluorinated and the other is at least partially fluorinated."[115] This definition included 6,504 PFAS, only half of the 12,034 PFAS listed in EPA's own Computational Toxicology database at the time.[116]

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[112] FDA, Analytical Results for PFAS in 2018-2021 Dairy Farm Sampling (Parts Per Trillion) (June 2021), https://www.fda.gov/media/127850/download?attachment; FDA, Analytical results for PFAS in 2018 Produce Sampling (Parts Per Trillion) (Oct. 2019), https://www.fda.gov/media/127848/download?attachment; FDA, Analytical Results for PFAS in 2022 Seafood Survey (Parts Per Trillion) (July 2022), https://www.fda.gov/media/159570/download?attachment.

[113] U.S. Food and Drug Administration, *supra* n.54.

[114] *See generally* EPA PFAS Working Definition Emails, https://peer.org/wp-content/uploads/2023/08/7_23_EPA_PFAS_Working_Definition_fragments.pdf.

[115] FOIA Document 1 (March 2020, internal emails reveal industry pushing for a limited definition of PFAS to protect their products); Tom Perkins, *EPA's New Definition of PFAS Could Omit Thousands of 'Forever Chemicals*, The Guardian (Aug. 18, 2023), https://www.theguardian.com/environment/2023/aug/18/epa-new-definition-pfas-forever-chemicals.

[116] Perkins, *supra* n.115; PEER, *EPA Sued Over Failure to Explain its Narrow PFAS Definition* (Apr. 28, 2022), https://peer.org/epa-sued-over-failure-to-explain-its-narrow-pfas-definition/.

Many experts described this initial definition as significantly underinclusive compared to state and international definitions.[117] It specifically excludes ultra-short-chain PFAS (C=2 or 3), despite their extremely high persistence in the environment. EPA had been advised that "the narrative that short-chain PFAS are safe is steadily repeated by the fluorochemical industry, but the narrative detracts from efforts to manage the entire PFAS class and continues the cycle of developing 'regrettable substitutions.'"[118] Nevertheless, EPA took a further step away from managing the entire PFAS class in August 2023 when it decided to define PFAS on a "case-by-case" basis during rulemakings and agency actions, instead of using one definition for all program areas.[119]

In contrast, the United State Geological Survey performance standard broadly defines PFAS as "a perfluoroalkyl substance or a polyfluoroalkyl substance with at least one fully fluorinated carbon atom"[120]; the U.S. National Defense Authorization Act (NDAA) includes the PFAS Act of 2019, defining PFAS as any compound with at least "one fully fluorinated carbon"[121]; and many states, including Colorado, Washington, Maine, Maryland, New York, and California[122] define PFAS

[117] FOIA Document 9.
[118] FOIA Document 2; *see also* FOIA Document 9.
[119] Perkins, *supra* n.116.
[120] 15 U.S.C. § 8931.
[121] H. Rep. No. 116-333 (2019).
[122] Various state statutes define PFAS as "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." *See, e.g.*, C.R.S. 25-5-1302; Rev. Code Wash. § 70A.350.010; 32 M.R.S. § 1732; Md. Environment Code Ann. § 6-1601; NY CLS ECL § 37-0101; Cal. Health & Safety Code § 109000.

as "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom."[123] This definition encompasses a broader range of compounds.

In the context of pesticide ingredients, the "one fully fluorinated carbon" definition encompasses up to 200 pesticide ingredients.[124] In Maine alone, it covers 55 active ingredients and 1400 pesticide products, which Maine will prohibit starting in 2030, following its ban on pesticides that include intentionally added PFAS and pesticides contaminated with PFAS.[125] And in Minnesota, the definition covers over ninety-one pesticide active ingredients.[126] For example, this definition covers bifenthrin,[127] a highly stable, fluorinated insecticide with a half-life ranging from 97 to 345 days,[128] and the main ingredient in over 600 pesticide formulations today.[129] In 2020, EPA concluded in its human health risk assessment that, when consumed at levels designated as safe, dietary exposure of bifenthrin was not of

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[123] *Id.*

[124] *See generally id.*

[125] EWG, *Maine data unveils troubling trend: 55 PFAS-related chemicals in over 1,400 pesticides* (June 6, 2023), https://www.ewg.org/news-insights/news-release/2023/06/maine-data-unveils-troubling-trend-55-pfas-related-chemicals; Me. Rev. Stat. Ann. Tit. 32, §1732 (5-C).

[126] Minnesota Department of Agriculture, *Active and Inert PFAS*, https://www.mda.state.mn.us/environment-sustainability/active-inert-pfas (last viewed May 22, 2024).

[127] Due to its potential health and environmental risks, bifenthrin has been banned in the European Union, while EPA has even classified it as a possible human carcinogen. *See* Danette Drew, et al., Memorandum from Health Effects Division of EPA to Pesticide Re-evaluation Division, Revised Draft Human Health Risk Assessment for Registration Review of Bifenthrin, U.S. Env't Prot. Agency, at 28 (Mar. 25, 2020), https://www.regulations.gov/document/EPA-HQ-OPP-2010-0384-0279.

[128] *Id.*; *see also* Wilcox, *supra* n.9.

[129] Wilcox, *supra* n.9.

concern,[130] yet recent testing has revealed elevated amounts of bifenthrin in numerous agricultural crops, exceeding the agency's safety levels.[131]

IV. EPA's Efforts to Address PFAS Generally.

EPA is well aware of PFAS chemicals' many risks, as its work on PFAS began six years ago following a National Leadership Summit on PFAS that brought together more than 200 federal, state, and local leaders to discuss steps to address PFAS contamination.[132] As a result of these meetings and approximately 120,000 public comments, EPA developed the 2019 PFAS Action Plan,[133] which outlined the tools EPA planned to use in addressing PFAS in drinking water, cleaning up PFAS contamination, expanding monitoring of PFAS manufacturing, increasing PFAS scientific research, and promoting effective enforcement tools.[134] Specifically, under this plan, EPA initiated the process to develop a national primary drinking water regulation for PFOA and PFOS; sought comment regarding a potential designation for PFOA, PFOS, and other PFAS chemicals as CERCLA hazardous substances and hazardous waste under RCRA; and released several assessments.[135]

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[130] Drew, *supra* n.127, at 27.

[131] Wilcox, *supra* n.9.

[132] U.S. Env't Prot. Agency, *Aggressively Addressing PFAS at EPA* (Jan. 7, 2020), https://www.epa.gov/newsreleases/aggressively-addressing-pfas-epa.

[133] *Id.*; U.S. Env't Prot. Agency, EPA's Per-and Polyfluoroalkyl Substances (PFAS) Action Plan, EPA 823R18004 (Feb. 2019), https://19january2021snapshot.epa.gov/sites/static/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.

[134] *Id.*

[135] U.S. Env't Prot. Agency, *EPA Delivers Results on PFAS Action Plan* (Jan. 19, 2021), https://www.epa.gov/newsreleases/epa-delivers-results-pfas-action-plan.

Over two years later, in October 2021, EPA continued its work to respond to PFAS chemicals' grave public health and environmental impacts through its PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, setting forth its "whole-of-agency" approach to address PFAS.[136] In the Roadmap, EPA described PFAS as an "urgent public health and environmental issue facing communities across the United States," and admitted that "the risks posed by PFAS demand that the Agency attack the problem on multiple fronts at the same time."[137] Later, EPA Administrator Regan discussed the Roadmap's purpose, stating:

> "For far too long, families across America – especially those in underserved communities – have suffered from PFAS in their water, their air, or in the land their children play on. This comprehensive, national PFAS strategy will deliver protection to people who are hurting, by advancing bold and concrete actions that address the full lifecycle of these chemicals. Let there be no doubt that EPA is listening, we have your back, and we are laser focused on protecting people from pollution and holding polluters accountable."[138]

In response to this critical issue, the Roadmap set forth timeframes for EPA actions to address PFAS under various statutory authorities including the Toxic Substances Control Act (TSCA), Resource Conservation and Recovery Act (RCRA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Safe Drinking Water Act (SDWA), Clean Water Act (CWA), and Clean Air Act (CAA), but not FIFRA. The Roadmap describes EPA's approach as centered on the following strategies: (i) consideration of the full lifecycle of PFAS; (ii) a focus

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[136] PFAS Strategic Roadmap, *supra* n.2.
[137] *Id*.
[138] U.S. Env't Prot. Agency, *supra* n.12.

on prevention of PFAS entering the environment as a "foundational step" to reducing potential risks; (iii) investment in scientific research to ensure science-based decision-making; (iv) accountability for polluters; and (v) prioritization of protecting disadvantaged communities.

Accordingly, EPA took several actions to address PFAS contamination. First, just before publishing the Roadmap in July 2020, EPA promulgated a significant new use rule (SNUR) under TSCA for long-chain perfluoroalkyl carboxylate (LCPFAC) and PFOS chemical substances.[139] This final rule required notification to EPA at least ninety days before manufacturing, importing, or processing these chemical substances for significant new uses, including (1) the manufacturing, importing, or processing of a subset of LCPFAC chemical substances for any use that was not an ongoing use as of December 31, 2015, (2) the manufacturing, importing, or processing of all other LCPFAC chemical substances for which there were no ongoing uses as of January 21, 2015, (3) the importing of a subset of LCPFAC chemicals as part of a surface coating on articles, and (4) the importing of PFOS as part of carpets.[140] The required SNUR initiated EPA's evaluation of potential risks associated with the significant new uses, such as "high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and

[139] 85 Fed. Reg. 45,109 (July 27, 2020).
[140] *Id.;* 40 C.F.R. §§ 721.10536, 721.9582.

kidney)"[141] to determine whether the "chemical presents an unreasonable risk of injury to health or the environment."[142]

Specific to fluorinated HDPE containers, in March 2022, EPA sent a letter to all fluorinated HDPE container manufacturers, informing them that the creation of incidental PFAS during the manufacturing process, or on containers to be imported, constituted a significant new use under this rule, requiring manufacturers to notify EPA. At the time, EPA already believed that "[g]iven [its] current understanding of PFAS, … PFAS are unlikely to receive a determination of 'not likely' to present an unreasonable risk."[143] And sure enough, the first evaluation EPA conducted on a significant new use of HDPE fluorinated containers found they are "highly toxic and present unreasonable risks,"[144] resulting in an EPA order to a manufacturer, Inhance, LLC, discussed *infra*, to stop manufacturing PFOA, PFNA, and PFDA produced from the fluorination of HDPE.[145]

Second, in September 2022, EPA proposed to designate PFOA and PFOS as CERCLA hazardous substances, as substantial evidence exists that they present "substantial danger … to the public health or welfare or the environment," in accordance with CERCLA section 102(a).[146] Specifically, EPA explained that PFOA and PFOS qualify as hazardous substances because they bioaccumulate, and their

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[141] 85 Fed. Reg. 45,113 (July 27, 2020).

[142] 15 U.S.C. § 2604(a)(3)(A).

[143] Framework for TSCA, *supra* n.3, at 14.

[144] EPA Orders to Inhance, *supra* n.3; *see also* Framework for TSCA, *supra* n.3, at 14.

[145] *Id.*

[146] *See* 87 Fed. Reg. 54,415-54,442 (Sept. 6, 2022).

"water-solubility allows them to migrate readily from soil to groundwater," contaminating both surface and groundwater sources of drinking water for long periods of time and threatening human health.[147] EPA further detailed human health impacts including "effects on the immune system, the cardiovascular system, human development (e.g., decreased birth weight), and cancer."[148] Thus, considering that "PFOA and PFOS are common contaminants in the environment because of their release into the environment since the 1940s and their resistance to degradation,"[149] EPA found these chemicals to meet the requirements of "hazardous substances" under CERCLA.

Third, EPA finalized a rule to require enhanced PFAS reporting to the Toxics Release Inventory under the Emergency Planning and Community Right-to-Know Act (EPCRA), designating PFAS as "chemicals of special concern" and acknowledging that PFAS are harmful, even at low levels, because of their high persistence in the human environment.[150] EPA did so out of "concern for even relatively small quantities of PFAS, and PFAS' persistence in the environment and growing evidence showing potential adverse human health effects."[151] EPA has also pledged to designate nine PFAS as "hazardous constituents" under RCRA, including

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[147] *Id*. at 54,424.

[148] *Id*.

[149] *Id*. at 54,426.

[150] Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern, Community Right-to-Know Toxic Chemical Release Reporting, 80 Fed. Reg. 74,360 (Oct. 31, 2023) (to be codified at 40 C.F.R. pt. 372).

[151] *Id*. at 74,365.

PFOA, PFOS, PFBS), HFPO–DA, PFNA, PFHxS, PFDA, PFHxA, PFBA, which would make these PFAS subject to investigation and cleanup activities at permitted hazardous waste facilities.[152]

And finally, most recently, in April 2024, EPA issued final National Primary Drinking Water Regulation for six PFAS, establishing legally enforceable Maximum Contaminant Levels (MCLs) and Maximum Contaminant Level Goals (MCLGs), for six PFAS in drinking water including PFOA, PFOS, PFHxS, PFNA, and HFPO-DA as contaminants with individual MCLs, and PFAS mixtures containing at least two or more of PFHxS, PFNA, HFPO-DA, and PFBS.[153] The MCLGs represent "the level of a contaminant in drinking water below which there is no known or expected risk to health," and the MCLs are enforceable standards for the highest level of a contaminant that is allowed in drinking water, set as close to MCLGs as feasible using the best available treatment technology.

Specifically, for PFOA and PFOS, EPA set an MCL of four parts per trillion and a Maximum Contaminant Level Goal of zero as a result of its determination that PFOS and PFOA are Likely to Be Carcinogenic to Humans.[154] Regarding

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[152] 89 Fed. Reg. 8606 (Feb. 8, 2024) (to be codified at 40 C.F.R. pts. 261 and 271).

[153] *Final PFAS National Primary Drinking Water Regulation*, *supra* n.89; U.S. Env't Prot. Agency, Maximum Contaminant Level Goals (MCLGs) for Three Individual Per- and Polyfluoroalkyl Substances (PFAS) and a Mixture of Four PFAS, EPA-815-R-24-004 (Apr. 2024), https://www.epa.gov/system/files/documents/2024-04/pfas-hi-mclg_final508.pdf (describing toxicity of numerous PFAS and impacts on human health).

[154] Maximum Contaminant Level Goals for PFOA and PFOS, *supra* n.63, at 27.

PFOA, EPA found "[t]he strongest evidence of an association between PFOA exposure and cancer in human populations is from studies of kidney cancer."[155] Under the Guidelines for Carcinogen Risk Assessment, EPA determined that PFOA is Likely to Be Carcinogenic to Humans, as a result of evidence of kidney and testicular cancer in humans and LCTs, PACTs, and hepatocellular adenomas in rats.[156] And regarding PFOS, EPA stated that the available epidemiology studies report elevated risk of liver, bladder, kidney, prostate, and breast cancers after chronic PFOS exposure in some studies from plausible epidemiological evidence alone.[157]

For PFHxS, PFNA, and HFPO-DA as contaminants with individual MCLs, and PFAS mixtures containing at least two or more of PFHxS, PFNA, HFPO-DA, and PFBS, EPA set both the MCL and MCLG at ten parts per trillion. In support, EPA described associations between PFBS exposure and thyroid, developmental, and kidney effects based on studies in animals;[158] between PFNA exposure and adverse effects on the liver, development, and reproductive and immune systems;[159] and between PFHxS exposure and reported health effects on the liver, thyroid, development, as well as potential breast cancer risk.[160]

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[155] *Id.* at 8-9; *see also Learn about the Human Health Toxicity Assessment for PFBS*, *supra* n.95.

[156] Maximum Contaminant Level Goals for PFOA and PFOS, *supra* n.63, at 12-13.

[157] *Id.* at 17.

[158] *Id.* at 2-5.

[159] *MCLGs for Three Individual Per- and Polyfluoroalkyl Substances*, *supra* n.153, at 2-8.

[160] *Id.* at 2-11.

ARGUMENT

Despite EPA's repeated acknowledgement of PFAS as hazardous chemicals and its regulatory action in other contexts, EPA has yet to address the "unreasonable" risks[161] of PFAS in pesticides under FIFRA. Instead, EPA has admitted several active and inert ingredients qualify as PFAS but has nonetheless failed to initiate any cancellation proceedings or suspensions, beyond cancelling inert ingredients no longer in use.[162] Further, EPA has failed to amend its regulations to thoroughly address these acknowledged impacts of PFAS and to prohibit fluorinated HDPE and polypropylene pesticide containers, despite repeatedly acknowledging their harms.

EPA must immediately act to cease the ongoing intentional spraying of PFAS on our nation's soils to safeguard human health and the environment as FIFRA mandates. First, EPA must cancel all active and inert ingredients in pesticides that qualify as PFAS chemicals. This reason for this is self-explanatory: FIFRA provides that cancellation is warranted when EPA finds that a registered pesticide has "unreasonable adverse effects on the environment," meaning "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[163] Considering that EPA has described the entire PFAS class as "an urgent public health and

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[161] EPA Orders to Inhance, *supra* n.3; *see also* Framework for TSCA, *supra* n.3, at 14.

[162] Dawson, *supra* n.5, at 16, 19.

[163] 7 U.S.C. § 136d(b); *id.* § 136(bb).

environmental issue"[164] and even designated PFOS and PFOA as hazardous substances that may present "substantial danger … to the public health or welfare or the environment,"[165] EPA must cancel and suspend these registrations. At a minimum, EPA must initiate special review to determine whether to cancel these registrations, as PFAS ingredients in pesticides undoubtedly "may pose a risk of serious acute injury to humans or domestic animals."[166]

Second, EPA must amend its FIFRA regulations to prohibit future registrations of pesticides with ingredients that qualify as PFAS, as any benefits from PFAS use cannot possibly outweigh the high costs. These chemicals' persistence and bioaccumulation result in numerous adverse effects on the environment, as well as human health and massive economic and societal costs, far exceeding short-term industry profits.

Third, EPA should define PFAS in its FIFRA regulations and, alternative to cancellation, amend the regulations for clarity to require consideration of PFAS chemicals' unique impacts on the environment. Specifically, EPA should define PFAS in its regulations as "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom,"[167] and require additional data and testing for persistent, bioaccumulative, and toxic chemicals in the PFAS class, as it does

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[164] PFAS Strategic Roadmap, *supra* n.2, at 5.

[165] *See* 87 Fed. Reg. 54,415-54,442 (Sept. 6, 2022).

[166] 40 C.F.R. § 154.7(a)(1).

[167] Conference Committee Report on S.F. NO. 1955, https://www.revisor.mn.gov/bills/text.php?number=SF1955&version=0&session=ls93.0&session_year=2023&session_number=0&type=ccr.

under TSCA. EPA should also amend its data requirements to include physical-chemical property testing, other testing such as environmental fate/bioaccumulation, toxicokinetic, and human health and/or environmental toxicity testing to ensure the agency has adequate information on PFAS's unique characteristics before making registration decisions.

Fourth, EPA must amend FIFRA regulations to prohibit fluorinated HDPE and polypropylene containers for pesticide storage. FIFRA mandates that EPA ensure "safe storage" of pesticides,[168] yet EPA has failed to act despite repeatedly admitting that these widely used pesticide containers leach PFAS chemicals into pesticides.

And finally, EPA must explicitly require reporting of PFAS contamination. EPA's numerous statements, assessments, and Roadmap make plain that PFAS are "toxicologically significant" contaminants, requiring mandatory reporting under FIFRA. If registrants fail to report, EPA must then issue a stop sale, use, or removal order to immediately halt the sale of adulterated pesticides, as FIFRA mandates.

I. EPA Must Cancel All Active and Inert PFAS Ingredients Currently Registered.

FIFRA prohibits the registration and use of pesticides that cause "unreasonable adverse effects on the environment."[169] As detailed *supra*, EPA

[168] 7 U.S.C. 136q(e)(1)(A).
[169] *Id*. § 136a(c)(5)(C).

possesses a mountain of evidence demonstrating that PFAS ingredients have caused and continue to cause unreasonable risk to humans and the environment, and furthermore, that the benefits of their continued use do not outweigh the costs. These ongoing harms present an imminent hazard, which EPA itself has found necessary to address in all other contexts yet has failed to address under FIFRA. As a result, and pursuant to its obligations under FIFRA, EPA must now cancel all registrations of pesticides with ingredients that qualify as PFAS and suspend all registrations pending completion of cancellation proceedings.

A. EPA Admits Numerous Active Ingredients Qualify as PFAS.

EPA itself has repeatedly acknowledged that at least several active ingredients qualify as PFAS, though the exact number depends on EPA's repeatedly shifting definition explained *supra*.[170] However, even under its own narrow definition from 2021, EPA admitted at least four active ingredients qualify as PFAS, with its Master List including lufenuron, novifluron, tetraconazole, and pyrifluquinazon as PFAS.[171] And just last April, EPA again confirmed that four

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[170] Documents obtained through FOIA may shed light on this narrow definition. In March 2020, internal emails show industry pressuring state regulators for a limited definition of PFAS to protect their products. *See* FOIA Document 1. And July 2020 internal EPA emails debate including short-chained PFAS in the definition because "the narrative that short-chain PFAS are safe is steadily repeated by the fluorochemical industry, but the narrative detracts from efforts to manage the entire PFAS class and continues the cycle of developing 'regrettable substitutions." FOIA Document 2.

[171] FOIA Document 3; *see also* Wilcox, *supra* n.9. However, it should be noted that just months later in March 2021, EPA boldly claimed no active pesticide ingredients qualified as PFAS. Internal emails from around this time explained this stark contradiction by stating: "Each pesticide product submitted for registration is

active ingredients qualify as PFAS: broflanilide, pyrifluquinazon, tetraconazole, and hexaflumuron.[172] In fact, despite its 2019 Action Plan, EPA's most recent registration of an active PFAS ingredient occurred on January 14, 2021, when EPA unconditionally registered broflanilide, despite the chemical plainly qualifying as PFAS under the definition of "a perfluoroalkyl substance or a polyfluoroalkyl substance with at least one fully fluorinated carbon atom,"[173] and EPA itself classifying it as a PFAS.[174] EPA even proposed new uses for broflanilide in April 2022, following its more recent Roadmap.[175]

Yet far beyond the four active ingredients EPA listed, state-based estimates suggest the number of PFAS active ingredients remains in the hundreds. Under the USGS's definition of "fully fluorinated carbon," 15 U.S.C. § 8931(2)(B), which informed Minnesota's definition of PFAS as "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom,"[176] ninety-one pesticide active

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evaluated considering all the ingredients in the product, including both active and inert ingredients. Pesticide active ingredients on the list are included because they have small subcultural elements similar to those of the substructures that informed the creation of the PFAS Master List. Pesticides that have small PFAS substituents could produce PFAS through various processes. However, current registered pesticides do not contain ingredients that have structures or properties comparable to prominent PFAS."

[172] Dawson, *supra* n.5.

[173] Notice of Pesticide Registration, *supra* n.4 (unconditional registration of broflanilide by EPA).

[174] Dawson, *supra* n.5.

[175] *See* 87 Fed. Reg. 24,556 (Apr. 26, 2022).

[176] Minnesota Department of Agriculture, *supra* n.126.

ingredients qualified as PFAS as of February 2024 in Minnesota alone.[177] And in Maine, this definition covers 55 active ingredients and 1400 pesticide products.[178]

B. EPA Has Admitted Several Inert Ingredients Qualify as PFAS.

Evidence also suggests that currently registered inert ingredients in pesticides qualify as PFAS. In March 2023, testing commissioned by the Center for Biological Diversity found PFAS in three out of seven agricultural pesticides tested, two of which, PFBS and PFHpS, are not known to leach from fluorinated containers.[179] Specifically, Oberon 2SC was found to contain 1,500 ppt perfluorobutanoic acid (PFBA), while Intrepid 2F—the most widely-used insecticide product in California—had 350 ppt of perfluorobutanesulfonic acid (PFBS).[180] Further, recent research from the United States Department of Agriculture (USDA) indicates inert PFAS ingredients in pesticides: Having detected PFAS in plants grown in their research laboratory greenhouse, the USDA carried out further

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[177] *Id*.

[178] Amarelo, *supra* n.10; *see also* https://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP1501&item=4&snum=130; https://www.mainelegislature.org/legis/statutes/32/title32sec1732.html#:~:text=5%2DA.,one%20fully%20fluorinated%20carbon%20atom.

[179] Although not as clearly from inert ingredients, the study also found Malathion 5EC to contain 510 parts-per-trillion (ppt) PFOA, a level over 100,000 times higher than the level EPA considers safe in drinking water (0.004 ppt).

[180] Over 1.7 million pounds of Intrepid 2F were applied on 1.3 million acres of California land in 2021. Over 22,000 pounds of Oberon 2SC and over 15,000 pounds of Malathion were also applied. These pesticides are used most heavily in California's Central Valley, which also has elevated levels of PFAS in drinking water. *See, e.g.*, Jeremy Tanner, *Map: Fresno Among U.S. Cities with High Levels of 'Forever Chemicals' in Tap Water*, YourCentralValley.com (Aug. 26, 2023), https://www.yourcentralvalley.com/news/u-s-world/map-fresno-among-u-s-cities-with-high-levels-of-forever-chemicals-in-tap-water/.

analysis for PFAS in the potting soil, water, fertilizer, insecticides, and other plants and found the source of PFAS contamination to be the insecticides used on the soil, which did not have PFAS as active ingredients.[181]

In April 2023, EPA also confirmed that at least two inert ingredients currently registered qualify as PFAS.[182] But EPA's only actions to address this issue consisted of a December 2022 notice, announcing the removal of twelve inert ingredients from EPA's list of approved ingredients, and a February 2024 notice proposing removal of one other, despite the fact that none of these inert ingredients were still in use.[183]

C. EPA Must Cancel Active and Inert Ingredients in the PFAS Class Due to Unreasonable Risks to Human Health and the Environment in Violation of FIFRA.

Cancellation is warranted when EPA finds that when "used in accordance with widespread and commonly recognized practice," a registered pesticide has "unreasonable adverse effects on the environment," that is "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[184] Here, EPA must cancel all registrations of PFAS active and inert ingredients because the uses for which they are approved continue causing unreasonable risk to humans, the environment, and endangered and threatened species. Stated another way, how

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[181] Lasee, *supra* n.8.
[182] Dawson, *supra* n.5.
[183] 87 Fed. Reg. 76,488 (Dec. 14, 2022); 89 Fed. Reg. 14,646 (Feb. 28, 2024).
[184] 7 U.S.C. § 136d(b); *Id.* § 136(bb).

PFAS are "used in accordance with widespread and commonly recognized practice,"[185] continues causing unreasonable risk to humans, the environment, and endangered and threatened species.

The continued use of PFAS ingredients actively endangers human health. As described *supra*, the medical scientific community, not to mention EPA itself, overwhelmingly agrees that certain PFAS causes numerous adverse human health impacts, including associations with testicular and kidney cancers, reproductive disorders, thyroid disease, high cholesterol levels, reduced immune response, and in-creased susceptibility to COVID-19.[186] EPA has characterized the entire PFAS class as "an urgent public health and environmental issue"[187] and even designed PFOS and PFOA as hazardous substances that may present "substantial danger to the public health or welfare or the environment."[188]

EPA has previously cancelled other pesticide ingredients for similar reasons. For instance, EPA cancelled the registration of carbofuran in 2009 because of "unacceptable" ecological, dietary, and worker risks posing "unreasonable adverse effects."[189] Likewise, in 2012, EPA cancelled the registration of methyl iodide after a petition prompted EPA and the producer, Arysta, to take a second look at the

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[185] *Id*. § 136a(c)(5)(D).
[186] Wilcox, *supra* n.9.
[187] PFAS Strategic Roadmap, *supra* n.2, at 5.
[188] 87 Fed. Reg. 54,415-54,442 (Sept. 6, 2022).
[189] U.S. Env't Prot. Agency, Carbofuran Cancellation Process, Pesticides: Reregistration, https://archive.epa.gov/pesticides/reregistration/web/html/carbofuran_noic.html.

unreasonable risks of the product.[190] Methyl iodide, too, has strong links to cancer, reproductive complications like late-term miscarriages, and neurological disorders, its toxicity far greater than EPA recognized when it initially registered the product in 2007.[191]

Further, the harms associated with PFAS ingredients' registered uses are by no means limited to humans, and EPA admitted as much when it acknowledged the ecological risks in other contexts. PFAS can enter the environment through production or waste streams and persist, causing adverse reproductive, developmental, and immunological effects in animals as well.[192] Specifically, EPA itself has explained that PFOA and PFOS are hazardous due to bioaccumulation and their water-solubility, which allows them to easily move from soil to water, contaminating both surface and groundwater for long periods of time.[193]

Most concerning, however, is the danger certain PFAS pose to federally protected endangered and threatened species. A literature review[194] of 220 peer-reviewed studies documenting PFAS contamination in wildlife found levels of

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[190] Beyond Pesticides, *Methyl Iodide Uses To Formally End in the U.S.*, Daily News Blog (Nov. 28, 2012), https://beyondpesticides.org/dailynewsblog/2012/11/methyl-iodide-uses-to-formally-end-in-the-us/.

[191] *Id.*

[192] U.S. Env't Prot. Agency, *Understanding PFAS in the Environment* (Dec. 21, 2018), https://www.epa.gov/sciencematters/understanding-pfas-environment#:~:text=PFAS%20can%20enter%20the%20environment,effects%20in%20animals%20and%20humans.

[193] 87 Fed. Reg. 54,424 (Sept. 6, 2022).

[194] Env't Working Group, *Global danger: Wildlife at risk from PFAS exposure*, https://www.ewg.org/interactive-maps/pfas_in_wildlife/map/.

several PFAS, including PFOS and PFOA, present in numerous endangered and threatened species, including the West Indian manatee,[195] Hawksbill turtle,[196] leatherback sea turtle,[197] Florida manatee,[198] Kemp's ridley sea turtle,[199] green sea turtle,[200] and Southern Resident Killer Whales.[201] Paired with the myriad of information on harms to wildlife more generally, described *supra*, these findings indicate grave concerns for listed species.

Petitioners believe that the facts pertinent to balancing the risks and benefits of PFAS active ingredients are peculiarly within the knowledge of the EPA, and thus the burden should not fall to Petitioners to conduct such balancing test in order to prove cancellation is warranted.[202] Nevertheless, Petitioners do so based on

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[195] Kady Palmer, et al., *Per- and polyfluoroalkyl substances (PFAS) in plasma of the West Indian manatee (Trichechus manatus*), 140 MARINE POLLUTION BULLETIN 610 (Mar. 2019), https://pubmed.ncbi.nlm.nih.gov/30803684/.

[196] Jennifer M. Keller, et al., *Perfluoroalkyl Contaminants in Plasma of Five Sea Turtle Species: Comparisons in Concentration and Potential Health Risks*, 31 ENV'T TOXICOLOGY AND CHEMISTRY 1223 (Jun. 2012), https://setac.onlinelibrary.wiley.com/doi/10.1002/etc.1818.

[197] *Id.*

[198] Emily K. Griffin, *Evaluation of Different Extraction Methods for the Analysis of Per- and Polyfluoroalkyl Substances in Dried Blood Spots from the Florida Manatee (Trichechus manatus),* 40 ENV'T TOXICOLOGY AND CHEMISTRY 2726, (Oct. 2021), https://pubmed.ncbi.nlm.nih.gov/34293220/.

[199] Keller, *supra* n.196.

[200] *Id.*

[201] Kiah Lee et al., *Emerging Contaminants and New POPs (PFAS and HBCDD) in Endangered Southern Resident and Bigg's (Transient) Killer Whales (Orcinus orca): In Utero Maternal Transfer and Pollution Management Implications*, 57 ENV'T SCIENCE TECHNOLOGY 360 (Dec. 2022), https://pubs.acs.org/doi/10.1021/acs.est.2c04126.

[202] "[T]he ordinary rule, based on considerations of fairness, does not place the burden upon a litigant of establishing facts peculiarly within the knowledge of his adversary." *Ellis v. Housenger,* 252 F. Supp. 3d 800, 809 n.7 (N.D. Cal. 2017) (citing *Campbell v. United States*, 365 U.S. 85, 96 (1961)).

the evidence before them in an attempt to demonstrate the impossibility of EPA concluding the purported benefits of PFAS active ingredients outweigh the risks. The costs resulting from PFAS use, described further *infra*, are numerous and significant and cannot be outweighed by the putative benefits of continued use.[203] For example, regarding broflanilide, EPA's registration decision offers insight into what the agency views as its benefits: namely a benefit for popcorn and sweet corn growers only, as they do not rely on Bacillus thuringiensis (Bt) traited varieties for production.[204] EPA also noted broflanilide's benefit of providing yet another pesticide for growers to use in their rotations.[205] However, these two factors are more than counterbalanced by the costs just discussed. While broflanilide may provide an additional tool, the negative human health and ecological impacts of continued PFAS contamination far outweighs its minor benefits.

So, while Petitioners fail to see how PFAS active ingredients offer any durable benefits, even if EPA concludes *some* benefits exist, such benefits simply cannot outweigh the laundry list of costs and irreparable environmental and public health harm EPA has already recognized from PFAS contamination. Cancellation of all PFAS ingredient registrations is not only warranted but absolutely critical to

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[203] *See also* Public Employees for Environmental Responsibility et al., *Petition for Rulemaking to Amend EPA's 1984 Pesticide Regulation that Waived Efficacy Data Requirements* (2023).

[204] Env't Prot. Agency, *Registration Decision for the New Active Ingredient Broflanilide* (Jan. 13, 2021), https://www.regulations.gov/document/EPA-HQ-OPP-2018-0053-0050.

[205] *Id.*

safeguard the public, farmers, farmworkers, children, the environment, and imperiled wildlife.

D. Immediate Suspension of PFAS Ingredient Registrations Pending Cancellation Is Necessary to Prevent an Imminent Hazard.

Because cancellation takes time, EPA may suspend the registration of a pesticide immediately if it finds it necessary "to prevent an imminent hazard during the time required for cancellation."[206] An imminent hazard exists if during the time required for cancellation the continued use of a pesticide would (1) "be likely to result in unreasonable adverse effects on the environment" or (2) "involve unreasonable hazard to the survival of a species declared endangered or threatened" by the Endangered Species Act (ESA).[207] "[C]ancellation ... proceedings may take one or two years to complete."[208] Courts have explained that an "'imminent hazard' is not limited to a concept of crisis[.]"[209] Rather, "[i]t is enough if there is substantial likelihood that serious harm will be experienced during the year or two required.'"[210]

As is laid out in great detail *supra*, the continued registration and use of PFAS ingredients in pesticide products continues resulting in unreasonable adverse effects on the environment and likely presents an unreasonable hazard to the

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[206] 7 U.S.C. § 136d(c)(1).

[207] *Id.* § 136(l).

[208] *Ellis*, 252 F. Supp. 3d at 806 (citing *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988), cert. denied, 490 U.S. 1035 (1989)).

[209] *Env't Def. Fund v. EPA*, 510 F.2d 1292, 1297 (D.C. Cir. 1975) (citing *Env't Def. Fund v. EPA*, 465 F.2d 528, 540 (D.C. Cir. 1972)).

[210] *Id.*

survival of hundreds of endangered and threatened species. These harms are occurring now and will continue to occur during the one to two years it will take EPA to complete cancellation proceedings for PFAS ingredient registrations. Thus, it is well within EPA's authority to take action and suspend PFAS ingredient registrations, and Petitioners urge EPA to do so.

1. Continued Use of PFAS Ingredients During Cancellation Proceedings Is Likely to Result in Unreasonable Adverse Effects on the Environment.

As is detailed *supra*, the currently approved uses of PFAS are causing unreasonable adverse effects on the environment, including "unreasonable risk to man [and] the environment," and these effects, coupled with the costs of PFAS chemicals' continued use, heavily outweigh any benefit the PFAS ingredients offer. Extensive research demonstrates that PFAS are harmful to human health even at minuscule concentrations.[211] EPA itself has categorized certain PFAS as "hazardous" due to "effects on the immune system, the cardiovascular system, development (e.g., decreased birth weight), and cancer."[212] These unreasonable adverse effects are happening *now*. PFAS ingredients continue leaching through soil

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[211] Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting, 80 Fed. Reg. 74,360 (Oct. 31, 2023) (to be codified at 40 C.F.R. pt. 372) (acknowledging that PFAS are harmful, even at low levels, because of their high persistence in the human environment).

[212] *Id.;* U.S. Env't Prot. Agency, *Technical Fact Sheet: Drinking Water Health Advisories for Four PFAS* (PFOA, PFOS, GenX chemicals, and PFBS), June 2022, https://www.epa.gov/system/files/documents/2022-06/technical-factsheet-four-PFAS.pdf.

into groundwater, the public continues consuming PFAS-contaminated foods, and PFAS chemicals continue impacting both human health and the health of wildlife.

While some PFAS impacts take time to manifest (e.g., cancer), the PFAS applications that are linked to cancer are occurring and will continue to frequently occur during the time required for cancellation if EPA does not suspend registrations. Preventing 1-2 years of further contamination of soils, food, and drinking water may very well prevent an eventual diagnosis, safeguard a vulnerable child from an impaired immune system, and may mean the difference between a family being able to have a child or not. Petitioners urge EPA to safeguard public health now and not delay action any further.

2. Continued Use of PFAS Will Involve Unreasonable Hazard to the Survival of Endangered or Threatened Species.

FIFRA does not define unreasonable hazard, and no court has clearly interpreted the meaning of the phrase to date. Thus, Petitioners reasonably interpret the phrase based on its plain language and the Northern District of California's discussion of the standard in *Ellis v. Housenger*,[213] to mean when the survival of an endangered or threatened species will be directly or indirectly threatened.

The facts pertinent to any effects certain PFAS might have on endangered or threatened species are peculiarly within the knowledge of the EPA and other expert

[213] *See Ellis,* 252 F. Supp. 3d at 809 n.6 (detailing that a claim of unreasonable hazard alone is insufficient and that the failure to "cite to a study or article" to show an unreasonable hazard to the survival of an endangered or threatened species renders such showing invalid).

agencies, and thus Petitioners alone should not bear the burden of proving the reality of unreasonable hazard.[214] Nevertheless, Petitioners note that a myriad of studies have found harm to wildlife from PFAS contamination.[215] And as described *supra*, numerous endangered species have been found with certain PFAS in them,[216] including the West Indian manatee,[217] Hawksbill turtle,[218] leatherback sea turtle,[219] Florida manatee,[220] Kemp's ridley sea turtle,[221] green sea turtle,[222] and Southern Resident Killer Whales.[223]

Only formal consultation will confirm whether the potential adverse effects are likely to jeopardize the continued existence of a species or destroy or adversely modify critical habitat. However, as is noted *supra*, many of these determinations are supported by strong evidence, providing no doubt that an imminent hazard exists. Ongoing unreasonable adverse effects on the environment undeniably exist. And all evidence to date points to an unreasonable hazard to the survival of likely hundreds or thousands of endangered and threatened species. EPA should accordingly suspend the registration of all PFAS ingredient registrations pending

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[214] *Id.* at 809 n.7 (N.D. Cal. 2017) (citing *Campbell v. United States*, 365 U.S. 85, 96 (1961) ("[T]he ordinary rule, based on considerations of fairness, does not place the burden upon a litigant of establishing facts peculiarly within the knowledge of his adversary.").

[215] *See supra* n.73-n.75 and accompanying text.

[216] *See supra* n.194-n.201 and accompanying text.

[217] *Palmer, supra* n.195.

[218] Keller, *supra* n.196.

[219] *Id.*

[220] *Griffin, supra* n.198.

[221] *Keller, supra* n.196.

[222] *Id.*

[223] *Lee, supra* n.201.

cancellation to safeguard human health, the environment, and threatened and endangered species.

E. EPA Must, at a Minimum, Initiate a Special Review.

Finally, if EPA is not convinced by the wealth of its own research recounted *supra* detailing PFAS chemicals' dangers, Petitioners implore EPA to initiate a special review and undertake its own evaluation of PFAS ingredients' effects on the environment. The purpose of Special Review is "to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment."[224] Special review is warranted for the foregoing reasons:[225]

> (a) The Administrator may conduct a Special Review of a pesticide use if he determines. . .that the use of the pesticide. . .:
>
> (1) May pose a risk of serious acute injury to humans or domestic animals.
>
> (2) May pose a risk of inducing in humans an oncogenic, heritable genetic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect, which risk is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk, based upon:
>
> (i) Effects demonstrated in humans or experimental animals.
>
> (ii) Known or predicted levels of exposure of various groups of humans.
>
> (iii) The use of appropriate methods of evaluating data and relating such data to human risk.
>
> (3) May result in residues in the environment of nontarget organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms, or at levels which produce adverse reproductive

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[224] 40 C.F.R. § 154.1.

[225] As is noted *supra*, "[t]he Administrator may evaluate a pesticide use under the criteria of § 154.7 either on his own initiative, *or at the suggestion of any interested person*." 40 C.F.R. § 154.10 (emphasis added).

effects in such organisms, as determined from tests conducted on representative species or from other appropriate data.

(4) May pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973, as amended.

(5) May result in the destruction or other adverse modification of any habitat designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act as a critical habitat for any endangered or threatened species.

(6) May otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration.

(b) In making any determination that a pesticide use satisfies one of the criteria for issuance of a Special Review specified by paragraph (a) of this section, the Administrator shall consider available evidence concerning both the adverse effect in question and the magnitude and scope of exposure of humans and nontarget organisms associated with use of the pesticide.[226]

PFAS ingredients implicate more than one of the above detailed criteria for special review; in fact, they implicate practically *all* the above criteria. First, PFAS ingredients pose a significant risk of oncogenic, teratogenic, and reproductive effects. As detailed above, exposure to certain PFAS has been linked to negative reproductive health effects, developmental effects in children, and increased cancer risks for decades. Evidence of these effects in humans has been documented using epidemiological studies, an appropriate methodology for estimating population-level exposures.[227] And these effects are severe in both "degree" and "number"—PFAS

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[226] 40 C.F.R. § 154.7.

[227] Pheruza Tarapore, *Perfluoroalkyl Chemicals and Male Reproductive Health: Do PFOA and PFOS Increase Risk For Male Infertility?*, 18 INT'L J. ENV'T RESEARCH PUBLIC HEALTH 3794, (Apr. 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8038605/; Wei Wang, et al., *The Effects of Perfluoroalkyl and Polyfluoroalkyl Substances on Female Fertility: A Systematic Review and Meta-Analysis*, 216 ENV'T RESEARCH 114718 (Jan. 2023),

have impacts that long outlast their intended uses, as they do not break down in the environment, instead accumulating in soils, waterways, plants, and wildlife and creating multiple pathways to PFAS exposure. The USGS estimates that *forty five percent* of the nation's drinking water is contaminated with PFAS;[228] therefore, the "number of humans at some risk" from PFAS exposure is certainly a "concern" warranting Special Review.

Second, widespread data indicates that PFAS contamination does result in toxic residues in nontarget organisms and the environment. PFAS are known to bioaccumulate in flora and fauna alike because of their persistence,[229] leading to chronically toxic and reproduction-disrupting levels of PFAS in many organisms.[230] Bioaccumulation of certain PFAS at toxic levels has been demonstrated in PFAS for many aquatic species,[231] warranting Special Review.

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https://pubmed.ncbi.nlm.nih.gov/36334833/#:~:text=Conclusion%3A%20Based%20on%20the%20evidence,in%20odds%20ratio%20for%20infertility.

[228] U.S. Geological Survey, *National News Release: Tap Water Study Detects PFAS 'Forever Chemicals' Across the US* (July 2023), https://www.usgs.gov/news/national-news-release/tap-water-study-detects-pfas-forever-chemicals-across-us#:~:text=At%20least%2045%25%20of%20the,by%20the%20U.S.%20Geological%20Survey.

[229] Certain PFAS can bioaccumulate in the human body. *Our Current Understanding*, *supra* n.56.

[230] Brittany P. Rickard, et al., *Per-and Poly-Fluoroalkyl Substances (PFAS) and Female Reproductive Outcomes: PFAS Elimination, Endocrine-Mediated Effects, and Disease*, 465 TOXICOLOGY (2022), https://www.sciencedirect.com/science/article/pii/S0300483X2100353X; Wang, *supra* n.227; Tarapore, *supra* n.227.

[231] Tingting Ma, et al., *Toxicity of Per- and Polyfluoroalkyl Substances to Aquatic Vertebrates*, FRONTIERS ENV'T SCIENCE (Jan. 2023), https://www.frontiersin.org/articles/10.3389/fenvs.2023.1101100/full.

Finally, PFAS certainly pose risks to humans, the environment, and federally listed species large enough to warrant proper analysis of whether their benefits outweigh the great risks associated with their continued use in pesticide products. As discussed in detail throughout this petition, certain PFAS are associated with severe human health effects, including cancers, reproductive disorders, developmental effects in children, and immunosuppression, as well as similar harms to wildlife. These severe effects surely are of sufficient magnitude to warrant a proper cost-benefit analysis, and such stark reality should demonstrate the danger PFAS ingredients in pesticides pose and the urgency this situation necessitates.

II. FIFRA Regulations Must Prohibit PFAS Ingredients in Pesticides.

In addition to canceling and suspending existing inert and active ingredient registrations, EPA must also cease any future registrations of PFAS ingredients in pesticides. As stated *supra*, FIFRA authorizes EPA to register a pesticide only upon determining that the pesticide "will perform its intended function without unreasonable adverse effects on the environment."[232] And EPA itself has stated that, "[g]iven [its] current understanding of PFAS … some PFAS are unlikely to receive a determination of 'not likely' to present an unreasonable risk."[233] Specifically, in the FIFRA context, EPA has already eliminated PFAS inert ingredients because they are "an urgent public health and environmental issue in

[232] 7 U.S.C. § 136a(c)(5)(C).
[233] Framework for TSCA, *supra* n.3, at 14.

the United States"[234] and to "better protect human health and the environment."[235] This is unsurprising, given EPA's laundry list of human health and ecological impacts from PFAS that render PFAS an unreasonable risk nationwide, warranting prohibition under FIFRA. EPA must then stick to its statutory mandate and cease registration of any additional PFAS ingredients.

A. FIFRA Regulations Require a Ban on Further PFAS Registrations.

In registering pesticides, the core baseline statutory standard EPA applies is the "unreasonable adverse effects" standard.[236] EPA must deny applications for registration when "necessary to prevent unreasonable adverse effects on the environment."[237] FIFRA defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[238] EPA and the courts have interpreted FIFRA's "unreasonable adverse effect" standard to require EPA to conduct a cost-benefit analysis "to ensure that there is no unreasonable risk created for people or the environment from a

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[234] Pesticides: Proposed Removal of Per-and Polyfluoroalkyl Substance Chemicals From Approved Inert Ingredient List for Pesticide Products, 87 Fed. Reg. 56,051 (Sept. 13, 2022).

[235] U.S. Env't Prot. Agency, *Pesticides: Per-and Polyfluoroalkyl Substances (PFAS) in Pesticide and Other Packaging*, https://www.epa.gov/pesticides/pfas-packaging#:~:text=In%20December%202022%2C%20the%20Agency,in%20any%20registered%20pesticide%20product.

[236] 7 U.S.C. § 136(bb).

[237] *Id*. §136a(a).

[238] 7 U.S.C. §136(bb).

pesticide."[239] Thus, EPA balances the claimed benefits against the pesticide's economic, social, and environmental costs.[240] Congress anticipated that EPA's careful balancing of costs and benefits would "take every relevant factor that the [agency] can conceive of into account."[241]

Specifically, FIFRA requires that EPA assess a pesticide's persistence,[242] the core issue with PFAS.[243] And its regulations also mandate that applicants submit information specific to seven basic categories: product performance, toxicology, hazards to nontarget organisms, applicator and post-application human exposure, pesticide spray drift evaluation, environmental fate, and residue chemistry to aid

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[239] *Pollinator Stewardship Council v. U.S. Env't Prot. Agency*, 806 F.3d 520, 522-23 (9th Cir. 2015) (quoting 7 U.S.C. § 136(bb)).

[240] *See* 7 U.S.C. § 136(bb) (defining "unreasonable adverse effects on the environment" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide").

[241] S. REP. NO. 92-838, at 10 (1972), reprinted in 1972 U.S.C.C.A.N. 3,993, 4,032. Congress intended for EPA, among other relevant factors, to carefully consider "hazards to farmworkers, hazards to birds and animals and children yet unborn . . . . the need for food and clothing and forest products, forest and grassland cover to keep the rain where it falls, prevent floods, provide clear water . . . . aesthetic values, the beauty and inspiration of nature, the comfort and health of man." *Id.*

[242] FIFRA specifically mentions data on persistence, requiring EPA to make public data on pesticides' "safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism." 7 U.S.C. § 136h(d)(1).

[243] Ian T. Cousins, et al., *The High Persistence of PFAS Is Sufficient for Their Management as a Chemical Class*, 22 ENV'T SCIENCE PROCESS IMPACTS 2307 (2020), https://pubs.rsc.org/en/content/articlelanding/2020/em/d0em00355g (identifying PFAS as "the most environmentally persistent substances among organic chemicals," and connecting this persistence with increased probabilities of effects).

the agency in determining whether a product has unreasonable adverse effects on the environment.[244]

B. Researchers Have Identified Major Costs Associated with PFAS.

As discussed *supra*, PFAS contamination results in extensive environmental and human health costs, weighing against any purported benefits. PFAS chemicals' persistence and bioaccumulation lead to numerous adverse effects on the environment, as well as human health, that EPA itself has found critical to address in numerous other contexts.

However, ubiquitous exposure to PFAS chemicals also results in massive economic and societal costs, far exceeding short-term industry profits. On a global scale, the societal cost of using toxic PFAS totals about $17.5 trillion annually, from several environmental and public health impacts.[245] First, PFAS exposure results in astronomical healthcare costs. A 2024 study attributed $22.4 billion healthcare costs in the United States during 2018 to PFAS exposure,[246] while another recent

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[244] FIFRA specifically mentions data on persistence, requiring EPA to make public data on pesticides' "safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism." 7 U.S.C. § 136h(d)(1).

[245] Tom Perkins, *Societal Cost of 'Forever Chemicals' About $17.5tn Across Global Economy-Report,* The Guardian (May 12, 2023), https://www.theguardian.com/environment/2023/may/12/pfas-forever-chemicals-societal-cost-new-report; Shannon Kelleher, *Research Ramps up but PFAS Pollution Remains Tough to Tackle*, The New Lede (Jan 21, 2024), https://www.thenewlede.org/2024/01/research-ramps-up-but-pfas-pollution-remains-tough-to-tackle/.

[246] Leonardo Trasande, et al., *Chemicals Used in Plastic Materials: An Estimate of the Attributable Disease Burden and Costs in the United States*, 8 J.

study estimates as much as $62.6 billion annually,[247] considering a broad range of health consequences across the lifespan. Similarly, the Nordic Council of Ministers estimates that the direct healthcare costs from exposure to PFAS in Europe alone are €52-84 billion annually.[248] From its National Primary Drinking Water Regulations alone, EPA predicts reductions in drinking water will save $1.5 billion annually in healthcare costs due to fewer cancers, lower incidents of heart attacks and strokes, and reduced birth complications,[249] although the benefit estimates are likely greater as several health benefits could not be quantified, including developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects.[250] And these costs are not paid by the polluter; they are borne by ordinary people, health care providers, and taxpayers.

ENDOCRINE SOCIETY (Jan. 2024), https://academic.oup.com/jes/article/8/2/bvad163/7513992?login=true.

[247] Vladislav Obsekov, et al., *Leveraging Systematic Reviews to Explore Disease Burden and Costs of Per-and Polyfluoroalkyl Substance Exposures in the United States*, 15 EXPOSURE AND HEALTH 373 (2023), https://link.springer.com/article/10.1007/s12403-022-00496-y; *see also* Alissa Cordner, et al., *The True Cost of PFAS and the Benefits of Acting Now*, 55 ENV'T SCIENCE AND TECHNOLOGY 9630 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8296683/ (estimating healthcare costs of $37–59 billion annually in the United States).

[248] Gretta Goldenman, et al., *The Cost of Inaction: A Socioeconomic Analysis of Environmental and Health Impacts Linked to PFAS*, Nordic Council of Ministers, at 15 (2019), https://norden.diva-portal.org/smash/get/diva2:1295959/FULLTEXT01.pdf.

[249] U.S. Env't Prot. Agency, *Fact Sheet: PFAS National Primary Drinking Water Regulation*, at 2, https://www.epa.gov/system/files/documents/2024-04/pfas-npdwr_fact-sheet_general_4.9.24v1.pdf; *see also* U.S. Env't Prot. Agency, *Final Rule: Economic Analysis for the Final Per-and Polyfloroalkyl Substances National Primary Drinking Water Regulation*, EPA-815-R-24-001 (Apr. 2024), https://www.epa.gov/system/files/documents/2024-04/pfas-npdwr_final-rule_ea.pdf.

[250] *Id.*

Furthermore, PFAS chemicals' indirect social costs are extensive, considering lost wages, lost years of life, reduced quality of life, increased stress, anxiety, and depression, and subsequent impacts on families and communities.[251] Such social costs are more difficult to quantify, but nonetheless weigh against continued use of PFAS in pesticides.

Second, the cost of remediating PFAS contaminated sites also lies in the billions.[252] The process of determining how to clean up these sites is labor-intensive, time-consuming, and expensive: each sample test of soil and water already costs hundreds of dollars, and few remediation options exist.[253] Further, the landfilling of contaminated soil involves transportation costs, and PFAS are only sequestered for the lifespan of the landfill.[254] Just last year, an investigation revealed that Europe's 17,000 sites contaminated with PFAS cost an estimated €2000 billion.[255]

PFAS contamination also reduces property values of homes and businesses.[256] The discovery of water contamination, or even the perceived risk of

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[251] Cordner, *supra* n.247.

[252] *Id.*

[253] *Id.*

[254] *Id.*

[255] Gary Dagorn, et al., '*Forever Pollution': Explore the Map of Europe's PFAS Contamination*, LE MONDE (Feb. 23, 2023), https://www.lemonde.fr/en/les-decodeurs/article/2023/02/23/forever-pollution-explore-the-map-of-europe-s-pfas-contamination_6016905_8.html; Chem Sec, *The Top 12 PFAS Producers in the World and the Staggering Societal Costs of PFAS Pollution* (May 25, 2023), https://chemsec.org/reports/the-top-12-pfas-producers-in-the-world-and-the-staggering-societal-costs-of-pfas-pollution/.

[256] Michelle M. Marcus & Rosie Mueller, *Unregulated Contaminants in Drinking Water: Evidence from PFAS and Housing Prices*, Working Paper 31731, NATIONAL BUREAU OF ECONOMIC RESEARCH (Revised April 2024), https://www.nber.org/system/files/working_papers/w31731/w31731.pdf.

potential contamination, can depress property values and stigmatize neighborhoods, potentially leading to lower home values and blocking residents from selling properties, particularly when contamination achieves a level of public notoriety.[257]

And farms in areas with PFAS-contaminated water or soil may need to destroy harvests or products, or even to cease operation. This contamination has already happened on a major scale: Currently, PFAS have contaminated an estimated 20 million acres of U.S. cropland.[258] For example, an organic farm near Colorado's Fort Peterson Air Force Base completely ceased production after learning that its irrigation water was highly contaminated.[259] And in Maine, PFAS contamination forced more than fifty farms to pause or cease operations in 2022.[260] PFAS contamination has also harmed dairy farmers, as they have been forced to dump contaminated milk and even euthanize their herds.[261]

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[257] AEI Consultants, *PFAS and Real Estate: An In-Depth Guide*, https://aeiconsultants.com/pfas-real-estate/ (last viewed May 29, 2024); Cordner, *supra* n.247.

[258] Jared Hayes, *EWG: 'Forever Chemicals' May Taint Nearly 20 Million Cropland Acres*, Env't Working Group (Apr. 14, 2022), https://www.ewg.org/news-insights/news/2022/04/ewg-forever-chemicals-may-taint-nearly-20-million-cropland-acres.

[259] The Associated Press, *The Toxins in Peterson Air Force Base Firefighting Foam Tainted Aquifer, Lawsuit Claims*, Air Force Times (Mar. 12, 2019), https://www.airforcetimes.com/news/your-air-force/2019/03/13/toxins-used-in-peterson-air-force-base-firefighting-foam-tainted-aquifer-lawsuit-claims/; Cordner, *supra* n.247.

[260] Kirsten Lie-Nielsen, *PFAS Shut Main Farms Down. Now, Some are Rebounding*, Civil Eats (Oct. 2, 2023), https://civileats.com/2023/10/02/pfas-shut-maine-farms-down-now-some-are-rebounding/.

[261] Megan Gleason, *Battle Between New Mexico and U.S. Air Force To Track Toxic Chemicals Drags On,* SOURCE NM (Apr. 17, 2023), https://sourcenm.com/2023/04/17/battle-between-new-mexico-and-us-air-force-to-track-toxic-chemicals-drags-

Third, another high remediation cost comes from water purification, a cost estimated at €238 billion in the EU alone.[262] Specifically, EPA estimates that compliance with its final National Primary Drinking Water Regulation will cost approximately $1.5 billion annually, using granular activated carbon, anion exchange, high-pressure membrane technologies, reverse osmosis, and nanofiltration.[263] These costs often fall onto public utilities, their ratepayers, and state and local governments rather than chemical manufacturers and other responsible parties,[264] leaving vulnerable communities[265] to struggle in covering such high expenditures. And beyond the actual water treatment, communities also incur costs of testing and monitoring the contamination, informing the public, gathering information on treatment alternatives, and studying the feasibility of infrastructure investments.

In light of these costs, any benefits from PFAS ingredients cannot outweigh the risks. On a broader scale, industry only needs 8% of PFAS for "essential" purposes,[266] none of which include pesticide formulations (or, as discussed *infra*,

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on/#:~:text=Outflows%20from%20Cannon%20AFB%20contaminated,and%20cleaning%20up%20PFAS%20chemicals.

[262] *The Top 12 PFAS Producers*, *supra* n.255 ; *see also* Chem Sec, Annual Societal Costs From the Use of PFAS (May 2023), https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fchemsec.org%2Fapp%2Fuploads%2F2023%2F05%2FMay-2023-ChemSec-PFAS-costs.xlsx&wdOrigin=BROWSELINK.

[263] Fact Sheet, *supra* n.249.

[264] Cordner, *supra* n.247.

[265] *Id.*

[266] Perkins, *supra* n.245.

pesticide containers).[267] As a result, EPA must adhere to its own regulations and explicitly prohibit all active and inert ingredient registrations of PFAS in the FIFRA regulations.

III. EPA Should Amend Regulations to Specifically Require Assessment of PFAS Chemicals' Unique Impacts in Determining "Unreasonable Adverse Effects" Under FIFRA.

As an alternative to explicitly prohibiting PFAS ingredients, EPA should amend its regulations to clearly consider PFAS chemicals' unique impacts on the environment. Again, FIFRA plainly does not allow EPA to register pesticides with "unreasonable adverse effects on the environment."[268] But to properly make such a determination for PFAS chemicals with "significant health concerns, widespread environmental exposures, and environmental persistence"[269] EPA requires more comprehensive testing than FIFRA regulations currently require, due namely to PFAS's bioaccumulation potential. Even small PFAS releases into the environment over time can contribute to considerable exposure and potential risk.[270] Accordingly, as under TSCA, EPA should amend its FIFRA regulations to ensure data submitted

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[267] Ian T. Cousins et al., *The Concept of Essential Use for Determining When Uses of PFASs Can Be Phased Out*, 11 ENV'T SCIENCE PROCESSES IMPACTS (2019), https://pubs.rsc.org/en/content/articlelanding/2019/em/c9em00163h.

[268] 7 U.S.C. § 136a(c)(5)(C).

[269] U.S. Env't Prot. Agency: Office of Pollution Prevention and Toxics, *TSCA Section 5 Order for a Significant New Use of Certain Chemical Substances*, at 2 (Dec. 21, 2023), https://www.epa.gov/system/files/documents/2023-12/sn-23-0002-0004-0005_order-signature-copy_12-01-2023_marked_redacted.pdf.

[270] U.S. Env't Prot. Agency, *Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs)*, at 6 (Jun. 28, 2023), https://www.epa.gov/system/files/documents/2023-06/PFAS%20Framework_Public%20Release_6-28-23_Final_508c.pdf.

for pesticides with PFAS ingredients, inert or active, capture all effects and potential unreasonable effects on the environment.

A. EPA Has the Authority to Issue Regulations to Require Specific Long-Term Data on PFAS Ingredients' Persistence in Formulations with PFAS Ingredients.

As a threshold matter, requiring thorough evaluation of PFAS ingredients is fully within EPA's authority. FIFRA commands that EPA "shall" publish guidelines for registration support information and shall revise them from time to time,[271] and authorizes EPA to require additional data to maintain existing registrations.[272] FIFRA already mandates data on pesticides' persistence in the environment and human health impacts, and it grants EPA broad discretion in determining data requirements for pesticide registrations.[273] In line with FIFRA's safety standard, EPA possesses authority to promulgate regulations to collect data on all pesticide ingredients and pesticide formulations, as well as evaluate their impact on the environment.

B. Current Regulations Fail to Require Adequate Information on PFAS.

[271] 7 U.S.C. § 136a(c)(2)(A).
[272] *Id*. § 136a(c)(2)(B).
[273] *See id*. § 136a(c)(2).

By its plain language, FIFRA already requires that EPA assess a pesticide's persistence,[274] the core issue with PFAS.[275] Specifically, EPA's regulations mandate that applicants submit information on product chemistry, as well as information specific to seven basic categories: product performance, toxicology, hazards to nontarget organisms, applicator and post-application human exposure, pesticide spray drift evaluation, environmental fate, and residue chemistry, to aid the agency in determining whether a product has unreasonable adverse effects on the environment.[276]

But despite already requiring data on persistence, environmental fate, and human health, EPA's regulations remain insufficient to evaluate PFAS for several reasons. First, EPA itself has already recognized under TSCA that it must evaluate PFAS ingredients differently in determining if they pose "unreasonable" risks. Specifically, under TSCA EPA requires additional data and testing for persistent, bioaccumulative, and toxic (PBT) chemicals in the PFAS class to determine whether "the relevant chemical substance or significant new use presents an unreasonable

[274] FIFRA specifically mentions data on persistence, requiring EPA to make public data on pesticides' "safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism." 7 U.S.C. § 136h(d)(1).

[275] Cousins, *supra* n.243 (identifying PFAS as "the most environmentally persistent substances among organic chemicals," and connecting this persistence with increased probabilities of effects).

[276] FIFRA specifically mentions data on persistence, requiring EPA to make public data on pesticides' "safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism." 7 U.S.C. § 136h(d)(1).

risk of injury to health or the environment."[277] EPA explained in its Framework that it must evaluate PBT PFAS qualitatively due to factors associated with PBT PFAS, including the known widespread background levels of PFAS present throughout both the environment and humans, as well as the highly persistent and bioaccumulative nature of most well-studied PFAS.[278]

In other words, EPA already knows it needs to qualitatively consider the potential extent of exposures to the general population, consumers, and the environment, throughout the lifecycle of the PFAS. This differs from quantitative assessment, as quantitative assessment provides only a "snap-shot" of the exposure at one point in time and fails to accurately reflect the overall environmental and human health risks PFAS pose over time.[279] There is no reason why EPA should not require this assessment in the FIFRA context to safeguard human health and the environment, as required.

Second, relatedly, the data requirements lack sufficient requirements for applicants on PFAS ingredient persistence and the unique effects of PFAS on human health and the environment,[280] despite EPA itself specifically stating that extensive testing is necessary for the intentional release of PFAS. Just last September, EPA made plain that when the "release of the substance is essential to its use or unavoidable because of the nature of the use," it likely requires "a full

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[277] 15 U.S.C. § 2604(a)(3)(A).

[278] *Framework for TSCA New Chemicals Review of PMNs and SNUNs, supra* n.270, at 7.

[279] *Id.* at 6.

[280] *See* 40 C.F.R. § 158.630(d).

suite of testing" under TSCA for EPA to ensure no unreasonable risks.[281] This "full suite" includes physical-chemical property testing, other testing such as environmental fate/bioaccumulation, toxicokinetic, and human health and/or environmental toxicity testing.[282] EPA should clarify that FIFRA also requires this data, and EPA must review ingredient registrations with this data in mind.

And finally, EPA's regulations fail to define PFAS, allowing EPA to pick and choose which PFAS ingredients to study qualitatively and with the full suite of testing instead of providing a uniform requirement. As a result, EPA must amend the definitions in 40 C.F.R. § 158.300 to include the state-based and USGS definitions of PFAS as "a class of fluorinated organic chemicals that contain at least one fully fluorinated carbon atom."[283] While the 2019 EPA definition includes at least four active pesticide ingredients approved by EPA, this definition includes more than 200 other approved pesticide ingredients,[284] which all require extensive study to ensure no unreasonable adverse environmental effects.

In sum, considering EPA's own explanations under TSCA for intentional release of PFAS chemicals into the environment, it only follows that PFAS ingredients in pesticides sprayed nationwide also require careful assessment of the unique characteristics.[285] Both TSCA and FIFRA hold EPA to the same standard of

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[281] Framework for TSCA, *supra* n.3, at 25-26.

[282] *Id.*

[283] *See, e.g.,*15 U.S.C. § 8931(2)(A).

[284] Wilcox, *supra* n.9.

[285] This is especially true, considering EPA already considers one PFAS in pesticides "unreasonable" under this new Framework. *See infra*; *see also Framework for TSCA New Chemicals Review of PMNs and SNUNs, supra* n.270, at 9.

no "unreasonable" risks to human health or the environment. Without following EPA's own reasoning under the TSCA Framework, EPA cannot adequately determine a pesticide with PFAS ingredients poses no "unreasonable adverse effects to the environment."[286]

C. EPA's Failure to Implement Regulations to Mandate Assessment of PFAS Chemicals' Unique Impacts in Pesticides Violates the APA.

Because FIFRA requires that pesticide products meet FIFRA's safety standard, and EPA has not yet clarified that additional data requirements apply to PFAS ingredients, EPA is violating the APA. By failing to require data that adequately captures PFAS chemicals' environmental persistence and bioaccumulation, as it has in other contexts, EPA has unlawfully withheld and/or unreasonable delayed agency action required by FIFRA. Especially considering EPA acknowledges the grave harms posed by PFAS ingredients as described *supra* and its admissions that several inert and active ingredients qualify as PFAS, the agency's failure to comprehensively require and collect safety data on PFAS ingredients is unreasonable and contrary to law. EPA cannot reasonably determine that a pesticide has no unreasonable adverse effects on the environment if it does not adequately consider PFAS chemicals' persistence and bioaccumulation potential. Requirements for additional testing and data of PFAS chemicals' unique impacts would provide the required remedy.

[286] 7 U.S.C. § 136a(c)(5)(C).

IV. EPA Must Amend FIFRA Regulations to Prohibit the Use of Fluorinated HDPE and Fluorinated Polypropylene Containers.

EPA must also amend FIFRA regulations at 40 C.F.R. § 165.25 to prohibit fluorinated HDPE and polypropylene containers for pesticide storage. FIFRA mandates that EPA "shall … promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides."[287] But EPA has repeatedly admitted that the most widely used pesticide containers—fluorinated HDPE containers used for 20% of pesticide products[288]—leach PFAS into pesticides and has nonetheless failed to act. And evidence suggests fluorinated polypropylene containers may leach PFAS chemicals as well due to the similar fluorination process.[289] This cannot possibly accord with the statutory mandate for "safe storage," nor does it comport with EPA's stated intention to "leverage the full range of statutory authorities to confront the human health and ecological risks of PFAS."[290] As a result, EPA must amend its FIFRA regulations to prohibit the use of fluorinated HDPE and polypropylene containers.

A. EPA Has Identified Significant Leaching from HDPE Fluorinated Containers into Pesticides.

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[287] 7 U.S.C. § 136q(e)(1)(A).

[288] U.S. Env't Prot. Agency Office of Chemical Safety and Pollution Prevention, *News Releases from Headquarters: EPA Takes Action to Investigate PFAS Contamination* (Jan. 14, 2021), https://www.maine.gov/dacf/php/pesticides/documents2/bd_mtgs/mar21/6o-EPA-PFAS-files-combined.pdf.

[289] BERLIN PACKAGING, *supra* n.6.

[290] PFAS Strategic Roadmap, *supra* n.2, at 5.

EPA has known of the grave human health and environmental risks fluorinated HDPE containers pose for at least four years. In accordance with the December 2019 National Defense Authorization Act for Fiscal Year 2020's mandate to "publish interim guidance on the destruction and disposal of perfluoroalkyl and polyfluoroalkyl substances and materials containing perfluoroalkyl and polyfluoroalkyl substances,"[291] EPA began working on a draft guidance regarding proper disposal of fluorinated HDPE pesticide containers almost five years ago.[292] However, this guidance never made it into EPA's published guidance document[293] due to EPA's concerns that the guidance might somehow conflict with regulations under FIFRA regarding pesticide containers, although internal emails reveal internal disagreement over this issue.[294]

But later that summer in 2020, Public Employees for Environmental Responsibility (PEER) notified both EPA and the Massachusetts Department of Environmental Protection of its testing results for a handful of publicly available herbicides and insecticides, including the widely used mosquito control product Anvil 10+10, a pesticide aerially sprayed in 25 states.[295] In the course of their testing, PEER found 250 ppt of PFOA and 260-500 ppt of hexafluoropropylene oxide

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[291] 15 U.S.C. § 8961(a).

[292] FOIA Document 4.

[293] U.S. Env't Prot. Agency, *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances: Interim Guidance for Public Comment* (Dec. 18, 2020), https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf.

[294] FOIA Document 4.

[295] January 2021 EPA Press Release, *supra* n.102.

dimer acid in the pesticide, the latter of which is a replacement for PFOA, neither of which were an Anvil ingredient.[296] Later that year, in December 2020, the Massachusetts Department of Environmental Protection conducted its own testing of Anvil 10+10 and also found levels of multiple PFAS substantially exceeding the state's drinking water limits, several of which were present at 700 ppt.[297]

In October 2020, EPA submitted an information request to the manufacturer, Clarke Mosquito Control Products Inc., to gather more information about the pesticide's production and distribution.[298] EPA also began to study the fluorinated HDPE containers used to store Anvil 10+10,[299] and soon after, confirmed the presence of eight different PFAS chemicals at levels ranging from 20,000 to 50,000 ppt in the containers.[300] EPA then issued a subpoena against Inhance Technologies, LLC under TSCA on January 14, 2021 regarding the fluorination process used to treat the containers.[301]

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[296] PEER, *supra* n.97.

[297] David Abel, *Toxic "Forever Chemicals" Found in Pesticide Used on Millions of Mass. Acres When Spraying for Mosquitoes,* Boston Globe (Dec. 1, 2020), https://www.bostonglobe.com/2020/12/01/metro/toxic-forever-chemicals-found-pesticide-used-millions-mass-acres-when-spraying-mosquitos/?p1=BGSearch_Advanced_Results.

[298] January 2021 EPA Press Release, *supra* n.102.

[299] *Id*.

[300] U.S. Env't Prot. Agency, *EPA Releases Testing Data Showing PFAS Contamination from Fluorinated Containers* (March 5, 2021), https://www.epa.gov/newsreleases/epa-releases-testing-data-showing-pfas-contamination-fluorinated-containers.

[301] *Id.*; *see also EPA Takes Action to Investigate PFAS Contamination*, *supra* n.288 (naming Inhance as the company supplying containers from Anvil).

Nearly a year later, on March 16, 2022, EPA notified manufacturers, processors, distributors, users and those that dispose of fluorinated HDPE containers and similar products via an open letter that containers contaminated with certain long-chain PFAS may constitute a violation of its SNUR under TSCA, described *supra.*[302] Following that notice, the Department of Justice filed a complaint against just one company, Inhance, the manufacturer of the Anvil 10+10 containers for failure to comply with TSCA.[303]

Nearly three years later, on December 1, 2023, EPA ordered Inhance Technologies LLC, to cease manufacturing PFAS in the production of its fluorinated high-density polyethylene HDPE plastic containers because they are "highly toxic and present unreasonable risks that cannot be prevented other than through prohibition of manufacture."[304] Specifically, EPA's risk assessment noted the bioaccumulation potential of the chemicals in humans,[305] the chemicals' persistence

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[302] U.S. Env't Prot. Agency, *Press Release: EPA Continues to Take Actions to Address PFAS in Commerce* (Mar. 16, 2022), https://www.epa.gov/newsreleases/epa-continues-take-actions-address-pfas-commerce [hereinafter March 2022 EPA Press Release].

[303] U.S. Env't Prot. Agency, *Press Release: EPA Completes Scientific Testing of Pesticide Products for PFAS* (May 30, 2023), https://www.epa.gov/pesticides/epa-completes-scientific-testing-pesticide-products-pfas [hereinafter May 2023 EPA Press Release].

[304] EPA Orders to Inhance, *supra* n.3; *see also* Framework for TSCA, *supra* n.3, at 14.

[305] U.S. Env't Prot. Agency Office of Pollution Prevention and Toxics New Chemicals Division Risk assessment Branches/Industrial Chemistry Branch, *Risk Assessment of the Per-and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011*, at 15 (Nov. 30, 2023), https://www.epa.gov/system/files/documents/2023-12/11-30-23-final-clean-inhance-risk-assessment-of-9-pfas-snuns_marked_redacted.pdf.

in the environment,[306] toxicity for aquatic organisms,[307] and significant human health concerns.[308] Accordingly, EPA concluded that "all nine SNUN substances [were] persistent, bioaccumulative, and toxic."[309] However, the Fifth Circuit has since vacated that order, allowing Inhance to continue fluorinating HDPE containers for pesticide storage and for the ongoing use of these "highly toxic" containers for storage. *Inhance Technologies, L.L.C. v. EPA*, No. 23-60620, at *13 (5th Cir. 2024) ("The EPA may not contort the plain language of TSCA's Section 5 to deem a forty-year-old ongoing manufacturing process a 'significant new use' subject to the accelerated regulatory process provided by that part of the statute.").

More recently, another EPA study in September 2022 again confirmed the leaching potential of certain PFAS from HDPE containers.[310] Internal emails from April 2021 described the testing process, in which both the interior and the exterior of the container were rinsed with methanol, and the rinsates were analyzed using standard EPA methods.[311] This study confirmed that eight different PFAS in the interior walls of fluorinated HDPE containers can leach into formulated liquid products, with higher total amounts seen in products formulated in organic solvents

[306] *Id.* at 15-17.
[307] *Id.* at 18.
[308] *Id.* at 19-21.
[309] *Id.* at 30.
[310] U.S. Env't Prot. Agency, *Press Release: EPA Releases Data on Leaching of PFAS in Fluorinated Packaging* (Sept. 8, 2022), https://www.epa.gov/pesticides/epa-releases-data-leaching-pfas-fluorinated-packaging [hereinafter September 2022 EPA Press Release].
[311] FOIA Document 5.

such as methanol, compared with water-based products.[312] For both methanol- and water-based products, the study also showed continued gradual leaching of PFAS over time.[313]

And beyond HDPE containers, evidence points to PFAS leaching from fluorinated polypropylene containers as well. Each year, the fluorination of plastic is commonly used to treat hundreds of millions of HDPE *and* polypropylene containers, including large drums.[314] And this fluorination process can lead to the inadvertent creation of PFAS in both materials.[315]

Throughout the course of the agency's investigation on pesticide storage containers, EPA advised manufacturers to report PFAS contamination under FIFRA section (6)(a)(2) but noted that EPA could not mandate reporting because PFAS is only of "potential toxicological significance."[316] Around that same time, EPA also encouraged the pesticide industry to explore "alternative packaging options, like steel drums or non-fluorinated HDPE [containers]."[317]

EPA's study of pesticide containers is ongoing, and the agency claims it remains committed to using "all available regulatory and non-regulatory tools to determine the scope of this emerging issue and its potential impact on human

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[312] September 2022 EPA Press Release, *supra* n.310.

[313] *Id.*

[314] Amy A. Rand and Scott A. Mabury, *Perfluorinated Carboxylic Acids in Directly Fluorinated High-Density Polyethylene Material*, ENV'T SCIENCE AND TECHNOLOGY (2011), https://pubs.acs.org/doi/10.1021/es1043968.

[315] Neltner, *supra* n.6.

[316] FOIA Document 6; FOIA Document 7.

[317] FOIA Document 6.

health and the environment."[318] EPA has advised any company that finds PFAS in their product to "notify EPA and take action to remove the contaminated product" no later than thirty days after the PFAS chemical is discovered.[319] EPA's website currently admits that FIFRA pesticide container regulations do not specifically address the fluorination of plastic containers, despite the agency's grave concerns.[320]

B. EPA Must Use Its Authority to Ban HDPE and Polypropylene Fluorinated Containers.

Because FIFRA requires safe storage for pesticides, EPA's failure to prohibit pesticide storage in fluorinated HDPE and polypropylene containers violates FIFRA. The Fifth Circuit's decision[321] to vacate EPA's order to Inhance provides even more support for the necessity of banning these containers under FIFRA: In issuing that order, EPA itself characterized these fluorinated HDPE containers as "highly toxic" and "present[ing] *unreasonable risks*"[322] due to bioaccumulation potential in humans,[323] the chemicals' persistence in the environment,[324] toxicity for aquatic organisms,[325] and significant human health concerns.[326] FIFRA's plain language provides unequivocal authority for EPA to ban these very containers to

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[318] FOIA Document 8 at 4.
[319] *PFAS in Pesticide and Other Packaging, supra* n.235.
[320] *Id.*
[321] *Inhance Technologies, L.L.C. v. EPA*, No. 23-60620, at *13 (5th Cir. 2024).
[322] EPA Orders to Inhance, *supra* n.3 (emphasis added).
[323] *Risk Assessment of PFAS, supra* n.305, at 15.
[324] *Id*. at 15-17.
[325] *Id*. at 18.
[326] *Id*. at 19-21.

ensure "safe storage" of pesticides, not just covering Inhance's product, but all containers that leach PFAS into pesticides.

Furthermore, EPA has historically viewed its authority over "safe storage" to include preventing contamination in storage containers. Specifically, the regulations largely focus on ensuring proper rinsing so that a prior pesticide mix in the storage container does not contaminate the next pesticide.[327] It only follows then that EPA's regulations must also prevent "highly toxic" PFAS contamination from fluorinated HDPE and polypropylene containers to adequately safeguard human health and the environment; refusal to do so would constitute arbitrary and capricious agency action under the APA.

V. EPA Must Require Registrants to Report PFAS Contamination.

In addition to requiring detailed evaluations for PFAS before approving their use in pesticides and prohibiting HDPE and polypropylene fluorinated containers, EPA must also inform registrants in a guidance document that it *does* consider PFAS of "toxicological significance." EPA's numerous statements, assessments, and Roadmap make plain that PFAS are "toxicologically significant" contaminants, requiring mandatory reporting under FIFRA. After EPA informs registrants of the toxicological significance, if registrants fail to report, EPA must then issue a stop sale, use, or removal order to immediately halt the sale of adulterated pesticides, as FIFRA mandates.

[327] *See* 40 C.F.R. § 156.146.

A. FIFRA Requires Reporting of Toxicologically Significant Contaminants Such as PFAS.

FIFRA section (6)(a)(2) requires that "[i]f at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator."[328] FIFRA regulations then provide that such information includes "[d]etection of … contaminates, impurities described in § 159.179."[329] This regulation, in turn, specifies that contaminants or impurities a registrant has not previously identified as part of the pesticide product's approved composition "*must be reported* … if the contaminant or impurity is present in the product in any of the following quantities," including "[q]uantities that EPA considers, and so informs registrants, to be of toxicological significance," "[q]uantities that the registrant considers to be of toxicological significance," or "[q]uantities above a level for which the registrant has information indicating that the presence of the contaminant or impurity may pose a risk to health or the environment.[330] EPA explained that this reporting requirement exists to "ensure that the Agency is informed when registrants learn of toxicologically significant new breakdown products or when they learn of higher levels of contamination than were previously known to be associated with their pesticide products."[331]

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[328] 7 U.S.C. § 136d(a)(2).

[329] 40 C.F.R. § 159.155(a)(5).

[330] *Id*. § 159.179(b).

[331] Reporting Requirements For Risk/Benefit Information, 62 Fed. Reg. 49,370-01 (Sept. 19, 1997).

Furthermore, along with the other data applicants must submit prior to registration, applicants must also submit data on "the impurities that may be present in the product, and why they may be present."[332] This includes information about "the starting materials, technical grade of active ingredient, inert ingredients, and production or formulation process."[333] And for PFAS, which EPA must consider "toxicologically significant," applicants must include "an expanded discussion of the possible formation of the impurity and the amounts at which it might be present."[334]

B. EPA Is Aware of Widespread PFAS Contamination in Pesticides.

EPA has been aware of PFAS contamination in pesticides for years, as described *supra*. But rather than requiring registrants and applicants to report, EPA has only encouraged optional reporting. In internal March 2021 emails, EPA discussed what pesticide manufacturers should do if they find PFAS in their products, stating only that manufacturers "should" report under FIFRA section (6)(a)(2), but that EPA cannot mandate reporting because PFAS is only "of *potential* toxicological significance."[335] And EPA's current website echoes that decision: "EPA considers any level of PFAS to be potentially toxicologically significant and may trigger 159.179(b) in the Code of Federal Regulations."[336]

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[332] 40 C.F.R. § 158.340.
[333] *Id.*
[334] *Id.*
[335] FOIA Document 7.
[336] *PFAS in Pesticide and Other Packaging, supra* n.235; *see also* FOIA Document 8 (draft of earlier version of webpage).

C. EPA Must Amend Its Guidance to Clarify PFAS Contamination Is of Toxicological Significance.

EPA must clarify through a guidance document that it does consider PFAS contamination of toxicological significance, as the agency itself has repeatedly stated in other contexts that some PFAS are toxicologically significant at *any level*. EPA's regulations then plainly mandate reporting for "[q]uantities that EPA considers, and so informs registrants, to be of toxicological significance," "[q]uantities that the registrant considers to be of toxicological significance," or "[q]uantities above a level for which the registrant has information indicating that the presence of the contaminant or impurity may pose a risk to health or the environment."[337] At the very least, EPA has already provided information on its website indicating risks to human health and the environment: EPA has multiple webpages with information on the harms of PFAS.[338] As described *supra*, EPA went so far as to designate PFAS as "chemicals of special concern" out of "concern for even relatively small quantities of PFAS, and PFAS' persistence in the environment and growing evidence showing potential adverse human health effects."[339] EPA has also stated that even small releases into the environment over time can contribute to considerable exposure and potential risk due to PFAS chemicals' propensity to

[337] 40 C.F.R. § 159.179(b).
[338] *See, e.g., Our Current Understanding*, *supra* n.56.
[339] 80 Fed. Reg. 74,365 (Oct. 31, 2023).

bioaccumulate.[340] And EPA's Maximum Contaminant Level Goals for PFOS and PFOA are zero, as EPA has found no amount of exposure to the compound is safe.[341]

Further, failing to require reporting would defeat the purpose of the regulation: to "ensure that the Agency is informed when registrants … learn of higher levels of contamination than were previously known to be associated with their pesticide products."[342] EPA has announced large scale efforts to address PFAS contamination using all the tools it has at its disposal. Allowing registrants to evade this reporting requirement because EPA has only advised that PFAS are of "*potential* toxicological significance" rather than "toxicological significance" allows the widespread contamination to continue unimpeded nationwide.

D. EPA Must Act to Stop the Sale of Pesticides Contaminated with PFAS by All Means Possible, Including the Issuance of Stop Sale, Use or Removal Orders.

If a registrant fails to immediately withdraw a PFAS-contaminated pesticide, EPA should issue an order to stop the sale or use of the pesticide. FIFRA specifically renders unlawful the sale of adulterated pesticides, such as those contaminated with PFAS,[343] and provides authority for the Administrator to issue a "stop sale, use, or removal" order to any person who owns, controls, or has custody of pesticides sold in violation of FIFRA.[344] And a pesticide contaminated with PFAS undoubtedly

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[340] *Framework for TSCA New Chemicals Review of PMNs and SNUNs, supra* n.270, at 6.

[341] *See Final PFAS National Primary Drinking Water Regulation, supra* n.89.

[342] Reporting Requirements For Risk/Benefit Information, 62 Fed. Reg 49,381 (Sept. 19, 1997).

[343] 7 U.S.C. § 136j(a)(1)(E).

[344] 7 U.S.C. § 136k(a).

qualifies as "adulterated," as "its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold."[345] EPA should therefore remove these toxic and dangerous chemicals from the market, using its FIFRA authority, to safeguard human health and the environment.

VI. Any EPA Activities or Programs Regarding PFAS in Pesticides Oversight Must Comply with the ESA.

The ESA obligates federal agencies "to afford first priority to the declared national policy of saving endangered species."[346] To that end, EPA must adhere to the numerous substantive and procedural provisions designed to protect threatened and endangered species in its activities or programs to address the critical issue of PFAS in pesticides.

One such provision, section 7, requires federal agencies to "insure that any action authorized, funded, or carried out by such agency … is not likely to jeopardize the continued existence of [endangered or threatened species] or result in the destruction or adverse modification of [critical] habitat."[347] Thus, before engaging in any type of activity that may have direct or indirect effects on endangered species or critical habitat, agencies must "consult" either the Fish and Wildlife Service (FWS) or the National Marine Fisheries Service (NMFS) in order to evaluate the impact of such agency action.[348] FWS regulations implementing section §7(a)(2) state that such formal or informal consultation must be initiated whenever

[345] *Id.* § 136(c).
[346] *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 185 (1978).
[347] 16 U.S.C. § 1536(a)(2).
[348] *Id.*

an agency determines its action may affect a listed species, and that ongoing actions must be re-evaluated when species that may be affect by those actions are listed.[349]

The Act's consultation provision applies to "activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas."[350] The concept of agency action has been given broad application by the courts and agency regulations, including the promulgation of regulations, the granting of licenses, and actions directly or indirectly causing modifications to land, water, or air.[351] Other examples of activities include the creation of interim management strategies and in some cases guidelines and revised criteria.[352]

Further, section 7(a)(1) includes an affirmative grant of authority, mandating that agencies "utilize their authorities in furtherance of the purposes of this chapter by carrying out programs for the conservation of [listed] species."[353] Section 7(a)(1) imposes a judicially reviewable obligation upon all agencies to carry out programs

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[349] 50 C.F.R. §§ 402.14, 402.16.

[350] *Id*. § 402.02.

[351] *Id*.

[352] *See, e.g.*, *Env't Def. Ctr. v. Bureau of Ocean Energy Mgmt*., 36 F.4th 850 (9th Cir. 2022) (issuing guidelines for oil treatment is an action); *Pac. Rivers Council v. Thomas*, 30 F.3d 1050 (9th Cir. 1994) (revising criteria for future forest management is an action); *Lane Cnty Audubon Soc'y v. Jamison*, 958 F.2d 290 (9th Cir. 1992) (setting criteria for selection of logging land is an action).

[353] 16 U.S.C. § 1536(a)(1).

for the conservation of endangered and threatened species, prohibiting total inaction.[354]

And section 7(d) prohibits EPA from making any irretrievable and irreversible commitments of resources "which [have] the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures" deemed necessary to avoid jeopardy or adverse modification after initiating consultation.[355] While non-jeopardizing activities may proceed during consultation processes, none deemed irreversible may continue, nor those that would prevent alternatives identified during consultation.

FWS regulations under the ESA require agencies to review their action "at the earliest possible time to determine whether any action may affect listed species."[356] The threshold for the requirement to make the determination of whether a particular agency action may affect a listed species is triggered where "an endangered or threatened species may be present in the area of the proposed action."[357]

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[354] *See, e.g., Sierra Club v. Glickman,* 156 F.3d 606, 617-18 (5th Cir. 1998); *Nat'l Wildlife Fed'n v. Norton*, 332 F. Supp. 2d 170, 186 (D.D.C. 2004) (Section 7(a)(1) confers discretion, but that "discretion is not so broad as to excuse total inaction."); *Defs. of Wildlife v. Sec'y, U.S. Dep't of the Interior*, 354 F. Supp. 2d 1156, 1174 (D. Or. 2005)("[C]ompliance is not committed to agency discretion by law.").

[355] 16 U.S.C. § 1536(d).

[356] 50 C.F.R. § 402.14(a).

[357] *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1215 (9th Cir. 2004); *Pacific Rivers Council v. Thomas*, 30 F.3d 1050, 1055 (9th Cir. 1994) (agency actions 'may affect' the protected salmon where "the plans set forth criteria for harvesting resources within the salmon's habitat").

A. The ESA Applies to Agency Actions Taken Pursuant to FIFRA, and EPA Must Comply with ESA Section 7 With Regard to a Program for PFAS in Pesticides.

Accordingly, any "agency action" EPA takes with regard to PFAS in pesticides triggers section 7 consultation procedures. EPA should now, "at the earliest possible time" consult with the applicable wildlife agency to determine whether its actions regarding PFAS in pesticides may affect listed species.[358]

EPA must comply with the ESA when acting under FIFRA: "FIFRA does not exempt the EPA from complying with ESA requirements when the EPA registers pesticides. Indeed, a pesticide registration that runs against the clear mandates of the ESA will most likely cause an unreasonable adverse effect on the environment under FIFRA."[359] Rather, the ESA "applies to any pesticide that may harm endangered or threatened species or their habitats: Before registering a pesticide, EPA must consult with the statutorily specified agencies that have expertise on risks to species' survival."[360] EPA has a procedural duty to evaluate pesticide registrations' effects "in consultation with and with the assistance of" the agencies that—unlike EPA—Congress designated as having endangered species expertise any time EPA determines its actions "may affect" protected species or critical habitat.[361] "[T]he strict substantive provisions of the ESA justify *more* stringent

[358] 50 C.F.R. § 402.14(a).
[359] *Defs. of Wildlife v. EPA*, 882 F.2d 1294, 1299 (8th Cir. 1989).
[360] *Ctr. for Biological Diversity v. EPA*, 56 F.4th 55, 60 (D.C. Cir. 2022).
[361] 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b).

enforcement of its procedural requirements, because [they] are designed to ensure compliance with the substantive provisions."[362]

Under the ESA, EPA must also base its decisions on "the best scientific and commercial data available."[363] "The obvious purpose of the [best available science requirement] is to ensure that the ESA not be implemented haphazardly, on the basis of speculation or surmise."[364] A failure by the agency to utilize the best available science is arbitrary and capricious.

These consultation requirements also apply to programmatic actions under FIFRA, including a "proposed program, plan, policy, or regulation providing a framework for future proposed actions," are subject to programmatic consultation.[365] A programmatic action "approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time," and thus, "any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out."[366] Any later project-specific consultation "does not relieve the Federal agency of the requirements for considering the effects of the action or actions as a whole."[367]

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[362] *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) (emphasis in original), *abrogated on other grounds by Cottonwood Env't Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1088-89 (9th Cir. 2015).

[363] 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(g)(8) ("In formulating its Biological Opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available.").

[364] *Bennett v. Spear,* 520 U.S. 154, 176 (1997).

[365] 50 C.F.R. § 402.02 (defining "programmatic consultation").

[366] *Id.* (defining "framework programmatic action").

[367] *Id*. § 402.14(c)(4).

B. PFAS Environmental Impacts and Potential Impacts on Protected Species.

As described *supra*, the use of PFAS in pesticides sprayed nationwide makes it increasingly likely that protected species and their critical habitat may be affected by the increasing PFAS contamination in the environment. Many PFAS are persistent, bioaccumulative, and toxic, with risks to fish and wildlife. The chemicals are linked to tumors in animals, lower reproductive success in birds, and liver, kidney and immunological effects in laboratory animals. Because many PFAS bioaccumulate (get taken up in organisms) and biomagnify (increase in concentrations up the food chain), the chemicals can have impacts on fish and wildlife. For example, a recent study found the median level of total targeted PFAS in fish from rivers and streams was 9,500 nanograms per kilogram, while the median in the Great Lakes was 11,800 nanograms per kilogram.[368] As a result, the presence of PFAS in listed species such as the West Indian manatee,[369] Hawksbill turtle,[370] leatherback sea turtle,[371] Florida manatee,[372] Kemp's ridley sea turtle,[373]

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[368] Nadia Barbo, et al., *Locally Caught Freshwater Fish Across the United States are Likely a Significant Source of Exposure to PFOS and Other Perfluorinated Compounds*, 220 ENV'T RESEARCH (2023), https://www.sciencedirect.com/science/article/pii/S0013935122024926?via%3Dihub.

[369] Palmer, *supra* n.195.

[370] Keller, *supra* n.196.

[371] *Id.*

[372] Griffin, *supra* n.198.

[373] Keller, *supra* n.196.

green sea turtle,[374] and Southern Resident Killer Whales[375] indicate grave concerns for listed species from PFAS contamination.

C. ESA Conclusion and Actions Requested.

Accordingly, EPA must act as soon as possible, using the best available science, to protect endangered and threatened species by complying with the ESA, including by consulting with the appropriate wildlife agency about the impacts on protected species of EPA's oversight actions, including *inter alia* any pesticide registration or classification decisions for PFAS ingredients, as well as carrying out a program for the protection of endangered and threatened species from PFAS in pesticides. And in the meantime, EPA may not make any irretrievable and irreversible commitments of resources.

CONCLUSION

For the reasons stated herein Petitioners request that EPA cancel and suspend the registrations of any pesticide ingredients that qualify as PFAS, in addition to amending its registration regulations to explicitly prohibit PFAS in pesticides. Petitioners also request that EPA clarify in its regulations that PFAS are prohibited and change its definition of PFAS to accord with the USGS and state-based definitions of PFAS as "a class of fluorinated organic chemicals that contain at least one fully fluorinated carbon atom." Petitioners further request that EPA prohibit the use of fluorinated HDPE and polypropylene containers, which leach

[374] *Id.*
[375] Lee, *supra* n.201.

PFAS into pesticides and that EPA mandate reporting of pesticide products contaminated with PFAS. Petitioners request these changes in order for EPA to comply with its statutory duty to protect human health and the environment from the unreasonable adverse effects of pesticides.

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