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IN THE U.S. DISTRICT COURT

DISTRICT OF ARIZONA

Tucson Environmental Justice Task Force, a grassroots organization; Arno Krotzky, PhD, a German independent consultant; and The Law Office of Sandra T. Daussin, PLLC, a North Carolina law office,

Plaintiffs,

v.

U.S. Food and Drug Administration, a government agency; and Robert M. Califf, MD, as Commissioner U.S. Food and Drug Administration

Defendants.

Case No._____

COMPLAINT

JURY TRIAL DEMANDED

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Plaintiffs Tucson Environmental Justice Task Force, Arno Krotzky, PhD and The Law Office of Sandra T. Daussin, PLLC ("Plaintiffs"), by and through their counsel, hereby submit this complaint against Defendants U.S. Food and Drug Administration ("FDA") and Robert M. Califf, MD, in his official capacity as FDA Commissioner, ("Defendants") for their failure to act on Plaintiffs' citizen petition filed on November 1, 2023 under docket FDA-2023-P-4826 ("the Petition"). The Petition, which is incorporated herein by reference, requests tolerance-setting for per- and polyfluoroalkyl substances ("PFAS") in or on certain foods. This unreasonable delay action is brought pursuant to 5 U.S.C. §§ 702 and 706(1) of the Administrative Procedures Act ("APA") and the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301, et seq. Plaintiffs state and alleges the following.

TABLE OF CONTENTS

I. NATURE OF THE ACTION 3
II. APPLICABLE LAW 4
A. ELEMENTS OF AN UNREASONABLE DELAY ACTION 4
B. FDA'S STATUTORY MANDATE UNDER THE FFDCA ("THE ACT") 5
III. PARTIES 8
A. PLAINTIFFS 8
B. DEFENDANTS 10
IV. JURISDICTION AND VENUE 10
V. STATEMENT OF FACTS 11
A. BACKGROUND ON PFAS 11

a. Chemical characteristics and practical applications of PFAS 11
b. Environmental PFAS contaminates food. 12
c. PFAS are absorbed into the body and have long half-lives..... 15
B. PFAS IS NOW REGULATED BY MULTIPLE AUTHORITIES 16
C. PLAINTIFFS EJ TASK FORCE HAS STANDING..... 18
a. Plaintiff EJ Task Force has already been exposed to PFAS..... 18
b. Further harm to Plaintiff EJ Task Force caused by Defendants' delay..... 19
D. PLAINTIFF DR. KROTZKY HAS STANDING..... 19
a. Plaintiff Dr. Krotzky has already been exposed to PFAS. 19
b. Further harm to Plaintiff Dr. Krotzky caused by Defendants' delay. 21
E. PLAINTIFF LOSD HAS STANDING 22
a. Plaintiff LOSD has already been exposed to PFAS. 22
b. Further harm to Plaintiff LOSD caused by Defendants' delay. 24
VI. FDA IS NON-RESPONSIVE 24
VII. CAUSE OF ACTION - UNREASONABLE DELAY 26

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I. NATURE OF THE ACTION

1. Multiple government authorities agree, and peer-reviewed scientific studies have shown, that PFAS are toxic, pervasive in the environment, highly resistant to breakdown, and contaminate foods. The Petition requests that FDA fulfill its statutory obligations under the FFDCA ("the Act") to set tolerances for certain PFAS in specific foods so that these foods, if found contaminated, are timely removed from the

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marketplace. Plaintiffs filed the Petition over a year ago. FDA has failed to substantively respond in any way to Plaintiffs. This is well beyond the 180-day response deadline provided in FDA's own regulations. 21 CFR §§ 10.25(a)(2), 10.30(e)(2).

2. FDA's delay in acting on the Petition is arbitrary and capricious. U.S. and/or European authorities already regulate PFAS in foods and water. For example, the U.S. Environmental Protection Agency ("EPA") has set enforceable limits for certain PFAS in drinking water; FDA has addressed PFAS in bottled water, which is regulated as a food; and European authorities have already established regulatory limits for certain PFAS in or on a variety of foods. 40 CFR § 141.61(c)(2); 21 U.S.C. §349(b); *Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006*, 2023 O.J. (L. 119/103) Annex 1, § 4.2, http://data.europa.eu/eli/reg/2023/915/oj.

3. Defendants' unreasonable delay harms Plaintiffs, who already suffer from PFAS-related illnesses, and violates the Act because adulterated foods remain in the market putting public health as well as global trade at risk.

4. Plaintiffs request this Court declare Defendants' delay unreasonable and order FDA to issue a final decision on the Petition by a date certain.

II. APPLICABLE LAW

A. ELEMENTS OF AN UNREASONABLE DELAY ACTION

5. The APA empowers courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. §706(1).

6. An unreasonable delay action concerning a citizen petition will lie if the

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petition requests "a *discrete* agency action that it is *required to take"* and if the plaintiffs are harmed by the agency's delay in taking such action. *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004).

7. To determine whether an agency's delay is unreasonable, two factors the Court must consider are if the enabling statute provides an indication of speed with which it expects the agency to proceed and if the delay impacts public health. *Telecomm. Rsch. & Action Ctr. v. F.C.C.*, 750 F.2d 70, 79–80 (D.C. Cir. 1984).

8. Here, the Act is the enabling statute, and it addresses both speed and public health. The Act provides that FDA shall "promote the public health by *promptly and efficiently*" and "*in a timely manner*" by "taking appropriate action" to ensure "foods are safe." 21 U.S.C. § 393 (emphasis added). The U.S. Supreme Court has held that if there is any statutory ambiguity concerning when, how, or if a regulation is promulgated, the Court, and not the agency, must interpret the law. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2261–62 (2024). Thus, this Court is empowered to decide if FDA has been timely.

B. FDA'S STATUTORY MANDATE UNDER THE FFDCA ("THE ACT")

9. The FDA is the federal agency charged with enforcing the Act as the designee of the Secretary of Health and Human Services ("the Secretary"). 21 U.S.C. § 371(a); *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 976 (1986) citing 21 CFR § 5.10 (1986); 86 Fed. Reg. 49337 (Sept. 2, 2021).

10. Under the Act, FDA "shall" ensure that "foods are safe" in order to "protect the public health," 21 U.S.C. § 393(b)(2)(A), and "shall promulgate regulations

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limiting the quantity" of "any poisonous or deleterious substance added to any food" when such an addition cannot be avoided, *id*. § 346.[1]

11. In 1986, the U.S. Supreme Court ruled that the statutory language in 21 U.S.C. § 346 was sufficiently ambiguous that deference should be given to FDA to determine whether or not to promulgate a regulation to set tolerances. *Young*, 476 U.S. at 974–75.[2] However, the Supreme Court has overruled this so-called *Chevron* deference, wherein Courts deferred to federal agencies in matters relating to statutory interpretation and rulemaking. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.,* 467 U.S. 837 (1984), *overruled by Loper*, 144 S. Ct. 2244. Thus, because Congress has plainly stated, FDA "*shall* promulgate regulations" setting tolerances for harmful substances unavoidably present in foods "*in a timely manner*," the only discretion FDA may exercise for such chemicals is the level of tolerance to be set. *Cmty. Nutrition Inst. v. Young,* 757 F.2d 354, 358 (D.C. Cir. 1985), *rev'd*, 476 U.S. 974.

12. The tolerance, or regulated limit, is set at a level that is "necessary for the

[1] The Petition concerns PFAS which are environmental contaminants; tolerance setting for these substances is under the authority of the FDA. Tolerance setting for pesticides, which are poisonous or deleterious substances unavoidably added to foods, falls under different statues not applicable here.

[2] In *Young*, petitioners sought tolerances for aflatoxin, a harmful environmental contaminant that is unavoidably added to corn. *See Young*, 476 U.S. at 974-75. FDA set action levels, which are not enforceable, instead of promulgating tolerances. *Id*. The trial court ruled in favor of FDA, and on appeal it was held that action levels were insufficient because "[t]he language of the statute clearly requires the issuance of formal regulations or tolerances" and that FDA's only discretionary act was to determine the level of the tolerance. *See Cmty. Nutrition Inst,* 757 F.2d at 358. The U.S. Supreme Court reversed, holding "In light of § 346's inherent ambiguity, the FDA's interpretation of the provision is sufficiently rational to preclude a court from substituting its judgment for that of the FDA." *Young*, 476 U.S. at 974–75.

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protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe," 21 U.S.C. § 346, rendering the food "adulterated" pursuant to 21 U.S.C. § 342. Adulterated foods are removed from the marketplace through the enforcement efforts of FDA and the U.S. Department of Agriculture, so that the U.S. food supply is maintained safely at all times. *Pesticides*, FDA (last updated Mar. 5, 2024), https://www.fda.gov/food/chemical-contaminants-pesticides/pesticides#; *About Pesticide Tolerances*, EPA (last updated Sept. 9, 2024), https://www.epa.gov/pesticide-tolerances/about-pesticide-tolerances.

13. The Delaney Clause of the Act, 21 U.S.C. § 348(c)(3), requires a *zero-tolerance* for carcinogenic substances added to foods. 21 U.S.C. § 348 (c)(3) ("… no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.").

14. Additionally, under 21 U.S.C. § 381(e)(1) of the Act, a food intended for export is considered adulterated, or unsafe, if it does not "accord[] to the specifications of the foreign purchaser" or is "in conflict with the laws of the country to which it is intended for export."

15. Thus, the Act seeks to ensure food safety by requiring by the Secretary, through its designee FDA, to set tolerances for harmful substances unavoidably added to foods so that appropriate monitoring and enforcement can be performed. The tolerance must be set at zero for carcinogens. Further, the Act requires the tolerances are established in an efficient and in timely manner so that global trade and public health

are protected.

III. PARTIES

A. PLAINTIFFS

16. **Plaintiff Tucson Environmental Justice Task Force ("EJ Task Force")**, whose address is 1402 N Craycroft Rd. #2, Tucson, Arizona 85712, was founded and is directed by Linda Shosie (previously known as Linda Robles, hereinafter "Ms. Shosie"). The EJ Task Force is a grassroots organization whose goal is to inform the local Latino community about PFAS contamination and other toxic environmental chemicals, while pressing local, state, and national officials to remediate contaminated sites and hold companies accountable. Ms. Shosie lives in the EJ Task Force community, which is predominantly Latino, low income and disadvantaged. The EJ Task Force is an offshoot of Mothers Safe Air Safe Water Force ("MSASWF"), an Arizona non-profit organization also founded and directed by Ms. Shosie. Ms. Shosie works tirelessly with the EJ Task Force and MSASWF because many of her family members, friends, and neighbors who live in South Tucson have suffered severe, life-altering illnesses and even death due to exposure to toxic chemicals, including PFAS.

17. **Plaintiff Arno Krotzky, PhD ("Dr. Krotzky")** is an independent consultant with his address at Unter Den Linden 22, 14542 Werder, Germany. Dr. Krotzky is an executive consultant with more than thirty years in leadership, innovation, and product development with BASF, a chemical company. Dr. Krotkzy lived, worked, and travelled throughout the U.S. during his long career at BASF. Dr. Krotzky's most recent work with BASF was at their Research Triangle Park, North Carolina location.

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There he served as an executive leader for the research and development of agricultural and plant biotechnology products, and for the regulatory approval of these same products. Dr. Krotkzy was also the founder and managing director of BASF's metanomics Health GmbH in Berlin, Germany. At metanomics, Dr. Krotkzy had an instrumental role in the invention of a computational toxicology program which has now been adopted by regulatory authorities worldwide. While with BASF, Dr. Krotzky also served as a senior science advisor consultant to German Chancellor Angela Merkel on matters related to genetics and genetically modified organisms. Prior to joining BASF, Dr. Krotzky earned his PhD at ICRISAT in India, in collaboration with Philipps-University Marburg, the Max-Planck-Institute of Biochemistry, and the German Agencies for Technical Cooperation. Dr. Krotzky did a fellowship in molecular genetics at the Australian National University, in Canberra, Australia and was the Research Director and co-founder of the Plant Molecular Genetics Department at the University of Tennessee, Knoxville. Dr. Krotzky has friends and family who live in Germany, other parts of the EU, and across the U.S.

18. **Plaintiff The Law Office of Sandra T. Daussin, PLLC ("LOSD")** is a law firm duly organized and existing under the laws of North Carolina, with its principal place of business at 52 Somerleigh Way, Pittsboro, North Carolina. Sandra Daussin ("Ms. Daussin") founded LOSD in 2020 after graduating from law school. She is the sole owner and operator of LOSD. Prior to becoming an attorney, Ms. Daussin worked as a regulatory chemist for more than twenty-five years in the fields of agricultural products and environmental protection. Ms. Daussin now works full-time as

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an employee of AVA Law Group, a law firm duly organized and existing under the laws of California. Ms. Daussin appears in this matter as an attorney for AVA Law Group. AVA Law Group has a registered office at 52 Somerleigh Way, Pittsboro, North Carolina, where Ms. Daussin works. Ms. Daussin has children, grandchildren, and other friends and family who live in the U.S. and Germany.

B. DEFENDANTS

19. **Defendant FDA** is a federal government agency. Upon information and belief, FDA has its principal offices at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. The FDA acts under the authority delegated to it by Congress and is a component of the U.S. Department of Health and Human Services, a federal agency that, upon information and belief, has its headquarters in the District of Columbia. The FDA is responsible for implementing the Act, including the Act's provisions regarding the regulation of harmful food additives.

20. **Defendant Robert M. Califf, M.D. ("Dr. Califf")**, is Commissioner of FDA and, upon information and belief, has ultimate responsibility for the FDA's activities, including the matters alleged in this Complaint. Plaintiffs name Dr. Califf as a defendant in this action solely in his official capacity as FDA Commissioner.

IV. JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over this action (a) pursuant to 28 U.S.C. § 1331 because the action arises under the Constitution, laws, or treaties of the U.S.; and (b) pursuant to 28 U.S.C. § 1361 because this is an action in the nature of mandamus to compel an officer or employee of the U.S. or any agency thereof to

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perform a duty owed to Plaintiffs.

22. Venue is properly laid in this Arizona District pursuant to 28 U.S.C. § 1391(e)(1) because this is an action in which the defendants are an agency of the U.S. and an officer or employee of that agency, acting in his official capacity; Plaintiff EJ Task Force resides in this District; and no real property is involved in this action. *See supra* ¶ 16.

V. STATEMENT OF FACTS

A. BACKGROUND ON PFAS

a. Chemical characteristics and practical applications of PFAS

23. PFAS are a class of synthetic chemicals made from carbon ("C") and fluorine ("F") atoms linked together in a chain. EREF Staff, *The Science of PFAS: Finding Strength in the Single Bond*, Waste 360 (May 13, 2021), https://www.waste360.com/pfas-pfoas/the-science-of-pfas-finding-strength-in-the-single-bond. The C-F bond is one of the strongest known, making PFAS extremely resistant to breakdown and giving PFAS the apt nickname "Forever Chemicals." *Id.*

24. PFAS have a wide variety of industrial and commercial applications because they are resistant to heat, grease, water, and oil. *ATSDR Per- and Polyfluoroalkyl Substances (PFAS) and Your Health*, ATSDR CDC (Nov. 12, 2024), https://www.atsdr.cdc.gov/pfas/about/?CDC_AAref_Val=https://www.atsdr.cdc.gov/pfas/health-effects/overview.html; *Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics*, FDA (Jan. 22, 2024), https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics. Some examples are fire-

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fighting foam, non-stick cookware, waterproof clothing, stain-resistant carpeting, cosmetics, shampoos, cleaning products, and food packaging. *Id*.

25. EPA lists a total of 14,735 individual PFAS in existence. *CompTox Chemicals Dashboard: PFAS|EPA: PFAS structures in DSSTox (update Aug 2022)*, EPA, https://comptox.epa.gov/dashboard/chemical-lists/PFASSTRUCTv5. Of these 14,735, only four are individually mentioned in this Complaint. These are PFOS, PFOA, PFNA and PFHxS.

b. Environmental PFAS contaminates food.

26. Multiple government authorities, including Defendant FDA, have concluded that because PFAS are widely used and do not breakdown, levels in the environment are increasing and this is contaminating our food. *Per- and Polyfluoroalkyl Substances (PFAS)*, FDA (last updated Jan. 3, 2025), https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas, ("PFAS in the environment can enter the food supply through crops and animals grown, raised, or processed in contaminated areas… The widespread use of PFAS and their persistence in the environment means that PFAS from past and current uses have resulted in increasing levels of contamination of the air, water, and soil."); *PFAS Explained*, EPA (last updated Oct. 8, 2023), https://www.epa.gov/pfas/pfas-explained, ("[b]ecause of their widespread use … PFAS … are present at low levels in a variety of food products and in the environment."); *In the Matter of: The United States Air Force and Arizona Air National Guard, Tucson International Airport Area Site, Pima County, Arizona*, Emergency Administrative Order for Response Action, Docket

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No. PWS-AO-2024-10 at 6 (May 29, 2024), ("Many PFAS chemicals are environmentally persistent...").

27. Peer-reviewed scientific studies have shown that environmental PFAS contaminates food crops and livestock, including dairy farms, through contaminated irrigation or drinking water, contaminated biosolids used as fertilizers, contaminated rainwater, and even by spraying PFAS-contaminated pesticides directly on food crops. *Testing Food for PFAS and Assessing Dietary Exposure*, FDA (last updated Jan. 3, 2025), https:// www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure; Isabella Grullon Paz, *PFAS: The 'Forever Chemicals' You Couldn't Escape if You Tried*, NY Times (Apr. 12, 2022), https:// www.nytimes.com/2022/04/12/us/pfas-chemicals-fast-food.html; Susan Cosier, *America's Dairyland May Have a PFAS Problem,* Nat. Res. Def. Council (Oct. 11, 2019), https://www.nrdc.org/stories/americas-dairyland-may- have-pfas-problem; Steve Lasee, et al, *Targeted analysis and Total Oxidizable Precursor assay of several insecticides for PFAS*, 3 J. of Haz'd Mater. Ltrs., 100067 (Nov. 2022); *Per- and Polyfluoroalkyl Substances (PFAS) and Your Health, How can I be exposed?* ATSDR CDC (Jan. 18, 2024), https://www.atsdr.cdc.gov/pfas/health-effects/exposure.html.

28. Two example studies conducted by Defendant FDA have confirmed that environmental PFAS transfers to foods:

- **EXAMPLE 1 - Milk:** In 2018 to 2021, Defendant FDA found PFAS in milk collected from a contaminated dairy farm in New Mexico at levels they deemed unsafe. *Analytical Results for PFAS in 2018-2021 Dairy Farm Sampling (Parts*

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Per Trillion) (New Mexico), FDA (June 2021), https://www.fda.gov/media/127850/download?attachment. In addition, FDA found PFAS in two control milk samples, which were analyzed with the contaminated samples. *Id.* These two controls, purchased in September 2019, should have been PFAS-free; and yet PFOA was found at 66 and 64 parts per trillion (ppt). *Id.* By comparison EPA's limit set for PFOA in drinking water is 4 ppt. 40 CFR § 141.61(c)(2); *see infra* ¶31.

- **EXAMPLE 2 – Leafy Vegetables and Corn:** In 2018, Defendant FDA found PFAS in food crop samples collected from a farm in North Carolina located near the Chemours Fayetteville Works PFAS production plant. *Analytical Results for PFAS in 2018 Produce Sampling (Parts Per Trillion) (North Carolina)*, FDA.gov (Oct. 2019), https://www.fda.gov/media/127848/download. Samples of corn, blueberries, tomatoes, a variety of leafy vegetables and cabbage were analyzed. *Id*. The vast majority (87.5%) of the leafy vegetables and cabbage samples bore PFOA residues, with levels up to 237 ppt. *Id.* Corn also was found to have PFAS at up to 29 ppt (PFNA). *Id.*

29. Two more recent studies show that the environmental contamination of foods with PFAS is spreading and worsening over time:

- **EXAMPLE 3 - Milk**: In a 2024 Consumer Report study, samples of retail milk purchased in three different states were analyzed for PFAS. L. Kirchner, *Forever Chemicals' Are Found in Some Milk, Including Organic*, *A Consumer Reports investigation highlights gaps in how the U.S. tests and regulates PFAS in food*,

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Consumer Reports (May 2, 2024), https://www.consumerreports.org/pfas/pfas-forever-chemicals-found-in-some-milk-including-organic-a1101576034/. Results were (1) twelve percent (12%) of all milk samples were contaminated with PFOS or PFOA; (2) samples with the highest PFAS levels were purchased in California; and (3) the highest level found in any single sample was PFOA at 84 ppt. *Id*. This highest level (PFOA at 84 ppt) is about thirty-percent higher than what FDA found in the September 2019 controls (PFOA at 64-66 ppt) from **EXAMPLE 1 – Milk** above. These data show that PFAS in milk is not limited to contaminated dairy farms and that the levels are increasing over time.

- **EXAMPLE 4 – Kale:** In a 2023 study conducted by Alliance for Natural Health, PFAS residues, including PFOA, were found in almost eighty-eight percent (87.5%) of the kale samples purchased from retail outlets in four different states. Michael Ames-Sikora, et al, *PFAS IN KALE PILOT STUDY*, Alliance for Natural Health (2023), https://anh-usa.org/wp-content/uploads/2023/06/230621-ANH-USA- PFAS-in-Kale.pdf.

c. PFAS are absorbed into the body and have long half-lives.

30. Government authorities and peer-reviewed scientific studies have concluded that PFAS are absorbed into the human body by drinking, eating, breathing, and skin contact; and that once absorbed, PFAS have a long half-life. Oddný Ragnarsdóttir, et al, *Dermal bioavailability of perfluoroalkyl substances using in vitro 3D human skin equivalent models*, 188 Env't. Int'l. 108772 (June 2024), https://doi.org/10.1016/j.envint.2024.108772; Kathryn A. Crawford & Nicola

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Hartmann, *Respiratory Exposure to Highly Fluorinated Chemicals via Application of Ski Wax and Related Health Effects*, 11(1) Curr. Env't. Health Rep. 39-45 (Mar. 2024), doi: 10.1007/s40572-023-00425-4; *In the Matter of: The United States Air Force*, Docket No. PWS-AO-2024-10 at 6.

B. PFAS IS NOW REGULATED BY MULTIPLE AUTHORITIES

31. In April 2024, EPA established enforceable maximum contaminate levels ("MCLs") for certain PFAS in drinking water pursuant to the Safe Drinking Water Act ("SDWA"). 40 CFR § 141.61(c)(2). The MCLs were based on their conclusion that adverse health effects associated with exposure to certain PFAS "include (but are not limited to): effects on the liver (*e.g.,* liver cell death), growth and development (*e.g.,* low birth weight), hormone levels, kidney, the immune system (reduced response to vaccines), lipid levels (*e.g.,* high cholesterol), the nervous system, and reproduction, as well as increased risk of certain types of cancer" and that "PFAS may lead to: … [d]evelopmental effects … including …. bone variations [,]….[and] [i]ncreased risk of some cancers, including prostate." *PFAS National Primary Drinking Water Regulation, A Rule by the Environmental Protection Agency*, 89 Fed. Reg. 32532 (Apr. 26, 2024); *see also Our Current Understanding of the Human Health and Environmental Risks of PFAS*, EPA (May 16, 2024), https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas.

32. EPA has also established zero as the maximum contaminant level goal for each PFOA and PFOS in drinking water based, on their conclusion that both are "Likely to Be Carcinogenic to Humans." 40 CFR §§ 141.50(a)(24), 141.50(a)(25); *Maximum*

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Contaminant Level Goals for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water, 2024, EPA Document Number: EPA-815-R-24-010 at 4 (Apr. 2024), https://www.epa.gov/system/files/documents/2024-04/mclg-doc-for-pfoa-pfos_final-508.pdf.

33. Bottled water is regulated as a food under the Act by FDA. *Bottled Water Everywhere: Keeping it Safe*, FDA (last updated Apr. 22, 2022), https://www.fda.gov/consumers/consumer-updates/bottled-water-everywhere-keeping-it-safe. When EPA's new MCLs for PFAS in drinking water were established, the so-called "hammer provision" of the Act was triggered. 21 U.S.C. §349(b). Under this provision, FDA has a set time to either issue a corresponding regulation for bottled water or publish a rationale for why EPA's drinking water standards should not apply to bottled water. *Id*. If FDA does neither, EPA's MCLs for PFAS in drinking water automatically apply to bottled water, by operation of law. *Id*.

34. European authorities have established enforceable limits and recommended monitoring levels for certain PFAS in various foods. *Commission Regulation (EU) 2023/915 of 25 April 2023* at Annex 1, § 4.2; *Commission Recommendation (EU) 2022/1431 of 24 August 2022 on the monitoring of perfluoroalkyl substances in food*, 2022 O.J. (L. 221/105), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022H1431.

35. European authorities have concluded that the environmental load of PFAS has become toxic to humans, stating that "PFOS, PFOA, PFNA and PFHxS can cause developmental effects and may have adverse effects on serum cholesterol, the liver and

the immune system and birth weight." *Commission Regulation (EU) 2022/2388 of 7 December 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkyl substances in certain foodstuffs*, 2022 O.J. (L. 316/38) 1:¶3, http://data.europa.eu/eli/reg/2022/2388/oj.

C. PLAINTIFFS EJ TASK FORCE HAS STANDING

a. Plaintiff EJ Task Force has already been exposed to PFAS.

36. EJ Task Force is located in a community in southeastern Tucson, in Pima County, Arizona.

37. The EJ Task Force headquarters is within an eight-mile radius of Tucson International Airport Area, a National Priority List Superfund site (hereinafter "the TIAA Site"). *ECH, Enforcement and Compliance History Online, Detailed Facility Report*, EPA (May 13, 2024), https://echo.epa.gov/detailed-facility-report?fid=110071101242.

38. On May 29, 2024, EPA issued an emergency order to the U.S. Air Force and the Arizona Air National Guard to clean-up the TIAA Site because a new PFAS plume was contaminating the Upper Santa Cruz aquifer, the source for drinking water there. *Id.* at 9:¶40. PFAS levels found in the contaminated water were *more than 7,500 times* EPA's new promulgated MCLs for drinking water. *Id.* at 8-9:¶¶31-39.

39. Because the EJ Task Force community lives near this PFAS contamination, it is likely that they have been unknowingly breathing, drinking, bathing, washing, and cooking in PFAS-contaminated water and air for some time.

40. In addition, as alleged above, PFAS environmental contamination

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transfers to foods. Thus, there is an elevated risk that the EJ Task Force community have consumed locally grown foods contaminated with this environmental PFAS.

b. Further harm to Plaintiff EJ Task Force caused by Defendants' delay.

41. The EJ Task Force has collected health assessments from its community members and found hundreds of people with PFAS-related illnesses such as adverse effects on the immune system and cancer. *See supra*, ¶¶ 31, 32, 35.

42. In addition, Ms. Shosie's family members have suffered from PFAS-related illness, including her daughter Tianna, who had a premature child and later died of lupus and nephrotic syndrome; her daughter Yessenia, who was born with a cleft palate, bone age delay, and a heart murmur; her daughter Clarissa, who has permanent kidney failure; her son Jojo, who has lupus; her nephew Eli, who passed away from kidney cancer; her niece Mia, who passed away from a brain tumor; and her husband, who has prostate cancer. *Id*.

43. By delaying a decision on the Petition, EJ Task Force and Ms. Shosie are at considerable risk of further exposure to PFAS adulterated foods, increasing their chances of developing even more PFAS-related illnesses.

D. PLAINTIFF DR. KROTZKY HAS STANDING

a. Plaintiff Dr. Krotzky has already been exposed to PFAS.

44. Dr. Krotkzy has lived in Werder, Germany, a town in the outskirts of Berlin, since 2016. Dr. Krotkzy lived and worked in Durham, North Carolina from 2011 to 2016. Before this, Dr. Krotzky lived and worked in Berlin, Germany and travelled frequently to Durham.

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45. Durham is at a sixty-five-mile aerial distance from Fayetteville, where there was a massive unauthorized PFAS release by Chemours. *See infra* ¶¶ 63 to 65.

46. PFAS is in Germany's drinking water. Vanessa Ingold, *Screening for 26 per- and polyfluoroalkyl substances (PFAS) in German drinking waters with support of residents*, 2:4 Eco- Env't & Health, 235-242 (2023); https://doi.org/10.1016/j.eehl.2023.08.004; *see also* A. Bernd Göckener, et al, *Tracking down unknown PFAS pollution – The direct TOP assay in spatial monitoring of surface waters in Germany*, 898 Science of the Total Env't. 165425 (2023); https://doi.org/10.1016/j.scitotenv.2023.165425 (2023 survey identified 1500 sites in Germany with detectable PFAS levels in water).

47. Furthermore, nearly all of the almost two thousand (n=1962) German study participants in a 2024 study had PFAS in their blood. Tariq O. Faquih, et al, *Per- and Polyfluoroalkyl Substances Concentrations are Associated with an Unfavorable Cardio-Metabolic Risk Profile: Findings from Two Population-Based Cohort Studies*, 16 Expo Health 1251 (2024), DOI: https://doi.org/10.1007/s12403-023-00622-4.

48. Because PFAS has been found in the drinking water in both Germany and North Carolina, where Dr. Krotkzy has been living and working for decades, it is highly likely that he has been exposed to PFAS-contaminated water for some time.

49. As alleged above, PFAS environmental contamination transfers to foods. Because Dr. Krotkzy has lived near PFAS-contaminated sites in both Germany and North Carolina, there is a substantial risk that Dr. Krotkzy has already consumed locally grown PFAS-adulterated foods from these areas.

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b. Further harm to Plaintiff Dr. Krotzky caused by Defendants' delay.

50. Dr. Krotzky has suffered adverse health effects which are associated with exposure to PFAS including impaired kidney function and a suppressed immune system. *See supra*, ¶¶ 31, 35.

51. The U.S. exports food to Germany. According to USDA's Office of Agricultural Affairs (OAA) in Berlin, the U.S. exported $810.0 million of agricultural products to Germany in 2023. *Germany Country Profile*, Food Export Association of the Midwest USA and Food Export USA–Northeast, https://www.foodexport.org/export-insights/market-country-profiles/germany (last visited on Jan. 23, 2025). For processed foods alone, the total was $319.9 million, making Germany the third largest processed food export market from the U.S. into Europe. *Id*.

52. In 2022, Germany imported a total of $2.76 million in whey and milk products from the U.S., according to the United Nations COMTRADE database on international trade. *Germany Imports from United States of Whey and milk products not specified elsewhere, flavored or not*, Trading Econs, https://tradingeconomics.com/germany/imports/united-states/whey-milk-products-flavored (last visited on Jan. 23, 2025).

53. Dr. Krotzky consumes agricultural commodities, processed foods, whey, and milk products as part of his daily diet.

54. By delaying a decision on the Petition, Dr. Krotkzy is at considerable risk of exposure to PFAS-adulterated foods imported from the U.S. into Germany. Because

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Dr. Krotkzy has already been exposed to environmental PFAS in foods and water, this continued additional exposure further increases his risk of developing even more PFAS-related illnesses.

E. PLAINTIFF LOSD HAS STANDING

a. Plaintiff LOSD has already been exposed to PFAS.

55. Ms. Daussin is the sole owner and operator of Plaintiff LOSD. For the purposes of PFAS exposure, Ms. Daussin and Plaintiff LOSD are one in the same.

56. Ms. Daussin lived in Wasilla, Alaska at time of filing the Petition in 2023. Ms. Daussin's drinking water came from a private, untested well in Alaska.

57. Wasilla is twenty-nine miles as the crow flies from Anchorage, Alaska. The State of Alaska reports several sites in and around Anchorage are contaminated with PFAS. *Per- and Polyfluoroalkyl Substances (PFAS) - PFAS Contaminated Sites*, Alaska Div. of Spill Prevention and Response, https://dec.alaska.gov/spar/csp/pfas/responses/ (last visited Jan. 23, 2025).

58. Ms. Daussin now lives and works in Pittsboro, North Carolina. The Town of Pittsboro draws its water from the Haw River, which connects to the Cape Fear River. *GenX Exposure Study*, NC State Univ., https://genxstudy.ncsu.edu/study-overview/ (last visited on Jan. 23, 2025).

59. Before 2020, the year LOSD was founded, Ms. Daussin lived in Apex, North Carolina, which is twenty miles away from Pittsboro and draws its water from Jordan Lake.

60. PFAS have been detected in the Haw River and in the nearby Jordan

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Lake. *Where Are PFAS Found?*, UNC-Chapel Hill, NC Pure, https://ncpure.collaboratory.unc.edu/science/where-are-pfas-found/ (last visited on Jan. 23, 2025).

61. A study conducted by North Carolina State University has shown that PFAS blood levels in Pittsboro residents are above the national average. Jane Hoppin, *GenX Exposure Study Update: PFAS results for blood samples collected 2023*, at sl. 24, 25 (Aug. 6, 2024), https://genxstudy.ncsu.edu/wp-content/uploads/sites/149/2024/08/final-2024-report-back-slides-PDF.pdf.

62. Pittsboro is forty-nine miles as the crow flies from Fayetteville, North Carolina.

63. Chemours, a spinoff of Dupont, has been the subject to litigation for releasing PFAS into the Cape Fear River from its Fayetteville Works site. *Chemours Consent Order*, N.C. Env't Quality, https://www.deq.nc.gov/news/key-issues/genx-investigation/chemours-consent-order (last visited on Jan. 23, 2025).

64. In February 2024, the United Nations declared the Chemours/DuPont contamination of the Cape Fear River so egregious that it is a human rights violation. *US companies DuPont and Chemours generated extensive contamination with toxic "forever chemicals" in North Carolina: UN experts*, United Nations (Feb. 21, 2024), https://www.ohchr.org/en/press-releases/2024/02/us-companies-dupont-and-chemours-generated-extensive-contamination-toxic.

65. It is now estimated that drinking water for at least 2.5 million North Carolinians is contaminated with the PFAS at levels that exceed EPA's new MCLs.

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Jared Hayes & Tasha Stoiber, *State 'forever chemicals' spotlight: North Carolina's drinking water contamination*, Env't Working Grp. (June 5, 2024), https://www.ewg.org/research/state-forever-chemicals-spotlight-north-carolinas-drinking-water-contamination.

66. Because PFAS has been found in the source water used for drinking water in both Apex and Pittsboro, where Ms. Daussin has or is living and working, it is likely Ms. Daussin has been exposed to PFAS-contaminated water for some time.

67. As alleged above, PFAS environmental contamination transfers to foods. Because Ms. Daussin has lived near PFAS-contaminated sites in both Alaska and North Carolina, there is a considerable risk that Ms. Daussin has already consumed locally grown PFAS-adulterated foods from these contaminated areas.

b. Further harm to Plaintiff LOSD caused by Defendants' delay.

68. Ms. Daussin has high cholesterol, which is an adverse health effect associated with PFAS exposure. *See supra*,¶ 31, 35.

69. By delaying a decision on the Petition, Ms. Daussin is at considerable risk of further exposure to PFAS adulterated foods, increasing her risk of developing even more PFAS-related illnesses.

VI. FDA IS NON-RESPONSIVE

70. The Petition, entitled Citizen's Petition for Temporary Tolerance Setting at the Method Detection Limit for 30 or 26 PFAS [per- and polyfluoroalkyl substances] in/on Various Fruits, Vegetables, Milk, Eggs, Fish and Bread, was filed on November 1, 2023. That same day, Ms. Daussin received an acknowledgement letter from FDA's

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Dockets Management Staff, stating that the petition had been received and processed under 21 CFR §10.30 and was assigned docket number FDA-2023-P-4826.

71. On April 29, 2024, Karen L. Strambler, Policy Advisor at FDA's Center for Food Safety and Applied Nutrition ("CFSAN"), Office of Regulations and Policy emailed Ms. Daussin, with a letter attached from Mark A. Moorman, PhD, Director of FDA's Office of Food Safety, CFSAN. The letter stated the Petition was under evaluation, but FDA had not reached its decision within the first 180 days due to competing agency priorities.

72. On May 28, 2024, Ms. Daussin requested an update by email from Ms. Strambler. Ms. Strambler responded on May 30, 2024, stating that "evaluating your petition is a priority for FDA, however we cannot provide a timeline for responding at this time given competing priorities and in consideration of our limited resources."

73. On July 30, 2024, Ms. Daussin requested another update by email from Ms. Strambler, but she did not respond.

74. August 8, 2024, Ms. Daussin sent a letter on behalf of all Plaintiffs, via electronic filing to the Petition's Docket, requesting a final decision. The August 8, 2024 letter in Docket No. FDA-2023-P-4826 is incorporated herein by reference. This letter was addressed to FDA's Commissioner, Defendant Dr. Califf.

75. Plaintiffs' August 8, 2024 letter cited new, recently released data that underscore the need for mandatory enforceable temporary tolerances, so that residues of PFAS in foods can be monitored and adulterated foods can be removed from the marketplace.

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76. The letter requested a response from Defendant Dr. Califf by September 2, 2024 with either a final decision or a date certain when the final decision will be made.

77. No one from FDA has responded, substantively or otherwise, to Plaintiffs' August 8, 2024 letter.

78. On November 22, 2024, Plaintiffs submitted a Litigation Notice And Evidence Preservation Demand letter to Docket FDA-2023-P-4826 regarding this unreasonable delay action. A copy of the letter, is incorporated herein by reference, was also emailed to Ms. Strambler, Dr. Moorman, and Dr. Califf on this same day. Plaintiffs received an auto response acknowledgement from the Docket. To date there has been no other response.

VII. CAUSE OF ACTION - UNREASONABLE DELAY

79. Plaintiffs repeat the allegations contained in paragraphs 1 to 78.

80. FDA's response to the Petition is unreasonably delayed. Even after one year has passed, Defendants have failed to respond substantively to the merits of the Petition. The only response has been to state that "competing priorities" was the reason Defendants have failed to act.

81. An unreasonable delay claim requires showing that plaintiffs are harmed by an agency's failure to take a *discrete* agency action that it is *required to take*. *Norton*, 542 U.S. at 64. To decide if a delay is *unreasonable,* the Court should determine if the delay impacts public health and can look to the enabling statute to see if Congress specified a speed with which the agency to act. *Telecomm. Rsch. & Action Ctr.*, 750 F.2d at 79–80.

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82. Defendants have unreasonably failed to act on the Petition, in violation of the Act, the APA, and its own regulations. 21 U.S.C. § 301, et seq; 5 U.S.C. §§ 702, 706(1); 21 CFR §§ 5.10, 10.25(a)(2), 10.30(e)(2).

83. The Petition calls for FDA to set tolerances for certain, named PFAS compounds on specifically identified foods, under 21 U.S.C. §346. Thus, the Petition requests FDA to take a *discrete* action.

84. By delaying a decision on the requested PFAS tolerances in the Petition, Defendants have ignored FDA's statutory mandates which *require* prompt action to keep food safe. Under the Act, Congress requires FDA to act "promptly and efficiently" to ensure "foods are safe" by promulgating tolerances poisonous or deleterious substances unavoidably added to foods and to set such tolerances on carcinogens at zero. *See* 21 U.S.C. §§ 342(a)(2)(A), 346, 348(c)(3), 371(a), 393.

85. Defendants' delay is unreasonable because by not acting, PFAS adulterated foods are left unchecked in the marketplace, and public health is at risk, in violation of the Act. *See* 21 U.S.C. §§ 342(a)(2)(A), 346, 348(c)(3), 371(a), 393. It is a common tenant of toxicologists that "the dose makes the poison." PFAS bioaccumulate and are persistent in the human body. This means each time a person is exposed, PFAS levels in the body increase, and the risk of that enough "dose" to cause a toxic effect gets higher. Even when considering only the levels of PFAS found in the foods mentioned in this Complaint (e.g., milk, leafy vegetables, cabbage, kale, corn, and fish), the dietary burden of toxic PFAS is unacceptably high. Thus, these facts show that FDA's failure to act on the Petition and set tolerances to remove adulterated foods from

the marketplace is putting the U.S. public at an unreasonable risk.

86. Defendants' delay is unreasonable because the undisputed facts establish that PFAS are poisonous substances, and foods that contain PFAS are adulterated as a matter of law under the Act. 21 U.S.C. §§ 342, 346.

87. Defendants' delay is unreasonable because FDA already has a mandate to address PFAS in the food item bottled water, and yet Defendants have capriciously failed to limit PFAS in on all other foods. 21 U.S.C. §349(b).

88. Defendants' delay is unreasonable because European authorities have already set limits for certain PFAS on foods, and adulterated items can be sent to Europe in violation the Act. *See Commission Regulation (EU) 2023/915 of 25 April 2023* at Annex 1, § 4.2; 21 U.S.C. § 381(e)(1). This puts global trade at risk.

89. Plaintiffs have standing to bring this action. Plaintiffs are harmed by Defendants delay because (1) tolerances are needed to remove adulterated foods from the marketplace, (2) the undisputed facts show that food are contaminated with environmental PFAS, (3) without PFAS tolerances set, Plaintiffs are at high risk of consuming more PFAS-adulterated foods, (4) Plaintiffs have already been exposed to PFAS and have suffered PFAS-related health issues, and (5) additional exposure to PFAS-adulterated foods puts Plaintiffs health at risk by worsening the PFAS-related illnesses they already suffer from or by causing them to develop new illnesses.

90. Defendants' unreasonable delay in acting on the Petition, and its failure to comply with its statutory and regulatory obligations, prevents Plaintiffs from exhausting administrative remedies by obtaining a final decision.

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91. Any statutory ambiguity in the Act must be decided by the Court, and not the agency. *See Loper Bright Enters.*, 144 S. Ct. at 2261–62. Thus, it is up to this Court, and not FDA, to determine if waiting more than one year to respond to the Petition is sufficiently prompt and efficient, given risks presented to Plaintiffs, public health, and global trade as alleged here and will be shown at trial. *Id.*; 21 U.S.C. §§ 346, 393; *Telecomm. Rsch. & Action Ctr.* at 79–80.

92. As a result of the FDA's ongoing delay, a court-ordered deadline is necessary to ensure that the FDA responds to the Petition within a specified time.

WHEREFORE, Plaintiffs respectfully request judgment against the Defendants as follows:

(a) Declaring that Defendants have unreasonably delayed acting on the Petition, in violation of the APA, the FFDCA ("the Act"), and FDA's own regulations;

(b) Directing Defendants to act on the Petition by a date certain, to be determined by the Court;

(c) Retaining jurisdiction of this matter, to ensure that Defendants comply with their legal obligations, and the Court's directives, to act on the Petition;

(d) Awarding Plaintiffs their costs and disbursements incurred in connection with this action, including reasonable attorneys' fees; and

(e) Awarding Plaintiffs such other and further relief as the Court deems just and proper.

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RESPECTFULLY SUBMITTED this 24th day of January 2025.

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