Andrew Van Arsdale
(CA Bar #323370) *Pro Hac Vice*
AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
Telephone: (800) 777-4141
andrew@avalaw.com

Sandra Daussin
(AZ Bar #037274, NC Bar #56465)
AVA LAW GROUP, PC
52 Somerleigh Way
Pittsboro, North Carolina 27312
Telephone 406-500-3245
sandra.daussin@avalaw.com

Attorneys for Plaintiffs

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

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 Kyle Diamantas, J.D., as Acting Commissioner U.S. Food and Drug Administration [1]

Defendants.

Case No. 4:25-cv-00035-JAS

SUPPLEMENTAL COMPLAINT

JURY TRIAL DEMANDED

[1] Under Fed. R. Civ. P. 25(d), Kyle Diamantas, J.D., the Acting Commissioner, automatically substitutes as a Defendant for former Commissioner Marty Makary.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

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 Supplemental Complaint against the U.S. Food and Drug Administration ("FDA") and Kyle Diamantas, J.D. in his official capacity as Acting Commissioner of the FDA, ("Defendants") for their unlawful denial of Plaintiffs' Citizen's Petition, filed on November 1, 2023 ("Petition"), and its Supplement, filed on May 15, 2025. The Petition and Supplement were filed on Regulations.gov and are in a public docket under FDA-2023-P-4826. The Petition, as amended by the Supplement, requested that FDA establish tolerances and/or action levels for certain per- and polyfluoroalkyl substances ("PFAS") in or on various foods, including milk, fish, eggs, produce, bread, and animal feed commodities.[2]

This lawsuit was originally filed on January 25, 2025, pursuant to 5 U.S.C. §§702 and 706(1) of the Administrative Procedure Act ("APA") and the Federal Food Drug and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 301, et seq, seeking relief for FDA's unreasonable delay in responding to the original Petition. FDA subsequently denied the Petition and its Supplement in their entirety on June 17, 2026, rendering Plaintiffs' claim for unreasonable delay moot. Plaintiffs now seek judicial review of FDA's denial. This Supplemental Complaint is filed pursuant to 5 U.S.C. §§ 702, 704, and 706(2) of the APA, the FD&C Act, Fed. R. Civ. P. 15(d), and the Court's July 1, 2026 Order. (Doc. 34). Plaintiffs allege and state the following.

[2] PFAS is a class of compounds comprised of roughly 15,000 individual chemicals, as recognized by US authorities. The Petition and Supplement relate to only 30 PFAS.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

TABLE OF CONTENTS

I. NATURE OF THE ACTION 5

II. APPLICABLE LAW – 5 U.S.C. § 706 9

III. PARTIES 10

A. Plaintiffs / Petitioners of the Citizen Petition. 10

B. Defendants. 12

IV. JURISDICTION AND VENUE 13

V. PROCEDURAL HISTORY 13

VI. STATEMENT OF FACTS 15

A. Background on PFAS. 15

a. Chemical characteristics and practical applications of PFAS. 15

b. Environmental PFAS contaminates food. 16

c. PFAS health effects. 18

B. Plaintiffs Are Harmed by FDA's Failure to Set Limits. 19

a. Plaintiff EJ Task Force. 19

b. Plaintiff Dr. Krotzky. 21

c. Plaintiff LOSD. 23

C. Petitioners' / Plaintiffs' Request. 26

D. Petitioners' / Plaintiffs' Alternative Request. 27

E. FDA's Response. 28

F. The Undisputed Facts. 29

G. FDA Did Not Consider Material Evidence. 30

a. FDA did not consider that certain PFAS are known carcinogens. 30

b. FDA did not consider that PFAS pollution is widespread and increasing. ... 31

H. FDA Ignored Its Mandate Under § 346 to Consider Cumulative Risks. 33

I. FDA Ignored its Mandate Under § 393 to Coordinate with EPA & USDA. 36

a. FDA did not coordination with EPA. 36

b. FDA did not coordination with USDA..... 42

J. FDA Denial Exceeds Its Authority Under § 346. 44

K. FDA's Achievability Rationale is Illogical. 47

L. FDA Deviates Without Reason from Past Practices. 48

a. FDA has set action levels for unavoidable lead and arsenic. 48

b. FDA has set tolerances for PCBs. 51

c. FDA has a process to regulate PFAS in bottled water as a food. 52

M. FDA's "Stability" Rationale is Implausible. 53

a. FDA's scientific "instability" rationale is unsupported. 53

b. FDA's "stability" concern stems from continuing PFAS pollution. 56

N. FDA's Denial Raises Constitutional and APA Concerns. 57

O. FDA Rejects MDL Limits Without Addressing the Facts in the Record. ... 59

P. Method C-010.03 Supports Efficient Regulatory Enforcement..... 61

Q. FDA Fails to Address Plaintiffs' International Trade Concerns..... 64

R. FDA's Claim that PFAS Are Not Subject to § 348 Is Irrational. 65

a. Governing law..... 65

b. Plaintiffs' position..... 66

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

c. FDA's unreasoned response. *68*

S. FDA's Denial Relies on Impermissible Factors. **70**

VII. CAUSE OF ACTION **72**

A. Unlawful Agency Action, 5 U.S.C. § 706(2) – Count One **72**

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

I. NATURE OF THE ACTION

1. Under 5 U.S.C. § 706(2), an agency action should be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law..[or if it is].. without observance of procedure required by law." Courts have held that an agency action can be held unlawful under § 706(2) if it fails to consider an important aspect of the problem, contradicts the evidence, is not reasonably explained, relies on impermissible factors, or departs from prior policy without explanation. *Ohio v. Env't Prot. Agency*, 603 U.S. 279, 292-294 (2024); *Bonumose, Inc. v. U.S. Food & Drug Admin.*, 747 F. Supp. 3d 211, 223 (D.D.C. 2024); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513-17 (2009).

2. Petitioners / Plaintiffs (hereinafter typically just "Plaintiffs") live and work in PFAS-contaminated areas and have suffered from PFAS-related illnesses. The original Petition, filed in 2023, was narrowly tailored to the PFAS compounds and food categories identified in FDA's validated analytical method. FDA developed that method to detect priority PFAS in foods that FDA and the European Commission had already identified as presenting the greatest concern for monitoring and regulatory purposes.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

3. In May 2025, Plaintiffs submitted an alternative request to mirror with the current Administration's focus only on PFOS and PFOA. [3] The alternative request was to set enforceable tolerances only for PFOS and PFOA in milk and fish, foods which showed the highest incidence of PFAS contamination. Action levels, which are not enforceable, were requested for everything else that was part of the original request.

4. FDA issued their final response denying to the Petition and Supplement on June 17, 2026. **Exhibit** ("**Ex**.") **1**. FDA does not dispute that PFAS are persistent synthetic chemicals that contaminate food through polluted soil, water, biosolids, pesticides, and other environmental pathways. FDA also does not dispute that certain PFAS cause serious adverse health effects or that a validated analytical method exists to detect the specific PFAS in the foods identified in the Petition and Supplement. Nor does FDA deny that its own testing has detected PFAS in numerous foods, including fish, milk, and produce. However, as revealed by the arguments set forth in their response (**Ex. 1**), FDA's denial is unlawful under 5 U.S.C. § 706(2).

5. ***First***, FDA admitted it evaluates the human health risk to exposure from foods adulterated with PFAS individually (i.e., one analyte at a time) and in one food type at a time. This is counter to FDA's statutory mandate under 21 U.S.C. § 346,

[3] After the original Petition was submitted, the U.S. Environmental Protection Agency ("EPA") set the enforceable limits for several PFAS in drinking water. *PFAS National Primary Drinking Water Regulation*, EPA (Final Rule), 89 Fed. Reg. 32532 (Apr. 26, 2024). A year later, in May 2025, EPA announced its intent to rescind all of these PFAS drinking water limits, except those set for PFOA and PFOS. *Proposed PFOA and PFOS Compliance Extension Rule*, EPA (last updated on July 23, 2026), https://www.epa.gov/sdwa/proposed-pfoa-and-pfos-compliance-extension-rule to 203.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

which requires an assessment of the total risks accounting for various sources (e.g., food and water), other routes of exposure (e.g., dermal and inhalation), and other similarly toxic compounds. FDA also failed to meaningfully address evidence provided by Plaintiffs showing that the EPA has found certain PFAS are carcinogenic, that PFAS contamination is widespread throughout the U.S., and that contamination is increasing over time because PFAS persist indefinitely in the environment.

6. ***Second***, Congress instructed FDA to coordinate with other science-based federal agencies on food-safety matters. 21 U.S.C. § 393(c). Nevertheless, FDA's decision does not reflect meaningful consideration of EPA's PFAS risk assessments; EPA's statutory mandates, regulations, and policies regarding cumulative and aggregate exposure; EPA's determination that no safe level of exposure has been identified for certain PFAS; or the United States Department of Agriculture's ("USDA") regulations and ongoing efforts to address PFAS contamination in dairy farming.

7. ***Third***, FDA claims it is "firmly" within their discretional purview to choose to set tolerances. (**Ex. 1**, 20, n. 89 citing *Young v. Community Nutrition Institute*, 476 U.S. 974 (1986)). However, as discussed herein, *Young* was decided under the deferential *Chevron* doctrine, which has since been overturned. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024). As a result, FDA has overreached its authority here in declining to set the requested tolerances.

8. ***Fourth***, FDA justified its denial by stating that scientific understanding, toxicological information, and analytical methods continue to evolve for PFAS. But FDA does not dispute that EPA and other authorities have already completed extensive

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

risk assessments for key PFAS, or that FDA has studied PFAS contamination in food for years. The possibility of future scientific developments does not justify refusing to address a current, acknowledged contamination problem. Scientific uncertainty, and the prospect of better understanding in the future, do not excuse an agency from its obligation to regulate. *Massachusetts v. EPA*, 549 U.S. 497, 534 (2007).

9. ***Fifth***, FDA departed from prior practices without a reasoned explanation. FDA has previously established tolerances and action levels for other unavoidable contaminants, including PCBs, lead, and arsenic. FDA also recognizes PFAS contamination in bottled water as a food-safety issue and must consider EPA's drinking-water standards when regulating bottled water. Yet FDA failed to explain why PFAS contamination in other foods warrants fundamentally different treatment despite many of the same public-health concerns.

10. ***Sixth***, FDA asserted tolerance setting is a complex and burdensome endeavor. However, this does not excuse FDA from carrying out its statutory duties under the FD&C Act to protect the food supply and evaluate the Petition based on the evidence before it. Moreover, all procedural steps required for tolerance setting have been complete here, with the exception of FDA issuing the order. 21 U.S.C. § 371. FDA's suggestion that ensuing litigation from stakeholders disputing the tolerances is not shown on the record. Since 2023, no public comments have opposed the Petition. As discussed herein, general consumers; dairy farmers seeking USDA indemnification when their livestock becomes contaminated with PFAS; and farmers seeking access to European market will likely welcome the requested tolerances.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

11. ***Seventh***, FDA's denial leaves food producers, consumers, and regulators without any objective standards to identify when PFAS contamination renders food adulterated. While FDA asserts that it addresses PFAS contamination through case-by-case enforcement, it refuses to establish any generally applicable tolerances or action levels and provides no clear criteria governing its decisions. The result is a regulatory regime that lacks transparency, consistency, and reasoned decision-making.

12. For these and other reasons, FDA's denial of the Petition as amended by its Supplement is unlawful and must be set aside under 5 U.S.C. § 706(2). Plaintiffs are harmed by FDA's denial because they are at an increased risk from continued consumption of PFAS-adulterated foods. Plaintiffs seek vacatur of the denial and remand to FDA for further proceedings consistent with the FD&C Act and the APA.

II. APPLICABLE LAW – 5 U.S.C. § 706

13. The APA at 5 U.S.C. § 706 provides: "[t]he reviewing court shall--(2) hold unlawful and set aside agency action, findings, and conclusions found to be--(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; [or]…(D) without observance of procedure required by law." 5 U.S.C. § 706.

14. The U.S. Supreme Court has held that "arbitrary" or "capricious" within the meaning of 5 U.S.C. § 706(2) means it is not "reasonable and reasonably explained." *Ohio*, 603 U.S. at 292-294. A decision will be set aside if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

ascribed to a difference in view or the product of agency expertise," *Bonumose, Inc.*, 747 F. Supp. 3d at 223. In addition, the agency decisions can be set aside if the agency deviates from past policies without a reasoned explanation or otherwise acted irrationally. *FCC*, 556 U.S. at 513-17 (2009).

III. PARTIES

A. Plaintiffs / Petitioners of the Citizen Petition.

15. **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. Plaintiff EJ Task Force is one of the Petitioners.

16. **Arno Krotzky, PhD ("Dr. Krotzky")** is an independent consultant with his address at Unter Den Linden 22, 14542 Werder, Germany. Dr. Krotzky is an

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

executive consultant with more than thirty years in leadership, innovation, and product development with BASF, a chemical company. Dr. Krotzky 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. 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. Krotzky was also the founder and managing director of BASF's metanomics Health GmbH in Berlin, Germany. At metanomics, Dr. Krotzky 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 European Union, and across the U.S. Dr. Krotzky is one of the Petitioners.

17. **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.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

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 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. LOSD is one of the Petitioners.

B. Defendants.

18. **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 FD&C Act, including its provisions regarding the regulation of harmful food additives.

19. **Kyle Diamantas, J.D. (**"Mr. Diamantas"**)**, is the Acting 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 Mr. Diamantas as a defendant in this action solely in his official capacity as Acting Commissioner of FDA.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

IV. JURISDICTION AND VENUE

20. This matter is ripe for judicial review. FDA's June 17, 2026 response to the Petition, and its Supplement is final. (Doc. 34, 3:8; **Ex. 1)**. A "final agency action for which there is no other adequate remedy in a court" is subject to judicial review. 5 U.S.C. § 704. The Ninth Circuit has held that "[a]n agency's denial of a petition for rulemaking constitutes final, reviewable agency action," interpreting §§ 704 and 706. *Weight Watchers Int'l, Inc. v. F.T.C.,* 47 F.3d 990, 992 (9th Cir. 1995).

21. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1361 because this action arises under the laws of the United States and seeks to compel FDA to perform duties required by law. Judicial review is authorized by the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706.

22. This action seeks relief other than money damages; therefore, sovereign immunity has been waived pursuant to 5 U.S.C. § 702. *See Trudeau v. FTC*, 456 F.3d 178, 185-86 (D.C. Cir. 2006).

23. 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. *Supra*, ¶15.

V. PROCEDURAL HISTORY

24. The Petition, entitled *Citizen's Petition for Temporary Tolerance Setting at the Method Detection Limit for 30 or 26 PFAS [per- and polyfluoroalkyl substances]*

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

in/on Various Fruits, Vegetables, Milk, Eggs, Fish and Bread was submitted to and received by FDA on November 1, 2023. (Dkt. FDA-2023-P-4826-0001 to -0008).[4] FDA was required to respond within 180 days. 21 C.F.R. § 10.30(e).

25. After FDA failed to provide a substantive response, Plaintiffs filed this lawsuit on January 24, 2025 with one count for unreasonably delayed under 5 U.S.C. §§ 702 and 706(1) of the APA and the FD&C Act. (Doc. 1).

26. Plaintiffs filed the Supplement to the Petition on May 15, 2025.[5]

27. FDA requested two continuances in this matter. Plaintiff did not oppose the first one (in March 2025) and opposed the second one (in Dec. 2025). The Court granted both requests, and this matter was continued until June 30, 2026. (Doc. 29).

28. On June 17, 2026, FDA issued its denial of the Petition, as amended by the Supplement, in its entirety. (**Ex. 1**).

29. On July 1, 2026, the Parties filed a Joint Status Report, wherein they agreed that FDA's final response to the Petition rendered Plaintiffs' unreasonable delay action moot. (Doc. 33, 3:8-9). They also reported that Plaintiffs' intended to challenge the denial, pursuant to APA, 5 U.S.C. § 706(2), and sought leave to supplement the complaint. *Id*., 3:9-11. That same day, the Court granted Plaintiffs' request to file this Supplemental Complaint, no later than August 3, 2026. (Doc. 34).

---

[4] The Petition, absent its appendices (i.e., Dkt. FDA-2023-P-4826-0001), has been previously filed with this Court. (Doc 24-3).

[5] The Supplement (i.e., FDA-2023-P-4826-0013) has been previously filed with this Court. (Doc. 24-9).

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

VI. STATEMENT OF FACTS[6]

A. Background on PFAS.

a. Chemical characteristics and practical applications of PFAS.

30. 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.*

31. 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 (Jul. 22, 2025), 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 (Dec. 29, 2025), https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics. Some examples are fire-fighting foam, non-stick cookware, waterproof clothing, stain-resistant carpeting, cosmetics, shampoos, cleaning products, and food packaging. *Id.*

32. 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.

---

[6] Allegations are made upon information or belief.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

33. The Petition lists the 30 PFAS at issue here in Table 1. (Doc. 24-3, 4, 5). From these 30, the only individual PFAS mentioned in this Complaint are PFOS, PFOA, PFNA PFHxS, and GenX (a/k/a HFPO-DA).

b. Environmental PFAS contaminates food.

34. Multiple government authorities, including FDA, have concluded that because PFAS are widely used and do not break down, levels in the environment are increasing and this is contaminating our food. *Per- and Polyfluoroalkyl Substances (PFAS)*, FDA (last updated on 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" (emphasis added).); *PFAS Explained*, EPA (last updated on Sept. 30, 2025), https://www.epa.gov/pfas/pfas-explained, ("[b]ecause of their widespread use and their persistence in the environment, … PFAS … are present at low levels in a variety of food products and in the environment."); *In the Matter of: The U.S. Air Force and Arizona Air National Guard, Tucson International Airport Area Site, Pima County, Arizona*, Emergency

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

Administrative Order for Response Action, Docket No. PWS-AO-2024-10 at ¶23 (May 29, 2024), ("Many PFAS chemicals are environmentally persistent...").[7]

35. 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 on 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, Exposure to PFAS*, ATSDR (Jul. 22, 2025),

[7] FDA's webpage *Per- and Polyfluoroalkyl Substances (PFAS)* dated Jan. 3, 2025 stated "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," but this statement does not appear on the Jul. 9, 2026 update of the same. See **Ex. 2**, 7, 8-12.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

https://www.atsdr.cdc.gov/pfas/about/index.html#cdc_environmental_basics_before-exposure-to-pfas.[8]

c. PFAS health effects.

36. EPA has concluded 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 such as "prostate, kidney, and testicular cancers" and a wide variety of other with adverse health effects, including "developmental effects…including…bone variations;" *PFAS National Primary Drinking Water Regulation*, EPA (Final Rule), 89 Fed. Reg. 32532, 32537, 32712 (Apr. 26, 2024).

37. PFOS and PFOA are both classified by EPA as "Likely to Be Carcinogenic to Humans." *Id.* at 32564.

38. EPA has also found GenX (a/k/a HFPO-DA) to be associated with cancer. (Doc. 23-4, 11, n. 4), citing U.S. EPA: *Technical Fact Sheet– Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)* (Nov. 2017) at p. 3, *Human Health Toxicity Assessment for GenX Chemicals* (Mar. 2023) at p. 2,

[8] FDA's webpage *Testing Food for PFAS and Assessing Dietary Exposure* dated Jan. 3, 2025 stated "the use of soil, water, or biosolids contaminated with PFAS to grow crops, feed animals intended for food, or raise fish or other seafood, can lead to PFAS entering the food supply," but this statement does not appear on the same webpage updated on Dec. 19, 2025. See **Ex. 3**, 1, 7-11.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

https://www.epa.gov/system/files/documents/2023-03/GenX-Toxicity-Assessment-factsheet-March-2023-update.pdf.

39. 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.

B. Plaintiffs Are Harmed by FDA's Failure to Set Limits.

a. Plaintiff EJ Task Force.

40. The EJ Task Force community has already been exposed to PFAS.

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

42. 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.

43. 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. *In the Matter of: The U.S. Air Force*, Docket No. PWS-AO-2024-10, 9:¶40. PFAS levels found in the contaminated water were *more than 7,500 times* EPA's new promulgated Maximum Contaminant Levels ("MCLs") for drinking water (PFOS found at 30,000 ppt v. 4 ppt MCL). *Id.*, 9:¶38.

44. Because EJ Task Force community lives near this PFAS contamination they have been unknowingly breathing, drinking, bathing, washing, and cooking in PFAS-contaminated water and air for some time. In addition, PFAS environmental contamination transfers to foods. Because of this, EJ Task Force community has consumed locally grown foods which were likely contaminated with this environmental PFAS.

45. 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. *Supra*, ¶¶36-38.

46. 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.*

47. Plaintiff EJ Task Force is harmed by FDA's denial of the Petition, as amended by the Supplement.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

48. By denying the request for tolerances and/or action levels, EJ Task Force and Ms. Shosie are at considerable risk of continued exposure to PFAS-adulterated foods, increasing their chances of developing even more PFAS-related illnesses.

b. Plaintiff Dr. Krotzky.

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

50. Dr. Krotzky has lived in Werder, Germany, a town in the outskirts of Berlin, since 2016. Dr. Krotzky 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.

51. Durham is at a sixty-five-mile aerial distance from Fayetteville, where there was a massive unauthorized PFAS release by Chemours. *Infra*, ¶¶70-72.

52. 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).

53. 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*

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

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.

54. Because PFAS has been detected in drinking water in both Germany and North Carolina, where Dr. Krotzky has lived and worked for decades, he has been exposed to PFAS-contaminated water for an extended period. In addition, PFAS contamination in the environment transfers to food. As a result, Dr. Krotzky has consumed locally grown foods, as well as food imported from the U.S., that were likely contaminated with PFAS from environmental sources.

55. Plaintiff Dr. Krotzky is harmed by FDA's denial of the Petition, as amended by the Supplement.

56. Dr. Krotzky has suffered adverse health effects which are associated with exposure to PFAS including impaired kidney function and a suppressed immune system. *Supra*, ¶¶36, 38.

57. The U.S. exports food to Germany. The USDA reports that "in 2025, total U.S. exports of agricultural and related products to Germany reached almost USD 3.1 billion" and the largest segments include tree nuts, soybeans, and seafood products. *Germany: Exporter Guide Annual*, USDA, Foreign Agricultural Service (Jul. 1, 2026), https://www.fas.usda.gov/data/gain/2026/07/germany-exporter-guide-annual.

58. Germany imported a total of $2.13 million during 2025 in whey and milk products from the U.S., according to the United Nations COMTRADE database on international trade. *Germany Imports from U.S. of Whey and milk products not specified elsewhere, flavored or not*, Trading Economics,

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

https://tradingeconomics.com/germany/imports/united-states/whey-milk-products-flavored (last visited on Jul. 24, 2026).

59. Dr. Krotzky consumes U.S. imported foods such as tree nuts, soybeans, seafood, whey, and milk products as part of his daily diet.

60. By denying the request for tolerances and/or action levels, Dr. Krotzky is at considerable risk of continued exposure to PFAS-adulterated foods imported from the U.S. into Germany.

61. Because Dr. Krotzky 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.

c. Plaintiff LOSD.

62. 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.

63. Plaintiff LOSD has already been exposed to PFAS.

64. 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.

65. 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 Jul. 30, 2026).

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

66. 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.

67. Pittsboro is currently being studied by North Carolina State University ("NCSU") because of the PFAS contamination in the area. *GenX Exposure Study*, NC State Univ., https://genxstudy.ncsu.edu/study-overview/ (last visited on Jul. 29, 2026). NCSU has found 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.

68. 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. PFAS have been detected in the Haw River and in the nearby Jordan Lake. *Where Are PFAS Found?*, UNC-Chapel Hill, NC Pure, https://ncpure.collaboratory.unc.edu/science/where-are-pfas-found/ (last visited on Jul. 29, 2026).

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

70. Chemours, a spinoff of Dupont, has been 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 Jul. 29, 2026).

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

71. 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. *U.S. 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.

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

73. Because PFAS has been detected in the source water used for drinking water in both Apex and Pittsboro, where Ms. Daussin has lived and worked, she has been exposed to PFAS-contaminated drinking water for an extended period. In addition, as discussed above, PFAS contamination in the environment transfers to food. As a result, Ms. Daussin has consumed locally grown foods that were likely contaminated with PFAS from environmental sources.

74. Ms. Daussin is harmed by FDA's denial of the Petition, as amended by the Supplement.

75. Ms. Daussin has high cholesterol, which is an adverse health effect associated with PFAS exposure. *Supra*, ¶¶36, 38.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

76. By denying the request for tolerances and/or action levels, Ms. Daussin is at considerable risk of continued exposure to PFAS-adulterated foods, increasing her risk of developing even more PFAS-related illnesses.

C. Petitioners' / Plaintiffs' Request.

77. The Petition requested the FDA Commissioner to establish new temporary tolerances at the MDLs for 30 PFAS in/on lettuce (head and leaf) and blueberries; and for 26 PFAS in/on ready-to-eat bread, milk, eggs, salmon, clams, corn silage, and corn snaplage. (Doc. 24-3, 2-5).

78. The request was for PFAS residues in these foods arising from the unavoidable environmental contamination, pursuant to 21 U.S.C. §346 of the FD&C Act. *Id.* Plaintiffs also invoked the FD&C Act's food additive provision (21 U.S.C. §348) because PFAS contamination in food is the direct result of human activity. *Id*., 3, 7, 12-14. This is most obvious when PFAS-contaminated pesticides, irrigation water, and biosolids are applied to food crops or when contaminated drinking water is provided to livestock. *Id*.

79. The Petition also requested that FDA lower the tolerances as their analytical methods improved and revoke the tolerances when there is no longer a reasonable risk of PFAS residues transferring to foods arising from environmental contamination. *Id.*

80. The specific foods and tolerances in the Petition were selected based on FDA's analytical method ("*PFAS 30 Method*"), which states that it was developed to target "analytes that have the potential to be found in the U.S. food supply" in the

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

"priority foods" identified by the European Commission, and using detection limits aligned with the European authorities. (*Id.*, 8; **Ex. 4**, 2, 7).[9]

81. Plaintiffs filed the Supplement to the Petition on May 15, 2025. Dkt. FDA-2023-P-4826-0013. The Supplement was previously filed with this Court. (Doc. 24-9).

82. In April 2024, FDA re-issued the *PFAS 30 Method* with additional validation data that covered all 30 PFAS in all foods at issue.

83. The re-issued method is entitled *Method No. C-010.03: Determination of 30 Per and Polyfluoroalkyl Substances (PFAS) in Food and Feed using Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)* (Apr. 12, 2024) (hereinafter "Method C-010.03"). (*Id*., 11; **Ex. 5**).[10]

84. The Supplement re-iterated the original request for tolerance-setting at the best available MDL for each food and PFAS identified. However, because FDA re-issued its method with additional validation data, the Supplement clarified that Plaintiffs sought tolerances for all 30 PFAS at the applicable MDLs in each of the previously identified food. (Doc. 24-9, 11-12).

D. Petitioners' / Plaintiffs' Alternative Request.

85. The alternative request provided in the Supplement sought enforceable tolerances only for PFOS and PFOA and only in milk and fish, which exhibited the highest incidence of PFAS contamination. *Id.*, 14, 17-27. Action levels, which are

[9] **Ex. 4** is FDA's *PFSA-30 Method* attached to the Petition as Appendix 1.
[10] Method C-010.03 attached here as **Ex. 5**.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

nonbinding and not directly enforceable, were requested for the remaining PFAS and food categories covered by the original Petition. *Id.*

86. The alternative request mirrors the current Administration's focus only on PFOS and PFOA in drinking water, and was intended to facilitate more immediate action. [11] *Id*.

E. FDA's Response.

87. FDA denied the Petition, as supplemented, in its entirety, because, allegedly, Plaintiffs did not provide enough evidence to support their requests. (**Ex. 1**, 25, 26).

88. FDA denied tolerance setting, contending the criteria for establishing tolerances had not been satisfied because there must be "[n]o technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established." *Id.*, quoting 21 C.F.R. § 109.6(b)(3).[12] Again quoting their regulation, FDA gave "anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable" and "anticipated studies expected to provide significant new toxicological or use data" as examples of such changes. *Id.*

89. FDA denied setting any action levels for PFAS on the same grounds, contending they had "achievability" concerns arising from what good manufacturing

[11] *Supra* at n. 3.

[12] As FDA has noted (**Ex. 1**, 11, n. 45), tolerances for corn silage and corn snaplage would be set under 21 C.F.R. part 509 not part 109. Nevertheless, because the criteria set forth in both parts are essentially the same, there is no distinction made here and there is only reference to 21 C.F.R. part 109 in throughout this Complaint.

practices ("GMPs") could be used to lower PFAS contamination, and the lack of toxicity data for some of the PFAS at issue. (**Ex. 1**, 18).

90. FDA justified their inaction on the basis that it already removes adulterated foods from the marketplace on a case-by-case basis, and therefore formal limits are unnecessary for it to protect public health. *Id*., 3, 5-7.

F. The Undisputed Facts.

91. FDA and Plaintiffs ("the Parties") agree that PFAS are a large class of persistent synthetic chemicals which have a widespread use in industrial and consumer products. (**Ex. 1**, 3, 4; Doc. 24-3, 6, 7; Doc. 24-9, 6.). Further, that these "forever chemicals" resist degradation and accumulate in the environment, humans, and animals. (**Ex. 1**, 4; Doc. 24-3, 7; Doc. 24-9, 7).

92. The Parties agree that certain PFAS compounds have been shown to cause serious adverse health effects, and that exposure of crops, livestock, and fish to PFAS-contaminated soil, water, and/or biosolids can result in PFAS-adulterated foods derived from those sources. (**Ex. 1**, 4, 5; Doc. 24-3, 7, 11, 12).

93. The Parties agree that data generated by FDA show that detectable PFAS residues have been found in milk, produce, fish, and other foods, demonstrating that PFAS contamination of the food supply is not speculative but already occurring. (**Ex. 1**, 5-7; Doc. 24-3, 9, 10; Doc. 24-9, 23, 27, 32).

94. The Parties agree that FDA's Total Diet Study has found PFAS in approximately 70% of the fish samples analyzed. (**Ex. 1**, 8; Doc. 24-9, 27).

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

95. The Parties agree that FDA currently does not consider cumulative effects from co-occurrence of multiple PFAS in a single sample when performing risk assessments on food contaminated with PFAS. (**Ex. 1**, 8; Doc. 24-3, 10).

96. Although FDA did not discuss Method C-010.03, there can be no dispute that it is capable of detecting the 30 PFAS in the foods at issue here. Method C-010.03 (**Ex. 5**) can be found following a link provided in FDA's response (**Ex. 1**, 5, n. 18) and is identified in the Supplement (Doc. 24-9, 11).

G. FDA Did Not Consider Material Evidence.

97. The primary reason FDA denied the Petition was because, allegedly, Plaintiffs did not provide enough evidence to support their request. (**Ex. 1**, 26). However, FDA ignored or did not consider material evidence provided by Plaintiffs, as follows.

a. FDA did not consider that certain PFAS are known carcinogens.

98. FDA failed to acknowledge or consider that EPA has found three of the PFAS at issue (PFOA, PFOS, and GenX (a/k/a HFPO-DA)) are carcinogenic. (Doc. 23-4, 11, n. 4, citing U.S. EPA: *Technical Fact Sheet– Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)* (Nov. 2017) at p. 3, https://19january2021snapshot.epa.gov/sites/static/files/2017-12/documents/ffrrofactsheet_contaminants_pfos_pfoa_11-20-17_508_0.pdf; *Human Health Toxicity Assessment for GenX Chemicals* (Mar. 2023) at p. 2, https://www.epa.gov/system/files/documents/2023-03/GenX-Toxicity-Assessment-factsheet-March-2023-update.pdf); *supra*, ¶¶37, 38.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

99. In fact, FDA admits that they evaluate PFAS using non-cancer toxic endpoints. (**Ex. 1**, 9, n. 36, citing *Toxicological Profile for Perfluoroalkyls*, ATSDR, https://wwwn. cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237).

b. FDA did not consider that PFAS pollution is widespread and increasing.

100. FDA ignored evidence cited in the Petition showing that PFAS contamination is widespread throughout the United States. This includes EPA data which shows that 95% of the wild-caught fish they sampled from rivers and streams nationwide contained detectable PFAS residues with some at extremely high levels. (Doc. 24-9, 26 citing *2018-2019 National Rivers and Streams Assessment Fish Tissue Study*, EPA (Last updated on Jul. 30, 2026) https://www.epa.gov/choose-fish-and-shellfish-wisely/2018-2019-national-rivers-and-streams-assessment-fish-tissue-study).

101. In addition, FDA ignored data cited in the Petition from the United States Geological Survey ("USGS"), which estimates that PFAS contaminate approximately 45% of U.S. drinking water. (Doc. 24-3, 7, n. 13 citing *Tap water study detects PFAS 'forever chemicals' across the U.S.*, USGS (Jul. 5, 2023); https://www.usgs.gov/news/national-news-release/tap-water-study-detects-pfas-forever-chemicals-across-us.

102. FDA also ignored the peer reviewed scientific study referenced in the Supplement, which notes that the U.S. is the global leader in PFAS-contaminated water. (Doc. 24-9, 21, citing Wee, S.Y., Aris, A.Z., npj Clean Water, *Revisiting the "forever chemicals," PFOA and PFOS exposure in drinking water* at pp. 5,6, Vol. 6, No. 57 (2023), https://doi.org/10.1038/s41545-023-00274-6).

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

103. FDA failed to acknowledge or address their own conclusion that because PFAS do not degrade, PFAS contamination in the environment is increasing over time. (Doc. 24-3, 7); *supra*, ¶34.

104. FDA likewise ignored evidence provided by Plaintiffs in an August 8, 2024 letter showing PFAS levels rising in milk over time, thereby demonstrating the need for urgent action. (Doc. 24-6).

105. Rather than address this evidence, FDA dismisses it by framing PFAS contamination as a problem with imported foods or is limited only to specific areas in the U.S., with the latter being handled on a case-by-case basis. (**Ex. 1**, 4-7).

106. However, Plaintiffs submitted data from the USDA data showing that five states produce more than half of the milk consumed in the United States. (Doc. 24-9, 22). Accordingly, foods such as milk are often produced in a limited number of regions but distributed nationwide. Thus, even if PFAS contamination were confined to certain areas, as FDA suggests (a premise contradicted by the EPA and USGS data discussed above), exposure would still be national because contaminated foods produced in those regions can enter the nationwide food supply. FDA failed to address the USDA data or explain why such food distribution patterns do not support regulation.

107. In addition, studies provided by Plaintiffs conducted by Consumer Reports found PFAS in 12% of the milk samples and 100% of infant formula samples purchased from stores located across the U.S. (Doc. 24-9, 24, 25, citing Kirchner, L. Consumer Reports, '*Forever Chemicals*' *Are Found in Some Milk, Including Organic, A Consumer Reports investigation highlights gaps in how the U.S. tests and regulates*

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

PFAS in food (May 2, 2024); and Kirchner, L. Consumer Reports*, We Tested 41 Baby Formulas for Lead and Arsenic* (Mar. 21, 2025), https://www.consumerreports.org/babies-kids/baby-formula/baby-formula-contaminants-test-results-a7140095293/).

108. FDA acknowledged the Consumer Report studies, but only to say they are unaware if the method used for data collection was validated or not. (**Ex. 1**, 14, n. 60).

109. Given the seriousness of these findings and the substantial public interest, FDA's failure to assess the Consumer Report data calls into question its assertion that their case-by-case method of monitoring the food supply is adequate. *Supra*, ¶¶90.

110. In addition, in early January 2025, right before this lawsuit was filed, FDA's own website included the statements regarding the widespread contamination of PFAS increasing over time, and that this contamination can enter the food supply. *Supra*, nn., 7, 8. However, these statements have since been removed. *Id*.

111. FDA ignored evidence in the Petition and Supplement, and its own prior statements, showing that PFAS contamination is widespread and increasing. As a result, FDA failed to explain how delaying regulation is rational given the undisputed facts that PFAS persist in the environment, migrate into food, and are linked to serious adverse health effects. *Supra*, ¶¶91-93.

H. FDA Ignored Its Mandate Under § 346 to Consider Cumulative Risks.

112. FDA claims the denial of the Petition was based on "our statutory authority and the available science." (**Ex. 1**, 16). However, the record shows otherwise.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

113. As explained in the Petition, consumers are exposed to multiple PFAS through food, drinking water, and other sources. (Doc. 24-3, 10; Doc. 24-9, 7).

114. For poisonous or deleterious substances unavoidably added to food, Congress expressly requires FDA to consider not only exposure from a particular substance, but also "*the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances*" (emphasis added). 21 U.S.C. § 346. FDA's regulations reiterate this requirement. (Doc. 24-3, 14, n. 57 citing 21 C.F.R. § 109.6(b)).

115. Here, FDA admits that it evaluates PFAS as *individual* compounds in each food sample and does not assess cumulative exposures to multiple PFAS at one time. **Ex. 1**, 8, 16-17. In addition, FDA states that when they evaluate a single food sample for a single PFAS, their scientists conduct a "safety assessment" to determine if the level of PFAS found was a health concern; however, there is no indication of how this assessment is done. *Id*., 6.

116. FDA does not discuss exposure to PFAS from other sources (e.g., drinking water, showering water, personal care products, dust) or through other routes (e.g. dermal or inhalation); nor do they explain how their individual compound / single food sample approach complies with the FD&C Act. *Id*., *generally*.

117. Thus, when responding to the Petition, FDA did follow the directive 21 U.S.C. § 346 to assess "*the other ways in which the consumer may be affected by the same or other poisonous or deleterious substance*."

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

118. Instead, FDA states methods for assessing cumulative PFAS exposure are still under development and points to future research, asserting that "the scientific understanding of PFAS occurrence in foods" has "began only recently." (**Ex. 1**, 7).

119. However, FDA has studied PFAS in the food supply for decades, including migration from food-contact substances since at least the early 2000s, and the Total Diet Study since 2019. (Doc. 24-9, 29; *Market Phase-Out of Grease-Proofing Substances Containing PFAS*, FDA (last updated on Jan. 03, 2025), https://www.fda.gov/food/process-contaminants-food/market-phase-out-grease-proofing-substances-containing-pfas).

120. Moreover, the existence of ongoing research does not relieve FDA of its present statutory obligation to consider cumulative and aggregate exposure when evaluating the Petition under 21 U.S.C. § 346.

121. FDA also fails to explain its departure from the approaches used by other public-health authorities.

122. As discussed in the Petition, EPA routinely evaluates both cumulative exposure to related chemicals and aggregate exposure across multiple pathways, including both food *and* drinking water. (Doc. 24-3, 10-11, 14).

123. Similarly, EFSA evaluates the combined risks of groups of PFAS rather than assessing each PFAS in isolation. (*Id*., 10-11).

124. FDA's reliance on its own failure to assess cumulative and aggregate PFAS exposure, despite the requirements of 21 U.S.C. § 346 and the practices of other public-health authorities, is arbitrary, capricious, and contrary to law.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

I. FDA Ignored its Mandate Under § 393 to Coordinate with EPA & USDA.

125. Congress expressly directed FDA to coordinate with "other science-based Federal agencies" on matters affecting food safety. 21 U.S.C. § 393(c).

126. Plaintiffs submitted a Freedom of Information Act request seeking communication documents FDA had with EPA or USDA concerning the Petition. (**Ex. 6**, 1, 6). FDA produced no responsive records. *Id.*

127. Moreover, FDA only recently (July 10, 2026) entered into an interagency memorandum of agreement with EPA and USDA to address environmental contaminants such as PFAS. (**Ex. 7**). This underscores a lack of coordination between the Agencies during the review process for this Petition.

128. The absence of documented interagency consultation is consistent with what is apparent from the face of FDA's response (**Ex. 1**): the conclusion that no PFAS tolerances or action levels are warranted was reached without meaningful consideration of, or input from, EPA's and USDA's relevant PFAS policies, regulations, scientific findings, or regulatory actions, as discussed below.

a. FDA did not coordination with EPA.

i. EPA's risk assessments under the FQPA are instructive.

129. The Petition relied on EPA's risk framework under the Food Quality Protection Act ("FQPA") as instructive because both pesticides and PFAS are toxic substances that contaminate food and water.

130. FDA dismissed the comparison on the grounds that PFAS tolerances would be established under 21 U.S.C. § 346 whereas pesticide tolerances are established under 21 U.S.C. § 346a. (**Ex. 1**, 22).

131. But noting in § 346a negates FDA's statutory duty is to ensure the nation's food is safe or to coordinate with its sister agencies to this end. 21 U.S.C. § 393.

132. Under the FQPA, when setting tolerances for pesticides, EPA must assess exposure to chemicals with a common mechanism of toxicity and across multiple exposure pathways. *Guidance for Identifying Pesticide Chemicals and Other Substances That Have a Common Mechanism of Toxicity*, EPA (Jan. 29, 1999), p. 1, available at https://www.epa.gov/sites/default/files/2015-07/documents/guide-2-identify-pest-chem_0.pdf. See also *Conducting a Human Health Risk Assessment*, EPA (last updated on Jan. 13, 2026), https://www.epa.gov/risk/conducting-human-health-risk-assessment. 21 U.S.C. § 346a of the FD&C Act also describes a similar cumulative risk assessment process.

133. Thus, EPA's requirements for tolerance-setting for pesticides in foods closely mirrors FDA's duty under 21 U.S.C. § 346 which, as above, also requires an assessment of cumulative risks. *Supra,* §VI.H.

134. Thus, FDA's dismissal of EPA's risk assessments for pesticides under the FQPA is irrational and groundless.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

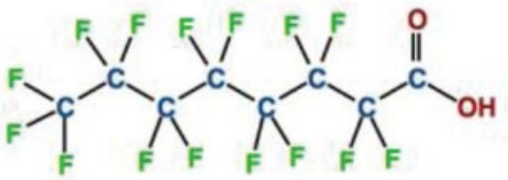
ii. EPA's treatment of structurally similar chemicals

135. Plaintiffs argued that, based on EPA's risk assessment processes under the FQPA, the similarly structured PFAS should be presumed to behave similarly in the human body. (Doc. 24-3, 13, 15).

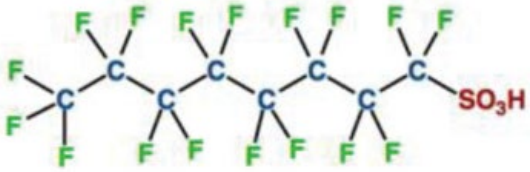
136. Plaintiffs referenced EPA's data which found that for all PFAS that have been adequately studied, essentially the same or similar toxic effects have been observed. (*Id*., 12, n. 41 citing *IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA, CASRN 375- 22-4) and Related Salt*s, EPA (Dec. 2022) at 4-4, available at https://iris.epa.gov/static/pdfs/0701tr.pdf).

137. FDA dismissed this by claiming Plaintiffs, "citing no data," want FDA to assume all of the thousands of PFAS known share a common mechanism of toxicity. (**Ex. 1**, 16). Plaintiffs made no such claim.

138. The broader class of PFAS, not at issue here, includes polymeric and high-molecular-weight compounds with dozens or even hundreds of Carbon atoms. The 30 PFAS identified in the Petition have only between 4 and 14 Carbon atoms and are similarly structured. For example, PFOA and PFOA each have 8 Carbon atoms and have substantially similar chemical structures as shown below.



PFOA - perfluorooctanoic acid



PFOS - perfluorooctanesulfonic acid

139. EPA has long held structurally related chemicals are be presumed to have similar toxicological behavior. *Guidance for Identifying Pesticide Chemicals and Other Substances That Have a Common Mechanism of Toxicity* (Jan. 29, 1999), EPA at pp. 6-7, available for download at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-pesticide-chemicals-and-other (last updated on Feb. 26, 2026).

140. The assumption is that "substances that are structurally analogous ... interact analogously with cellular biomolecular sites to cause a common toxic effect." *Id.*, 7.

141. In fact, FDA's own data shows it is fair to assume that, for at least PFOA and PFOS, there is a common toxic mechanism. For instance, data cited by FDA's notes that for PFOS and PFOA "it is not unreasonable to speculate that interactions at the [gene] receptor level might occur." (**Ex. 1**, 9, n. 36, citing *Toxicological Profile for Perfluoroalkyls*, ATSDR (2021), https://wwwn.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237 (quotation found in Ch. 3, p. 634, available following links)).

142. Thus, FDA failed to provide a reasoned explanation for rejecting EPA's risk assessment principles regarding similarly structured compounds in violation of 21 U.S.C. § 393(c).

iii. EPA's risk assessment as applied to PFAS in drinking water.

143. FDA largely ignored EPA's risk assessments for PFAS as applied to drinking water, except to mention that they are assessing EPA's PFAS National Primary Drinking Water Regulation as it relates to bottled water, and that the Trump Administration's EPA has proposed rescinding certain PFAS the from Biden-era 2024 drinking water standards. (**Ex. 1**, 15, 16, n. 75). Otherwise, FDA did not account for the PFAS drinking water standards. *Id*., *generall*y.

144. EPA set the standards for certain PFAS in drinking water under the Safe Drinking Water Act ("SDWA") in April 2024. 89 Fed. Reg. 32532.

145. Under the SDWA, the Maximum Contaminant Level Goal ("MCLG") is "set at the level at which no known or anticipated adverse effects on the health of persons occur," and reflects a purely health-based determination considering exposures for sources other than drinking water and health effects on sensitive subpopulations, such as infants and children. 42 U.S.C. §§ 300g-1(b)(4)(A), 300g-1(b)(3)(C)(i)(V).

146. EPA sets a zero MCLG where a contaminant is both "there is evidence that a chemical may cause cancer" and "there is no dose below which the chemical is considered safe." *How EPA Regulates Drinking Water Contaminants*, EPA (last

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

updated on Mar. 2, 2026), https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants.

147. The MCL reflects the closest enforceable standard that is technologically feasible by water treatment facilities in practice, taking into consideration costs as required by the SWDA. 42 U.S.C. §§ 300g-1(b)(4)(B)&(D).

148. For each PFOA and PFOS, EPA set the MCLG at zero, having determined that there is no known level in drinking water that can be considered protective of human health, taking into account all other exposure routes. 89 Fed. Reg. 32535, 32563. MCLs were set at 4 ppt for each PFOS and PFOA. *Id*. at 32573.

149. FDA acknowledged that EPA has recently reaffirmed its conclusion that no safe level of exposure exists for either PFOS or PFOA. (**Ex. 1**, 16, n. 75).

150. Under federal law, EPA may not arbitrarily disregard relevant routes or sources of human exposure when establishing health-based drinking-water standards. *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290-91 (D.C. Cir. 2000). See also *Conducting a Human Health Risk Assessment*, EPA (last updated on Jan. 13, 2026), https://www.epa.gov/risk/conducting-human-health-risk-assessment; *Regulating Contaminants Under the Safe Drinking Water Act (SDWA)* (updated Sept. 10, 2024) Cong. Rsch. Serv, https://www.congress.gov/crs-product/R46652 (available at following link).

151. Similarly, FDA cannot arbitrarily disregard drinking water when establishing PFAS limits in foods. *Chlorine Chemistry Council*, 206 F.3d at 1290-91.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

152. Yet FDA never explains how *any* additional exposure through food can be considered safe, considering the zero MCLGs for PFOS and PFOA in drinking water, nor why tolerances at the MDLs for food as requested in the Petition would be inappropriate.

153. More importantly, FDA offers no reasoned explanation for rejecting EPA's risk assessment framework used for drinking water, which accounts for sensitive populations such as children, notwithstanding their previous acknowledgement that children are particularly vulnerable to PFAS exposure. (Doc. 24-10, 43, 44).

154. Thus, FDA's denial failed to consider one of the most important aspects of the problem here. That is, *any* additional exposure to at least PFOS and PFOA through adulterated foods is too much. Using EPA's terminology, "the risk cup is full."[13]

b. FDA did not coordination with USDA.

155. Since 2021, USDA has operated a program to assist dairy farmers affected by PFAS contamination. *Dairy Indemnity Payment Program Expanded to Assist with Livestock Losses Due to Contamination*, USDA (Dec. 9, 2021),

[13] EPA's "risk cup" concept developed for evaluating risk of exposure to pesticides is instructive, but FDA completely ignores it. See PRN 97-1, *Agency Actions Under the Requirements of the Food Quality Protection Act*, EPA (Jan. 31, 1997), https://www.epa.gov/pesticide-registration/prn-97-1-agency-actions-under-requirements-food-quality-protection-act. For a given pesticide, if adding another exposure source (e.g., allowing the new use on a new crop), increases the risk beyond the health-based standards, the risk cup is deemed full, and the new use will not be permitted. *Id*.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

https://www.fsa.usda.gov/news-events/news/12-09-2021/dairy-indemnity-payment-program-expanded-assist-livestock-losses-due.

156. FDA does not discuss this USDA program, even though milk is one of the commodities at issue here.

157. USDA's decision to establish and continue this program reflects its recognition that PFAS contamination of livestock and dairy products is an ongoing and significant problem, contrary to FDA's characterization of such incidents as isolated occurrences. (**Ex. 1**, 5, 6, 14; Farmers.gov, *Per- and Polyfluoroalkyl Substances (PFAS)*, USDA, https://www.farmers.gov/protection-recovery/pfas (last visited on Jul. 24, 2026)).

158. Notably, FDA only acknowledged PFAS-contaminated milk from New Mexico (~2050 miles from Maine as the crow flies) in its response. (**Ex. 1**, 5, 6, 14). There is no mention of Maine. *Id*., *generally*.

159. Under the USDA program, dairy producers qualify for assistance when their livestock produces whole milk that is removed from a commercial market at the direction of a public agency. Farmers.gov, *Per- and Polyfluoroalkyl Substances (PFAS)*, USDA*; see also* 7 C.F.R. Part 760, Subpart A.

160. Maine is currently the only state that has established regulatory limits for PFAS in milk. *PFAS and Agriculture*, Maine Center for Disease Control & Prevention, https://www.maine.gov/dhhs/mecdc/healthy-living/health-and-safety/pfas-in-maine/pfas-and-agriculture (last visited Jul. 24, 2026).

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

161. Because FDA has never established an action level or tolerance for PFAS in milk, or publicly disclosed how it determines what is "unsafe," the vast majority U.S. dairy farmers are left no clear standard to evaluate contamination, no mechanism for obtaining the USDA-required government directive to remove milk from commerce, and therefore no obvious path to indemnification.

162. Dairy farmers outside of Maine are in impossible position: if they do not test, they risk unknowingly selling contaminated milk; if they do test and discover PFAS contamination, they have no guidance as to whether the milk should be withheld from the market, discarded, or sold.

163. Thus, FDA's failure to coordinate with USDA not only violates 21 U.S.C. § 393(c) but also creates a perverse incentive for dairy farmers to avoid testing milk for PFAS contamination. Without coordinated federal standards and a clear regulatory framework, farmers outside of Maine who test and discover contamination may face significant economic consequences, while those who do not test avoid identifying adulteration. This lack of coordination undermines early detection, discourages transparency, and increases the risk that PFAS-contaminated milk will remain in the food supply.

J. FDA Denial Exceeds Its Authority Under § 346.

164. FDA stated, "the question of whether it is necessary to establish a tolerance to protect the public health *is firmly within FDA's purview*" and "there is no legal requirement that FDA to do so." (**Ex. 1**, 20, n. 89 citing *Young v. Community Nutrition Institute*, 476 U.S. 974, 981-82 (1986)).

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

165. However, FDA has misconstrued *Young* and has overreached its authority. In *Young*, the Supreme Court evaluated 21 U.S.C. § 346 in the context of setting action levels or tolerances for aflatoxin, a naturally occurring toxic mold. *Young*, 476 U.S. at 975.

166. *Young* was decided applying the deferential *Chevron* doctrine, which has since been overturned. *Id.* at 974; *Loper Bright Enters*, 603 U.S. 369.

167. *Young* did not address synthetic poisons such as PFAS, and FDA's own regulations show that this distinction is material. See 21 U.S.C. § 342(a)(1); 21 C.F.R. § 109.3(d) [14]

168. Nevertheless, FDA contends that its absolute discretion under 21 U.S.C. § 346 is settled law, stating that reliance on *Chevron* does not justify overruling *Young*. (**Ex. 1**, 20, n. 89, citing dicta *Loper Bright*, 603 U.S. at 376 discussing *stare decisis*)). However, the *Loper Bright* reference to *stare decisis* it is not as broad as FDA represents; it applies only to "specific" agency actions. *Loper Bright* at 376.

169. The holding of *Loper Bright* is "[c]ourts *must* exercise their independent judgment in deciding whether an agency has acted within its statutory authority" (emphasis added). *Loper Bright* at 412-13.

[14] Naturally occurring poisonous or deleterious substances are deemed "added poisonous or deleterious substances" only to the extent that their levels have been increased abnormally through mishandling or other intervening acts. 21 C.F.R. § 109.3(d).

170. Thus, although *Loper Bright* did not overrule *Young*'s result regarding tolerance-setting for aflatoxin, a naturally occurring deleterious substance, it eliminated the deferential framework on which *Young* relied and requires judicial review here.

171. In *Loper Bright*, the Court explained that *Chevron* was "unworkable" because the threshold determination whether a statute is "ambiguous" can itself be highly subjective as statutory ambiguity "has always evaded meaningful definition." *Id.* at 407-08.

172. This was an issue in *Young*, as shown by the Justice Steven's dissent where he argues the words "shall promulgate regulations" in 21 U.S.C. § 346 were unambiguous and leaving the agency no discretion. *Id.*

173. It is well-established that "[t]he word 'shall' generally indicates a command" allowing "no discretion." *Nat. Res. Def. Council v. Regan,* 67 F.4th 397, 402 (D.C. Cir. 2023).

174. Indeed, before being reversed by the Supreme Court, the D.C. Circuit agreed with Justice Stevens and concluded that 21 U.S.C. § 346 imposed a mandatory duty on the FDA to promulgate tolerance regulations for aflatoxins. *Cmty. Nutrition Inst. v. Young*, 757 F.2d 354, 358 (D.C. Cir. 1985), *rev'd*, 476 U.S. 974 (1986).

175. Accordingly, the better reading of 21 U.S.C. § 346 on these facts is that the FDA *must* establish tolerances for the PFAS at issue, while retaining discretion only as to the tolerance level itself. Nevertheless, the extent of FDA's discretion here is a question for this Court; not FDA. *Loper Bright*, 603 U.S. at 412-13.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

176. Finally, even if FDA has discretion to set tolerances for PFAS under § 346, they have unlawfully abused this discretion as alleged herein, and their refusal to set PFAS tolerance should be set aside pursuant to 5 U.S.C. § 706 (2).

K. FDA's Achievability Rationale is Illogical.

177. FDA asserts that action levels and tolerance setting must take into consideration "achievability" using GMPs. See **Ex. 1**, 18 discussing action levels, and **Ex. 1**, 23 discussing tolerances.

178. However, GMPs address contamination arising during manufacturing, handling, and processing of foods. 21 C.F.R. Part 110.

179. The FD&C Act defines raw agricultural commodities ("RACs") as "any food in its raw or natural state ... in its natural form prior to marketing." 21 U.S.C. § 321(r). Courts have recognized fish as RACs. *See U.S. v. Goodman*, 486 F.2d 847, 850 (7th Cir. 1973). GMPs do not apply to RACs. 21 C.F.R. Part 110, *generally*.

180. Here, the requested tolerances and/or action levels are for the RACs lettuce (head and leaf), blueberries, milk, eggs, salmon, clams, corn silage, and corn snaplage and for ready-to-eat bread. (Doc. 24-3).

181. RACs are in their natural state, at harvest (for crops and fish) or collection (for milk). Adulteration of RACs arising from environmental contamination occurs before handling, manufacturing, or processing. Thus, GMPs are irrelevant for RACs.

182. Although bread is a processed food, the requested tolerances and/or action levels address PFAS contamination from the environment, not from manufacturing**.** (Doc. 24-3, 3).

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

183. Moreover, FDA admits it is "not aware of a way to remove PFAS from foods once contaminated." (**Ex. 1**, 23, n.108). That is, PFAS arising from environmental contamination cannot be removed through GMPs. Thus, it makes no sense to delay or deny action levels or tolerances based on whether manufacturers can reduce PFAS contamination through GMPs.

184. Nothing in the FD&C Act requires FDA to determine how much of a poisonous or deleterious substance can be removed from food before establishing a tolerance or action level. Rather, Congress recognized that some contaminants are *unavoidable* and directed FDA to establish safe limits where appropriate. 21 U.S.C. § 346.

185. That is, achievability / GMPs has no relevance here because the contamination at issue occurs before food enters the manufacturing chain. FDA fails to address this critical distinction.

186. To the extent achievability might be relevant, the germane question is whether environmental contamination can be prevented. However, that inquiry falls outside FDA's statutory mandate under the FD&C Act.

L. FDA Deviates Without Reason from Past Practices.

a. FDA has set action levels for unavoidable lead and arsenic.

187. FDA has regulated naturally occurring lead and arsenic with action levels, but FDA offers no reasoned explanation why PFAS, which are entirely man-made, should remain without comparable limits.

188. FDA defends its refusal by asserting its prior decisions for arsenic and lead actions were supported by a sufficiently robust scientific record, while the PFAS record is not. (**Ex. 1**, 17, 18).

189. However, FDA's comparison to lead and arsenic is flawed because those substances are subject to a different legal and scientific framework than PFAS, as discussed below.

190. ***First***, from the legal standpoint, the distinction between naturally occurring and man-made substances is material. Naturally occurring poisonous or deleterious substances are deemed "added poisonous or deleterious substances" only to the extent that their levels have been increased abnormally through mishandling or other intervening acts. 21 U.S.C. § 342(a)(1); 21 C.F.R. § 109.3(d).

191. In contrast, for a synthetic compound, such as PFAS, any level found in food above zero can only be present due to human activity. Therefore, any level above zero could be deemed unsafe. See 21 C.F.R. § 109.4(a), "[a] tolerance may prohibit *any* detectable amount of the substance in food."

192. Moreover, the action levels for arsenic and lead were set on processed commodities (e.g., apple juice), where GMPs are relevant. (**Ex. 1**, 18). However, as discussed above, GMPs have no relevance here. *Supra*, §VI.K.

193. ***Second,*** from a scientific viewpoint, FDA's description of its risk assessment for lead and arsenic again illustrates a material distinction.

194. FDA cites human health data, not toxicology studies, that were used to set the lead and arsenic action levels. For example, the lead action levels were based on a

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

Blood Lead Reference Value, which "is not a health-based standard or a toxicity threshold;" rather, it is a human population-based benchmark. (**Ex. 1**, 18; *CDC Updates Blood Lead Reference Value*, CDC (Apr. 2, 2024), https://www.cdc.gov/lead-prevention/php/news-features/updates-blood-lead-reference-value.html).

195. Similarly, the arsenic action levels were set using human epidemiological studies of Taiwanese populations exposed to arsenic in drinking water. (**Ex. 1**, 13, 18, nn. 54, 86, citing *Guidance for Industry: Inorganic Arsenic in Rice Cereals for Infants* (Aug. 2020) & *Guidance for Industry: Action Level for Inorganic Arsenic in Apple Juice* (Jun. 2023), each citing Chen C-L et al., *Cancer Epidemiology, Biomarkers & Prevention* 19(1):101-110 (2010), and Chen C-L et al., *Environmental Research* 110(5):455-462 (2010)).

196. In contrast, FDA admits that 10 of the 30 PFAS at issue have toxicological reference values ("TRV") which they use to perform PFAS risks assessments in food. (**Ex. 1**, 8). Unlike the human data (BLRV and the epidemiology studies) used for lead and arsenic, the TRVs are experimentally derived from toxicology studies. *Id*.

197. ***Finally***, FDA fails to explain how animal toxicology studies compare to human epidemiological studies or what level of evidence it considers sufficient to support regulation. For naturally occurring substances, where humans are already exposed to background levels, reliance on epidemiological evidence to demonstrate health effects above background exposure may be rational. However, for synthetic compounds with known toxicity, FDA's apparent insistence on additional

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

epidemiological evidence before conducting a risk assessment defies logic. Under that approach, FDA would effectively be waiting for further human exposures and resulting health effects before determining what level of exposure is safe in food.

b. FDA has set tolerances for PCBs.

198. FDA has set tolerances for PCBs, synthetic industrial chemicals that became widespread environmental contaminants, which are a more relevant comparator to PFAS than lead or arsenic. However, FDA fails to provide a logical rationale for why tolerances should not also be set for PFAS.

199. Under 21 C.F.R. § 109.30, FDA established temporary tolerances for PCBs after determining that they had become a "persistent and ubiquitous contaminant in the environment" as a result of their "widespread, uncontrolled industrial applications." 21 C.F.R. § 109.30(a).

200. FDA found that, like PFAS, PCBs entered the food supply through environmental contamination *and* food-contact materials. *Id*.; **Ex. 1**, 4, n. 16.

201. However, unlike PCBs, whose manufacture was prohibited in the U.S. in 1979 (44 Fed. Reg. 31514 (May 31, 1979)), PFAS continue to be manufactured, used, imported, and released into the environment.

202. By some accounts, PFAS are even more difficult to control than PCBs. In the words of one 3M scientist spoken in 1999, PFAS are "probably more damaging than PCB, because it does not degrade and PCB does." (Doc. 24-9, 9; Doc. 24-4, 2). Moreover, PFAS are highly mobile in water and readily migrate through groundwater, drinking-water systems, irrigation supplies, and livestock watering systems. (Doc. 24-3,

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

7). Whereas PCBs, which are more lipophilic, do not disperse as readily through water pathways.

203. Yet, FDA did not decline to set tolerances for PCBs, notwithstanding the legal challenges they faced in doing so. FDA notes that the tolerance-setting process began in 1972 but did not culminate in a final regulation until 1983 because of objections and litigation. (**Ex. 1**, 25).

204. Here, there are no such obstacles. All procedural steps have been followed, and no one has challenged the requests in the Petition or its Supplement.

205. FDA's only argument for not following the same path as PCBs is that the record for PFAS lacks the "stability" needed before tolerance-setting. As below, this argument runs counter to the evidence before the agency and is implausible. *Infra,* §VI.M.

c. FDA has a process to regulate PFAS in bottled water as a food.

206. Bottled water is a food under the FD&C Act. See 21 U.S.C. § 321(f) which encompasses bottled water as an "article used for drink for humans." FDA's regulations governing bottled water's identity, quality standards, labeling, and manufacturing practices confirm this, as they are all within the "Food for Human Consumption" subchapter. 21 C.F.R. §§ 100.1–190.6.

207. FDA acknowledges it is responsible for regulating PFAS in bottled water pursuant to 21 U.S.C. § 349. (**Ex. 1**, 15, n. 68). When EPA's new MCLs for PFAS in drinking water were established, the so-called "hammer provision" of the FD&C Act was triggered. 21 U.S.C. § 349(b). Under this provision, FDA has a set time to either

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

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*. See also *FDA Shares Testing Results for PFAS in Bottled Water*, FDA (last updated on Apr. 14, 2025), https://www.fda.gov/food/hfp-constituent-updates/fda-shares-testing-results-pfas-bottled-water.

208. However, FDA does not reconcile its inconsistent treatment of EPA's MCLs, relying on them for the food bottled water, and disregarding them for the other foods at issue here.

M. FDA's "Stability" Rationale is Implausible.

209. FDA argues that PFAS do not present the type of "stable" circumstances necessary for tolerance-setting under 21 U.S.C. § 346 (Section 406 of the FD&C Act). (**Ex. 1**, 24-26). FDA relies on historical statements that 21 U.S.C. § 346 should be used primarily in "relatively static circumstances." (**Ex. 1**, 24, citing 39 Fed. Reg. 42734, 42745 (Dec. 6, 1974)).

210. FDA's discussion reveals that its claimed lack of stability rests on two distinct rationales: (1) alleged scientific instability and (2) ongoing manufacturing and environmental releases of PFAS. Neither rationale support denying the Petition.

a. FDA's scientific "instability" rationale is unsupported.

211. FDA does not dispute the central scientific facts underlying the Petition: PFAS are persistent in the environment and contaminate food, PFAS exposure presents

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

significant toxicological concerns, and validated methods exist to detect the PFAS at issue in the identified foods. (**Ex. 1**, 4-5).

212. Nor does FDA dispute that other regulatory authorities, including EPA and EFSA, have already completed extensive risk assessments and established regulatory standards for at least PFOA and PFOS. *Id*., 16, 22 nn. 75, 101.

213. FDA attempts to show the purported lack of scientific instability by noting EPA has lowered its RfD (Reference Dose, an experimentally determined health benchmark) for PFOA by approximately 700-fold between 2016 and 2024.[15] *Id*., 9.

214. But this does not reflect uncertainty about whether PFOA is harmful. Rather, it reflects the accumulation of additional scientific evidence demonstrating that PFOA is substantially more toxic than previously understood.

215. FDA's position here is also inconsistent with its past practice.

216. When FDA set action levels for lead, it expressly sought public comment on whether the proposed levels should be lower, recognizing that standards may be refined over time without delaying initial regulatory action. ("We are particularly interested in whether there is data and information that would support a lower action level." 88 Fed. Reg. 4797, 4798, (Jan. 25, 2023)). This shows that FDA has not treated future stricter limits as a reason to refrain from establishing any limits at all.

[15] FDA refers to an experimentally determined health-based threshold as the Toxic Reference Value or "TRV." For the purposes of this Complaint, a Reference Dose ("RfD") is a sub-type of a TRV.

217. FDA further argues that it cannot establish tolerances or action levels because TRVs are available for only 10 of the 30 PFAS identified in the Petition. (**Ex. 1**, 8, 18).

218. Yet this does not explain why FDA failed to establish limits for the 10 PFAS for which TRVs already exist. The lack of TRVs for some PFAS is not a reason to forgo regulation of those for which the necessary toxicological benchmarks are already available.

219. FDA also states their analytical methods will "likely" improve in the future, providing this as a reason to delay regulation. *Id*., 9. They reference the possibility that detection limits may be lowered or more food types could be added to the method. *Id*.

220. However, the possibility of improved detection methods at some point in the future is not a scientific or legal basis for declining to set action levels or tolerances now. More sensitive analytical methods in the future will only strengthen FDA's ability to identify contaminated food, enforce regulatory limits, and protect public health.

221. FDA's stability rationale is particularly untenable for PFOS and PFOA. EPA, including under the current Administration, has reaffirmed that there is effectively no safe level of exposure to either compound. *Supra*, ¶149. Accordingly, FDA cannot plausibly contend that additional study is necessary before minimizing PFOS and PFOA exposure in food to the greatest extent possible.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

222. The Supreme Court has held that an agency may not "avoid its statutory obligation" by invoking scientific uncertainty as a basis for inaction. *Massachusetts,* 549 U.S. at 534.

223. Scientific uncertainty and better understanding in the future is "a possibility that will always be present." *Chlorine Chemistry Council*, 206 F.3d at 1290-91.

224. Thus, FDA's scientific stability argument is illogical, unsupported by the record, and not consistent with federal law.

b. FDA's "stability" concern stems from continuing PFAS pollution.

225. In the discussion regarding the need for stable circumstances, FDA notes that although the PCB tolerance-setting process began in 1972 and it was delayed by objections and litigation until 1983 (**Ex. 1**, 25).

226. FDA does not highlight the fact that 1983 was four years after PCB manufacture was largely prohibited in the United States. *Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions*, 44 Fed. Reg. 31514 (May 31, 1979). This fact suggests that FDA is attempting to avoid the litigation they experienced with PCBs by waiting until PFAS is no longer manufactured before setting tolerances.

227. However, nothing in 21 U.S.C. § 346 provides that elimination of all contamination sources must be achieved before tolerances may be established.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

228. Furthermore, FDA did not wait for PCB contamination to disappear before acting; it established temporary tolerances while requiring contamination reductions. 21 C.F.R. § 109.30.

229. Plaintiffs' request for temporary PFAS tolerances follows that same model by addressing unavoidable contamination today while driving contamination downward over time. *Id*.

230. FDA's position is particularly irrational with respect to PFOA and PFOS.

231. It has long been recognized that PFOA and PFOS can be formed through the degradation of other PFAS compounds that continue to be manufactured, used, and imported. (Doc. 24-3, 12, n.40, citing EPA, *Technical Fact Sheet: Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)* (Nov. 2017) at 5).

232. Thus, even though PFOA and PFOS are no longer manufactured domestically, waiting to establish limits in foods until all precursor PFAS are banned will delay regulation indefinitely.

233. Under FDA's reasoning, the more persistent and widespread PFAS contamination becomes, the less likely FDA is to establish tolerances. That approach turns 21 U.S.C. § 346 on its head.

234. FDA's interpretation effectively rewards continued environmental releases by allowing contamination to remain unregulated until the contamination problem largely resolves itself, a result that finds no support in the statutory text or the purpose of the FD&C Act.

N. FDA's Denial Raises Constitutional and APA Concerns.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

235. FDA admits the Agency addresses PFAS contamination through a case-by-case enforcement approach. (**Ex. 1**, 3). FDA conducts safety assessments, issues recalls, and removes contaminated products from the market, yet refuses formal tolerances or action levels that would define when PFAS renders food adulterated. *Id*., 5-7.

236. This inconsistency raises serious concerns under the APA. Agencies must provide a reasoned explanation when their policies or practices are inconsistent or reflect a change in position. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) (" [u]nexplained inconsistency" in agency policy is "a reason for holding an interpretation to be an arbitrary and capricious change from agency practice;" *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books); *Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 966 (9th Cir. 2015) ("Unexplained inconsistency" between agency actions is "a reason for holding an interpretation to be an arbitrary and capricious change.").

237. What's worse, FDA provides no specific guidance on what criteria they use to determine if a PFAS-contaminated food is considered unsafe. FDA only refers to the "evolving science" and their other priorities which have prevented them from gathering the necessary information, whatever that is, to establish transparent action levels or tolerances. (**Ex. 1**, 7-9, 16, 17, 25, 26).

238. FDA's website fairs no better. Reiterating the case-by-case approach, FDA provides only general guidelines, stating it "considers a number of factors,

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

including how much of the specific food people typically eat, the level of the PFAS detected in that food, and scientific information on the toxicity of the specific PFAS detected" and that it "monitors the scientific literature and available toxicological reference values (TRVs) for PFAS and updates the values used for assessments, as warranted." *Testing Food for PFAS and Assessing Dietary Exposure: FDA Approach to Human Health Assessments*, FDA (last updated on Dec. 19, 2025), https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure.

239. Introducing adulterated food into interstate commerce is a prohibited act subject to civil and criminal penalties. 21 U.S.C. §§ 331, 333.

240. FDA's failure to set objective standards identifying the levels of PFAS that render food adulterated, renders §§ 331, 333 as applied to PFAS, unconstitutional under the void-for-vagueness doctrine. Fair notice of prohibited conduct is required as a guard against arbitrary enforcement. *Berger v. U.S.*, 200 F.2d 818, 821 (8th Cir. 1952) (criminal statutes that fail to provide adequate notice are unconstitutional).

241. Without such standards, FDA's case-by-case determinations for PFAS risk become the type of "standardless sweep" that permits enforcement based on the personal predilections of regulators, prosecutors, or juries. *Kolender v. Lawson*, 461 U.S. 352, 357-58 (1983) (regulators must provide guidelines to prevent arbitrary enforcement).

O. FDA Rejects MDL Limits Without Addressing the Facts in the Record.

242. FDA criticizes Plaintiffs' reliance on MDLs for tolerance setting as insufficiently "science-based," noting that its arsenic action levels were "not solely based on method detection limits." (**Ex. 1**, 13).

243. However, FDA's *PFAS 30 Method* was specifically developed to detect the PFAS most likely to occur in the U.S. food supply in the priority foods and at detection limits identified by the European Commission. (Doc. 24-3, 8; **Ex. 4**, 2, 7).

244. The alignment with the EU is significant because under 21 U.S.C. § 381(e)(1) of the FD&C 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."

245. The European Commission has now 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, https://eur-lex.europa.eu/eli/reg/2023/915/oj/eng; *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.

246. The proposed MDL-based tolerances would serve the dual purpose of protecting public health and helping ensure that foods exported from the United States to jurisdictions such as Germany, where Plaintiff Dr. Krotzky resides, comply with applicable foreign PFAS standards.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

247. By reducing the risk that exported foods will be deemed unsafe or adulterated abroad, the MDL-based tolerances also would benefit U.S. growers and producers who depend on access to foreign markets.

248. Moreover, FDA failed to assess cumulative risks in violation of §346 (*supra*, §VI.H.) and ignored EPA's risk assessment methods and results for drinking water in violation of §393 (*supra*, §VI.I.a). Because of this they failed to reach the reasoned conclusion that there is no more room in the "risk cup" for the PFAS at issue in food, particularly PFOA and PFOS. Therefore, tolerance-setting at the lowest reliably measurable level is both scientifically and legally justified.

249. Plaintiffs acknowledged that a true zero-tolerance standard is not analytically practicable and that FDA's regulations permit tolerance setting at the MDL. (Doc. 24-3, 16, citing 21 C.F.R. §§ 109.4, 109.6(b)).

250. Recognizing that regulatory limits are meaningful only if they can be enforced, Plaintiffs selected commodities and MDLs based on FDA's existing validated method. (Doc. 24-3, 14).

251. Finally, as discussed above, arsenic is a naturally occurring contaminant subject to a different legal and scientific framework than PFAS, and any comparison is irrelevant. *Supra*, ¶¶191, 192.

P. Method C-010.03 Supports Efficient Regulatory Enforcement.

252. There is no dispute that Method C-010.03 has been validated for the PFAS compounds and food commodities identified in the Petition. (**Ex. 5**).

253. Plaintiffs assert that Method C-010.03 is now available for tolerance enforcement for all the commodities and PFAS at issue here. (Doc. 24-9, 11).

254. However, FDA characterizes their PFAS analytical methods generally as an evolving area in which lower detection limits are being developed and additional commodities remain under study. (**Ex. 1**, 8, 16).

255. The possibility of future methodological improvements, however, is not a valid basis for refusing regulation today. FDA identifies no scientific, technical, or regulatory limitation that would prevent the Agency from relying on Method C-010.03 to establish and enforce tolerances for the PFAS compounds and commodities identified in the Petition.

256. Moreover, as provided in the Supplement, the existence of a validated enforcement method provides a means for prompt intervention when contaminated food is detected, and is preferable to FDA's current method of monitoring through the Total Diet Study. (Doc. 24-9, 28-32).

257. Unlike the Total Diet Study, FDA's tolerance-enforcement program is designed to support regulatory action by identifying and removing adulterated products from commerce quickly. *Id.* For example, FDA's Total Diet Study samples collected between FY2018 and FY2021 were not analyzed until 2019-2023, reflecting delays that may be acceptable for research purposes but are poorly suited to addressing known contamination risks. *Id.* By contrast, tolerance-based monitoring supports real-time enforcement and marketplace intervention. *Id*

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

258. In addition, the tolerance enforcement program screens far more samples. For instance, FDA analyzed 172 fish samples and 39 dairy samples through its enforcement program in FY2019 alone. *Id.*, 30. By contrast, FDA took six years (2019-2025) to test only 28 fish samples, 28 milk samples, and a single milk-based infant-formula sample under the Total Diet Study. *Id*., 31.

259. Nevertheless, FDA argued that Plaintiffs' reference to the pesticide tolerance-enforcement program is irrelevant because (1) FDA is not required to establish a new enforcement system for substances that are not pesticides, (2) an enforcement program is not a statutory criteria to determine if a tolerance should be set, and (3) the PFAS at issue are not pesticides. (**Ex. 1**, 26, n. 128, citing 21 U.S.C. § 1401).

260. However, the statute cited by FDA, while providing the rules of a computerized monitoring system for pesticide residues, does not limit FDA's authority to enforce tolerances for other contaminants using the same system. 21 U.S.C. § 1401. Just the opposite; Congress expressly authorized FDA to use system "to facilitate the regulation of any substance or product covered under the requirements of the [Act]." 21 U.S.C. § 1401(3)(A).

261. One of FDA's core statutory responsibilities is to ensure that food is safe. 21 U.S.C. § 393(b)(2)(A).

262. Accordingly, the Supplement references FDA's pesticide tolerance-enforcement program not because PFAS are pesticides, but because FDA already

operates a functioning monitoring and enforcement infrastructure capable of supporting rapid identification and removal of PFAS-adulterated foods.

263. FDA offers no reason why that existing capability cannot be used to support enforcement of PFAS tolerances once established.

Q. FDA Fails to Address Plaintiffs' International Trade Concerns.

264. Plaintiffs explained that FDA's failure to establish PFAS tolerances creates risks for international trade in U.S. agricultural commodities. (Doc. 24-3, 17).

265. FDA noted the concern but did not address it. Instead, FDA responded only that Plaintiffs did not explain how the proposed tolerances would correspond to the maximum levels established by European authorities. (**Ex. 1**, 22, n. 101).

266. However, this was explained in Petition and Supplement. As above, the proposed foods and tolerances were based on FDA's analytical method which by their own words was developed to target the PFAS compounds likely to be found in the U.S. food supply, at detection limits set by the European Commission, and in the foods European authorities identified as priorities. (Doc. 24-3, 8; **Ex. 4**, 2, 7; *supra*, ¶¶2, 80, 244).

267. Lack of compliance with the European trade partners is an area of growing concern. (E.g., See *Impacts of the PFAS Restriction on Trade Between the U.S. and the European Union*, U.S. Chamber of Commerce (Sept. 2023), https://www.uschamber.com/assets/documents/Impacts-of-PFAS-Restriction-on-Trade-Between-the-U.S.-and-the-European-Union_9.25.2023.pdf; *PFAS in Food Import Regulations: Border Testing and International Trade Compliance*, Bluelabs Korea

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

(May 15, 2026), https://pfasfilter.io/pfas-in-food-import-regulations-border-testing-and-international-trade-compliance/ ("As the EU implements more stringent PFAS food standards, U.S.-EU trade may require convergence on PFAS food contaminant standards...").

268. The European Union maintains an extensive import-control system under which Member States test, inspect, and restrict imported foods that fail to comply with applicable EU food-safety requirements. *Import Controls of Food and Feed: Questions and Answers*, European Commission, https://food.ec.europa.eu/horizontal-topics/official-controls-and-enforcement/import-controls-food-and-feed-qas_en (last visited on Jul. 24, 2026).

269. FDA's refusal to establish PFAS tolerances creates uncertainty for U.S. producers seeking access to international markets that are increasingly adopting PFAS-specific food standards. FDA did not address this issue.

R. FDA's Claim that PFAS Are Not Subject to § 348 Is Irrational.

a. Governing law.

270. ***First***, 21 U.S.C. § 342, at the relevant part provides: "A food shall be deemed to be adulterated-… (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health… [; or] (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than…a food additive...) that is unsafe within the meaning of section 346 of this title; …or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title." 21 U.S.C. § 342.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

271. ***Second***, the FD&C Act broadly defines a "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component ... of any food… if such substance is not generally recognized… to be safe." 21 U.S.C. § 321(s).

272. ***Third***, poisonous or deleterious substances unavoidably added to food provides that any such substance is deemed unsafe, "except where such substance *is required in the production thereof or cannot be avoided by good manufacturing practice*" (emphasis added). 21 U.S.C. § 346. In those circumstances, FDA "shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health." *Id*. In establishing tolerances, FDA must consider both the extent to which the substance cannot be avoided and the cumulative ways in which consumers may be exposed to the same or other poisonous or deleterious substances. *Id*.

b. Plaintiffs' position.

273. The Petition explains that PFAS become components of food through multiple pathways, including exposure to contaminated rainwater or other environmental sources, and by more deliberate means such as the direct application of PFAS-contaminated agricultural inputs such as PFAS-contaminated pesticides, biosolid fertilizers, and irrigation water. (Doc. 24-3, 7). Although contamination may eventually reach food through environmental pathways, the source of the contamination remains identifiable human activity. *Id*.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

274. Because PFAS are demonstrably toxic and are not generally recognized as safe ("GRAS"), the Petition contends that FDA has effectively allowed their widespread introduction into the food supply without the safety data, premarket review, and regulatory oversight ordinarily required for food additives. *Id*., 3.

275. The Petition further argues that federal case law supports treating contaminants introduced into food through human-caused environmental contamination as food additives subject to regulation. *Id*., 18. Specifically, in *Gerber Products Co. v. Fisher Tank Co.*, 833 F.2d 505 (4th Cir. 1987), an accidentally introduced contaminant from a food liner was treated as a food additive; in *U.S. v. Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974), DDT residues in fish resulting from environmental contamination were deemed added substances; and in *U.S. v. Anderson Seafoods, Inc.*, 622 F.2d 157, 158-62 (5th Cir. 1980), mercury was treated as an added substance because at least part of the contamination resulted from human activity.

276. FDA responds that these cases are inapposite, asserting that *Gerber* involved a food-contact substance, *Ewig Bros.* concerned a pesticide provision that is no longer part of the FD&C Act, and *Anderson Seafoods* involved naturally occurring mercury, a poisonous or deleterious substance comparable to lead or arsenic, rather than a food additive. (**Ex. 1**, 22, n. 99).

277. However, FDA does not address the central reasoning underlying these decisions. In each case, the court's key inquiry was whether the contaminant entered the food as a result of human activity, thereby warranting regulation as an added substance. *Gerber*, 833 F.2d at 508; *Ewig Bros. Co.*, 502 F.2d at 724 n. 28; *Anderson Seafoods,*

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

Inc., 622 F.2d at 160-61. FDA fails to explain why that same principle would not apply to PFAS contamination resulting from intentional human manufacture, use, and environmental release. (**Ex. 1**, *generally*).

278. The Petition also argues that PFAS-contaminated agricultural inputs, particularly biosolid fertilizers, pesticides, and irrigation water, fall squarely within the statutory definition of a food additive. (Doc. 24-3, 3, 12-13, 18-19). The deliberate land application of these items all foreseeably result in PFAS becoming components of food crops through known and predictable pathways. *See* 21 U.S.C. § 321(s).

279. For food additives which are carcinogenic, FDA has no discretion and must set the tolerance at zero under 21 U.S.C. § 348(c)(3)(A) (i.e., the Delaney Clause), which provides "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal..."

280. As above, Plaintiffs find PFAS is a food additive, and Delaney should apply. Therefore, tolerance setting at least for PFOA, PFOS, and GenX, should be set at zero as they are all carcinogenic. (Doc. 24-3, 12, n. 43). Because zero is analytically unachievable, the tolerances should be set at the MDL.

c. FDA's unreasoned response.

281. FDA rejected the Petition's reliance on the food-additive provisions and the Delaney Clause (21 U.S.C. § 348(c)(3)(A)), asserting that environmental contaminants are regulated exclusively under the adulteration provisions at 21 U.S.C. § 346 (Section 406 of the FD&C Act) rather than under § 348 (Section 409 of the FD&C Act). (**Ex. 1**, 20-22). However, FDA provides little analysis supporting this conclusion

and does not explain why PFAS-contaminated agricultural inputs should be categorically excluded from the food-additive framework. *Id*.

282. In addition, FDA incorrectly treats the designation *food additive* under § 348 and *unavoidable added poisonous or deleterious substance* under § 346 as mutually exclusive. *Id*. Nothing in the FD&C Act requires such a binary approach.

283. PFAS contamination may arise simultaneously from food-contact substances, contaminated agricultural inputs, and ambient environmental contamination. Thus, the same PFAS residue may implicate both § 348 and § 346 depending on the pathway by which it entered the food supply.

284. FDA's own regulations recognize this overlap, where it is provided that "[u]se of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive, will be controlled by a regulation issued under section 409 [21 U.S.C. § 348] of the FD&C Act when possible. When such a use cannot be approved under the criteria of section 409 of the FD&C Act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section." 21 C.F.R. § 109.6(a).

285. FDA also fails to explain why PFAS introduced into food through agricultural inputs should be treated differently from PFAS introduced into food through food-contact materials. (**Ex. 1**, *generally*).

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

286. FDA has long recognized that PFAS migrating from food packaging into food are substances that require premarket review and authorization as food additives under § 348. *Id*., 1, 4, n. 16.

287. Consistent with that approach, after concerns arose that PFAS were in some food contact substances and pre-market reviews had *not* been conducted, FDA began *post-market reviews*. *Id*.

288. Yet FDA offers no coherent explanation for why PFAS in agricultural inputs, such as fertilizers and pesticides, should be treated differently. In each case, PFAS enter food through a foreseeable consequence of an intentional human use of a product containing PFAS. The distinction drawn by FDA is therefore arbitrary.

289. In sum, FDA has long treated PFAS used in food-contact materials as food additives because their migration into food is reasonably foreseeable. Yet FDA now asserts that PFAS entering food through PFAS-contaminated agricultural inputs are categorically not food additives subject to the Delaney Clause of § 348, despite the same foreseeable transfer of PFAS into food. FDA provides no reasoned scientific or statutory basis for this distinction.

S. FDA's Denial Relies on Impermissible Factors.

290. FDA justified its denial on the grounds that promulgating tolerances is an "elaborate" process which they do not commonly undertake. (**Ex. 1**, 22, 24).

291. Congress, however, granted FDA broad authority to issue regulations necessary for the "efficient enforcement" of the FD&C Act. 21 U.S.C. § 371(a). The procedure for promulgating tolerances is straightforward: (1) a proposal by FDA or a

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

petition from an interested person; (2) publication of the proposal; (3) an opportunity for written or oral comments; and (4) issuance of an agency order. 21 U.S.C. § 371(e)(1).

292. These procedural requirements have been satisfied here. Plaintiffs submitted the Petition in November 2023, FDA published it on Regulations.gov, interested parties had an opportunity to comment. At this point, FDA could have issued the order, granting the Petition as Supplemented pursuant to 21 U.S.C. § 371(e)(1).

293. As FDA points out, in their response, after the order issues, affected persons may request a hearing. (**Ex. 1**, 22-23 citing 21 U.S.C. § 371(e)(2)). However, since 2023, there have been no comments filed in the public docket opposing the Petition. Thus, there is no indication that there will be objections to tolerance or action level setting.

294. Moreover, as discussed above, dairy farmers would likely welcome tolerance setting for PFOS and PFOA in milk, as was proposed in Supplement. *Supra*, ¶162.

295. Additionally, food crop farmers would also likely welcome the tolerances, to ensure that their products will not face trade barriers in Europe. *Supra*, ¶¶268-270.

296. FDA has been studying the occurrence of environmental PFAS in foods since at least 2019 and has also taken several enforcement actions involving PFAS-contaminated foods. (**Ex. 1**, 5-9). Thus, FDA has already recognized the public health significance of PFAS-adulterated foods.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

297. FDA's suggestion that PFAS tolerances or action levels present an extraordinary procedural challenge is difficult to reconcile with the record here.

298. More fundamentally, FDA has a duty to act when it determines that unavoidable toxic substances are present in the food supply. The FD&C Act provides that when a poisonous or deleterious substance added to food "cannot be avoided," FDA "shall promulgate regulations limiting the quantity therein or thereon to such extent as [it] finds necessary for the protection of public health." 21 U.S.C. § 346.

299. Nothing in the FD&C Act suggests that Congress intended procedural inconvenience to excuse compliance with that mandate.

300. Therefore, relying on the allegedly "elaborate" procedural requirements of 21 U.S.C. § 371 which they do not commonly undertake (**Ex. 1**, 22, 24) is no basis for refusing to establish PFAS tolerances.

VII. CAUSE OF ACTION

A. Unlawful Agency Action, 5 U.S.C. § 706(2) – Count One[16]

301. Plaintiffs repeat the allegations contained in paragraphs 1 to 301 as if stated fully here.

302. Under the APA, a reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law or without observance of procedure required by law. 5 U.S.C. § 706(2)(A)-(D). Courts have held that an agency action or

[16] In the original complaint, Count One was for Unreasonable Delay, which is now moot.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

conclusion should be set aside under § 706(2) if it is not reasonably explained, fails to consider an important aspect of the problem, relies on impermissible factors, contradicts the evidence, acts irrationally, or departs from prior policy without a reasoned explanation. *Ohio*, 603 U.S. at 292-94; *Bonumose, Inc.*, 747 F. Supp. 3d at 223; *FCC*, 556 U.S. at 513-17.

303. Plaintiffs' Petition, as supplemented (Dkt. FDA-2023-P-4826), requested the establishment of new temporary tolerances at the MDLs for all 30 target analytes in Method C-010.03 (update of the *PFAS-30 Method*) in/on each lettuce (head and leaf), blueberries, ready-to-eat bread, milk, eggs, salmon, clams, corn silage, and corn snaplage.

304. As an alternative, the Petition, as supplemented, requested FDA to establish action levels at the MDLs for all 30 PFAS identified in Method C-010.03 for lettuce (head and leaf), blueberries, ready-to-eat bread, eggs, corn silage, and corn snaplage. For milk, salmon, clams (1) establish tolerances for PFOS and PFOA at the MDLs, and (2) establish action levels at the MDLs for the remaining 28 PFAS identified in the Petition.

305. FDA denied the Petition, as supplemented, in its entirety by letter dated June 17, 2026, citing alleged evidentiary deficiencies, concerns regarding the achievability of limits under current good manufacturing practices, and gaps in toxicity data, while maintaining that its case-by-case enforcement approach is sufficient to protect public health.

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

306. From their denial letter, it is shown that the FDA agrees PFAS are persistent, bioaccumulative chemicals that contaminate food through environmental pathways affecting crops, livestock, and fish. For example, FDA has detected PFAS in multiple food categories, including approximately 70% of fish samples in its Total Diet Study.

307. However, in their June 17 denial letter, FDA failed to meaningfully address evidence submitted by Plaintiffs regarding PFAS carcinogenicity, widespread and increasing environmental contamination, and the rising PFAS levels in foods observed over time.

308. In addition, FDA acknowledged that it did not assess the cumulative exposure to multiple PFAS or across the relevant sources and exposure routes, despite Congress's directive under 21 U.S.C. § 346. For example, FDA did not consider exposure to PFAS arising from both PFAS-adulterated foods and PFAS-contaminated drinking water.

309. Moreover, FDA's denial relied on GMP-based "achievability" considerations which are irrational because GMPs address manufacturing and processing practices, not environmental PFAS contamination. Also, because most of the foods at issue are RACs, not processed commodities. FDA further admits it is unaware of any method to remove PFAS from contaminated food.

310. From the June 17 letter it is evident that FDA failed to coordinate with EPA and USDA as directed by 21 U.S.C. § 393(c); and that FDA departed from prior

practice without explanation by refusing to establish PFAS limits despite establishing comparable controls for unavoidable contaminants such as lead, arsenic, and PCBs.

311. FDA discussed its reliance on EPA's PFAS drinking-water standards to assess the food item bottled water pursuant to the FD&C Act, yet irrationally disregards those same standards for other foods with no explanation.

312. FDA referenced its case-by-case enforcement approach as its way of protecting public health, but they provide no objective criteria for determining when PFAS contamination renders a food adulterated.

313. FDA rejected Plaintiffs' MDL-based proposal as insufficiently "science-based" while ignoring that its own analytical method was developed to detect PFAS likely to occur in the U.S. food supply at detection limits identified by the European Commission.

314. FDA also failed to address Plaintiffs' international trade concerns and relied on the impermissible factor that tolerance setting may be burdensome. The record does not support FDA's claim that tolerance-setting would be onerous.

315. FDA's denial is arbitrary and capricious under 5 U.S.C. § 706(2) because FDA failed to consider important aspects of the problem, relied on impermissible factors, and departed from prior policy without a reasoned explanation. *Ohio*, 603 U.S. at 292-94; *Bonumose, Inc.*, 747 F. Supp. 3d at 223; *FCC*, 556 U.S. at 513-17.

316. FDA's denial is also an abuse of discretion and without observance of procedure required by law, because it disregarded directives requiring consideration of

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

cumulative exposure, 21 U.S.C. § 346, and interagency coordination, 21 U.S.C. § 393(c). 5 U.S.C. § 706(2)(A)(D).

317. Plaintiffs EJ Task Force and its members, Dr. Krotzky, and LOSD, through Ms. Daussin live near PFAS-contaminated areas and have been exposed to PFAS. Members of EJ Task Force, Dr. Krotzky, and Ms. Daussin have experienced PFAS-related health effects. Plaintiffs face ongoing exposure risks through PFAS-adulterated foods and are harmed by FDA's refusal to establish the requested PFAS tolerances and/or action levels.

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

(a) Hold unlawful and set aside FDA's findings and conclusions in its June 17, 2026 final response to the November 2023 Citizen Petition, as amended by its May 2023 Supplement (Docket FDA-2023-P-4826), pursuant to 5 U.S.C. § 706 (2);

(b) Declare that FDA's denial of the Citizen Petition, as supplemented, was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and without observance of procedure required by law, under 5 U.S.C. § 706 (2);

(c) Declare that 21 USC § 346 requires FDA to establish tolerances for harmful substances covered by the statute, while retaining discretion only as to the tolerance level itself, and remand this matter to FDA for further proceedings consistent with this holding;

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

(d) Remand with instructions that FDA reconsider the Citizen Petition, as supplemented, consistent with the FDC&A Act and the APA statutory requirements, including coordination with EPA and USDA and consideration of the total risks to PFAS in foods accounting for various sources (e.g., food and water), other routes of exposure (e.g., dermal and inhalation), and other similarly toxic compounds;

(e) Award Plaintiffs costs and reasonable attorney fees to the extent permitted by law; and

(f) Grant such other relief as this Court may deem just and proper.

RESPECTFULLY SUBMITTED this 31 July 2026.

AVA LAW GROUP, INC.

By: */s/ Andrew Van Arsdale*
Andrew Van Arsdale
AVA Law Group, Inc.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
Telephone (800) 777-4141

By: */s/ Sandra Daussin*
Sandra Daussin
AVA Law Group, PC
52 Somerleigh Way
Pittsboro, NC 27312
Telephone (406)-500-3245

Attorneys for Plaintiffs

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141

CERTIFICATE OF SERVICE

I hereby certify that the foregoing *SUPPLEMENTAL COMPLAINT* was electronically filed with the Clerk of Court using the CM/ECF system, which will notify all counsel of record.

This 31st day of July 2026.

/s/ Sandra Daussin
Sandra Daussin
AVA Law Group, PC
52 Somerleigh Way
Pittsboro, NC 27312
Telephone (406)-500-3245
Email: sandra.daussin@avalaw.com

AVA LAW GROUP, INC.
3667 Voltaire Street, Ste. 101
San Diego, CA 92106
(800) 777-4141