



April 30, 2025

Environmental Working Group comments to the Food and Drug Administration requesting that the FDA establish action levels for residues of either twenty-six (26) or thirty (30) PFAS in a variety of foods.

Docket ID: FDA-2023-P-4826

Submitted via regulations.gov

These comments are submitted on behalf of the Environmental Working Group (EWG) in support of the citizen petition by the Tucson Environmental Justice Task Force (TEJTF) urging the FDA to set tolerances for PFAS on certain foods.

EWG is a national environmental health research and advocacy organization focusing on the potential risks from chemicals, including PFAS, in food, water, consumer products, and the environment. EWG provides information to consumers about which food chemicals to avoid,¹ and maintains a database that rates food products based on concerns about their ingredients, as well as nutrition and processing.² EWG also advocates for stronger protections from PFAS exposure in food,³ and advises consumers on how to avoid PFAS exposure from food and food packaging.⁴ EWG welcomes the opportunity to provide comments to FDA on the proposed action.

I. The FDA should establish PFAS tolerances and revoke PFAS Food Contact Notifications

EWG expresses its strong support for the tolerances that the TEJTF proposes. Considering the state of scientific research on the safety of PFAS and the health effects related to its consumption, the text and purpose of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its accompanying regulations support establishing tolerances for PFAS in food. Relatedly, EWG requests that the FDA approve the June 9th petition to revoke authorization for the use of PFAS as a food contact substance submitted by the Environmental Defense Fund, EWG, and

¹ Iris Myers, *EWG's Dirty Dozen Guide to Food Chemicals: The Top 12 to Avoid*, Env't Working Group (Sept 19, 2024), <https://www.ewg.org/consumer-guides/ewgs-dirty-dozen-guide-food-chemicals-top-12-avoid>.

² User's Guide to EWG's Food Scores, ENV'TL WORKING GROUP, <https://www.ewg.org/foodscores/content/user-guide/> (last accessed Nov. 12, 2024).

³ *PFAS Resources*, Env't Working Group, <https://www.ewg.org/pfas-resources> (last accessed Nov. 12, 2024).

⁴ *EWG's Guide to Avoiding PFAS Chemicals*, Env't Working Group (June 2018), <https://static.ewg.org/ewg-tip-sheets/EWG-AvoidingPFCs.pdf>.

others.⁵ Additionally, EWG supports FDA action to set action levels for PFAS contamination until tolerances can be established.

II. The FDA should establish action levels during the development of PFAS tolerances

While we agree that the FDA should establish PFAS tolerances, establishing a tolerance requires undertaking formal rulemaking, which will leave many Americans unprotected from PFAS adulteration for the time required to publish a final rule. Therefore, we recommend that the FDA establish risk-based action levels, which do not require either formal or informal rulemaking, to protect consumers' health in the interim.⁶

A. PFAS contamination of the food supply is an immediate threat to Americans' health

Contamination from PFAS chemicals is a national public health and environmental emergency. PFAS contaminate the blood and organs of nearly every living being, and biomonitoring conducted by the Centers for Disease Control and Prevention (the CDC) indicates that 97 percent of Americans or more have at least one detectable PFAS in their blood serum.⁷

Food is the most important pathway of human exposure to PFAS compounds. PFAS compounds are ubiquitous environmental contaminants that transfer to foods at levels sufficient to pose health risks. PFAS contaminate groundwater, soil, and air, and are present in sludge and biosolids applied to cropland.⁸ Plants bioaccumulate PFAS from soil and water,⁹ and present a source of exposure for humans as well as a source of PFAS in animal feed that then transfers to animal products. FDA's own testing shows that PFAS is found in fish, eggs, milk, food, and animal feed.¹⁰ The European Union has found that most people's main source of PFAS exposure

⁵ *Citizen Petition from Environmental Defense Fund, Requests that the FDA comply with the Federal Food and Drug Cosmetic Act (FFDCA) and its implementing regulations* (2021) <https://www.regulations.gov/docket/FDA-2021-P-0653> (last visited Mar. 18, 2025).

⁶ 21 C.F.R. § 109.4(c).

⁷ Ryan Lewis *et al.*, *Serum Biomarkers of Exposure to Perfluoroalkyl Substances in Relation to Serum Testosterone and Measures of Thyroid Function among Adults and Adolescents from NHANES 2011–2012*, 12 *Int'l J. Env't Rsch. Pub. Health* (<https://pmc.ncbi.nlm.nih.gov/articles/PMC4483690/>) (last visited Feb. 20, 2021)

⁸ See Gwynn R. Johnson, *PFAS in soil and groundwater following historical land application of biosolids*, 211 *Water Research* 118035 (2022);

Elsie M Sunderland *et al.*, *A review of the pathways of human exposure to poly- and perfluoroalkyl substances (PFASs) and present understanding of health effects*, 29 *J Expo Sci Environ Epidemiol* 131(2019); U.S. Env't Protection Agency, *Draft Sewage Sludge Risk Assessment for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS)* (2025) <https://www.epa.gov/biosolids/draft-sewage-sludge-risk-assessment-perfluorooctanoic-acid-pfoa-and-perfluorooctane> (last visited Jan. 1, 2025).

⁹ Juyi Li, Jing Sun, Pengyang Li, *Exposure routes, bioaccumulation and toxic effects of per- and polyfluoroalkyl substances (PFASs) on plants: A critical review*

¹⁰ See US FDA, *Testing Food for PFAS and Assessing Dietary Exposure*, (April 18, 2023)

<https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure> (last visited Dec. 14, 2024).

is from the diet.¹¹ The Environmental Protection Agency has similarly concluded that, for the general population, “the dominant source of human exposure to PFOA [and PFOS] is expected to be from the diet.”¹²

PFAS are associated with serious health effects, even at very low doses.¹³ PFAS exposure has been linked to kidney and testicular cancer, preeclampsia, ulcerative colitis, thyroid disease, high cholesterol,¹⁴ reproductive and developmental harm,¹⁵ and damage to the immune system.¹⁶ PFAS chemicals have long half-lives, and many can stay in the human body for decades.¹⁷

The FDA should act now to protect the public, especially children and pregnant people, from the long-term damage that PFAS can cause. Like heavy metals, which the FDA is working to address through the Closer to Zero initiative,¹⁸ PFAS are an environmental contaminant that presents special risks to children and pregnant people, in addition to health risks to the public at large. Both heavy metals and PFAS present these risks even at extremely low levels, and over long timeframes. Taking action now to address this contaminant will not only prevent harm to the public but will also prevent harm to the reputations of the FDA and the many otherwise healthful foods (such as fish) that the FDA’s testing has shown to be most contaminated with

¹¹ See EFSA Panel on Contaminants in the Food Chain, *Risk to Human Health Related to the Presence of Perfluoroalkyl Substances in Food*, 18 EFSA J. 6223, 6226 (2020).

¹² See Environmental Protection Agency, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)* at 18 (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final_508.pdf; Environmental Protection Agency, *Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS)* at 19 (May 2016); https://www.epa.gov/sites/production/files/2016-05/documents/pfos_health_advisory_final_508.pdf.

¹³ Impacts to mammary gland development have been associated with low-level doses of PFOA. See, e.g., Dierdre K. Tucker et al., *The Mammary Gland is a Sensitive Pubertal Target in CD-1 and C57Bl/6 Mice Following Perinatal Perfluorooctanoic Acid (PFOA) Exposure*, 54 *Reproductive Toxicology* 26 (2015), <https://www.ncbi.nlm.nih.gov/pubmed/25499722>; Madisa B. Macon et al., *Prenatal Perfluoroocynoic Acid Exposure in CD-1 Mice: Low Dose Developmental Effects and Internal Dosimetry*, 122 *Toxicological Sciences* 131 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3143465/>; Sally S. White et al., *Gestational and Chronic Low-Dose PFOA Exposures and Mammary Gland Growth and Differentiation in Three Generations of CD-1 mice*, 119 *Env’tl Health Perspectives* 1070 (2011), <https://www.ncbi.nlm.nih.gov/pubmed/21501981>; PFOA, PFOS, PFHxS and PFDeA are also associated with reduced effectiveness of vaccines, even at low doses. See Anna Reade, Tracy Quinn, & Judith S. Schreiber, *Scientific & Policy Assessment for Per- and Polyfluoroalkyl Substances in Drinking Water*, Natural Resources Defense Council (April 12, 2019), https://www.nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf.

¹⁴ C8 Science Panel, *C8 Probable Link Reports*, http://www.c8sciencepanel.org/prob_link.html (last visited Jan. 25, 2020).

¹⁵ Alexis Temkin, *PFAS and Developmental and Reproductive Toxicity: An EWG Fact Sheet*, Environmental Working Group (Sept. 19, 2019), <https://www.ewg.org/news-and-analysis/2019/09/pfas-and-developmental-and-reproductive-toxicity-ewg-fact-sheet>.

¹⁶ Tasha Stoiber, *PFAS Chemicals Harm the Immune System, Decrease Response to Vaccines*, New EWG Review Finds, Environmental Working Group (June 21, 2019), <https://www.ewg.org/news-and-analysis/2019/06/pfas-chemicals-harm-immune-system-decrease-response-vaccines-new-ewg>.

¹⁷ Half-life estimates range from over two years from PFOA and PFNA to 5.4 years for PFOS to 8.5 years for PFHxS. See Reade *et al. supra* note 13 at 12.

¹⁸ See Food and Drug Admin., *Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods* (last updated 09/16/2024) <https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods>. (last visited Nov. 25, 2024).

PFAS. PFAS compounds are increasingly of concern to everyday Americans, and the FDA should act now.

B. The FDA has the authority to establish action levels for PFAS in food.

An action level is a non-binding determination by the FDA that food exceeding a certain level of contamination is “adulterated.”¹⁹ Under FDA regulations, the FDA has the authority to set action levels for “added poisonous or deleterious substances” in food.²⁰ This includes substances unintentionally introduced through environmental contamination,²¹ even if only a part of the contamination is introduced by human acts.²² An “added poisonous or deleterious substances . . . may be a food additive,”²³ and establishing an action level for such an additive is appropriate where it cannot be approved as a food additive.²⁴ Therefore, a substance is an “added poisonous or deleterious substance” in food if it is at least in part added to foods from anthropogenic sources and is not approved as a food additive.

Because it is a ubiquitous environmental contaminant with a human source, PFAS is an “added poisonous or deleterious substance.” The FDA itself has noted that PFAS are a large group of chemicals that are widespread in the environment, have a human source, and are often absorbed into the foods they contaminate.²⁵ As such, PFAS are unavoidable contaminants of food and qualify as “added poisonous or deleterious substances” and establishing action levels is appropriate if certain criteria are met.

There are 3 criteria that must be met for an action level to be appropriate. The action level itself must be (1) based on the unavoidability of a substance in food,²⁶ and (2) be “sufficient for the protection of the public health” taking into account the effects on a consumer of “the same or related” substances.²⁷ We agree with TEJTF that 109.6(b) requires the FDA to consider exposure to multiple PFAS from multiple sources in deciding the level at which to establish a tolerance or action level. Finally, (3) “technological or other changes that might affect the appropriateness of [a] tolerance” must be “foreseeable in the near future.”²⁸

¹⁹ 21 U.S.C. § 342(a).

²⁰ 21 C.F.R. §§ 109.3(d), 109.4(c)(1).

²¹ See *United States v. Ewig Bros. Co.*, 502 F.2d 715, 723 (7th Cir. 1974).

²² See *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157, 161 (5th Cir. 1980).

²³ 21 C.F.R. § 109.4(b)

²⁴ 21 C.F.R. § 109.6.

²⁵ See US FDA, *Per- and Polyfluoroalkyl Substances (PFAS)*, (June 26, 2024)

<https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas>, (last accessed Nov. 13, 2024).

²⁶ See 21 C.F.R. § 109.7(a)

²⁷ 21 C.F.R. § 109.6(b)

²⁸ 21 C.F.R. § 109.6(d)

These three criteria to establish action levels are easily met here. As discussed earlier, PFAS are ubiquitous and impossible to completely avoid, meaning that action levels would be based on the unavailability of the contaminant in food. The FDA has also acknowledged that PFAS threaten public health.²⁹ As TEJTF notes, some PFAS are carcinogenic and therefore have no level of safe exposure. Others cause harmful effects even at very low concentrations.³⁰ The FDA has already taken steps to encourage the voluntary removal of PFAS from various food contact materials,³¹ and has raised concerns about others.³² Therefore, action levels would protect the public health. Finally, there are foreseeable changes in PFAS regulations, PFAS contamination, and testing methods for PFAS that might affect the appropriateness of a tolerance due to, for example, improved limits of quantification. PFAS are unavoidable and threaten the public health. Because there are foreseeable changes that would affect the appropriateness of a tolerance, the FDA has the authority to establish PFAS action levels to protect public health.

C. EPA's Approach to PFAS risk assessment provides a validated framework for FDA to establish action levels

To establish these action levels, the FDA should conduct a risk assessment. Thankfully, the FDA does not have to reinvent the wheel to do this, they can borrow from analysis that EPA has already completed and from their own method of establishing tolerances for food additive classes.

The EPA, to assist local, state, regional, and tribal governments in assessing the health effects of fish consumption, publishes guidance to help these governments monitor for contaminants and calculate fish consumption advisory levels. In July of 2024, the EPA updated that list to add PFAS contaminants to monitor, based on a peer-reviewed determination of screening levels.³³ The EPA's screening levels were determined using risk assessment, which the FDA can adopt to establish its own action levels for fish and foods beyond fish.

²⁹ See US FDA, *Per- and Polyfluoroalkyl Substances (PFAS)*, (June 26, 2024) <https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas>, (last accessed Nov. 13, 2024).

³⁰ For this reason, the EPA has set advisories for PFAS in water near zero. See Kevin Loria, *EPA Says Even Extremely Low Levels of PFAS in Drinking Water May Be Unsafe*, Consumer Reports (2022) <https://www.consumerreports.org/water-quality/even-extremely-low-levels-of-pfas-in-drinking-water-unsafe-a1147585461/> (last accessed Nov 13, 2024).

³¹ See e.g. *Indirect Food Additives: Paper and Paperboard Components*, 81 Fed. Reg. 5 (2016).

³² See e.g. *FDA, Letter from Dr. Dennis Keefe to Devon Wm. Hill of Keller and Heckman representing Daikin, Oct. 1, 2019*, http://blogs.edf.org/health/files/2021/04/Daikin-PNC-2422-PFAS_Daikin-Final-10-1-2019-and-response-combined.pdf. (last accessed Nov. 15, 2024).

³³ Env't Protection Agency, *Contaminants to Monitor in Fish and Shellfish Advisory Programs: Compilation of Peer Review-Related Information* (2024) <https://www.epa.gov/system/files/documents/2024-06/contaminants-monitor-fish-peer-review-package.pdf> (last accessed Nov. 14, 2024).

To address understudied PFAS, the EPA utilized a “grouping and read across approach” to determine screening levels. Based on EPA’s general framework for assessing the non-cancer effects of PFAS mixtures,³⁴ the EPA’s approach classified PFAS compounds as either long or short-chain, and as either carboxylic or sulfonic acids, resulting in 4 groups of similar PFAS compounds. This allowed the EPA to assess the health effects of PFAS that lacked specific toxicity data by using the lowest toxicity value from each group. This approach is similar to the method FDA regulations require when the FDA sets tolerances for related food additives. When additives cause similar or related pharmacological effects (as these PFAS do) FDA regulations require the establishment of a combined total limit for the group of related additives at the lowest tolerance within the class.³⁵

The following table contains the values the EPA’s methodology arrived at:

Table 1: Updated List of Generalized Reference Doses Derived from EPA’s Methodology

PFAS Group Name	EPA Advisory PFAS in Group	Generalized Screening Level and Source
Short-chain PFCAs	PFBA, PFHxA, PFHpA, PFPeA	PfHxA: 5×10^{-4} mg/kg-d (final RfD - IRIS)
Long-chain PFCAs	PFDA, PFDaA, PFNA, PFOA, PFTeDa, PFTrDA, PFUndA	PFDA: 2×10^{-9} mg/kg-d (final RfD - IRIS) ³⁶
Short-chain PFSAs	PFBS	PFBS: 3×10^{-4} mg/kg-d (final human health toxicity value - PPRTV)
Long-chain PFSAs	PFDS, PFHpS, PFHxS, PFOSm, PFOSA	PFOS: 1×10^{-7} mg/kg-d (final RfD - OW) PFHxS: 4×10^{-10} mg/kg-d (draft RfD - IRIS) ³⁷

Next, the EPA determined the food contamination level at which those toxicity values would lead to an exceedance of the reference dose (in units of mg/kg-d) and set that as the screening level. The EPA used the following equation:

³⁴ Env’t Protection Agency, *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)*, (2024) https://www.epa.gov/system/files/documents/2024-04/final-pfas-mix-framework-3.25.24_final-508.pdf (Last accessed Nov. 14, 2024).

³⁵ 21 C.F.R. 170.18

³⁶ Between the publication of EPA’s assessment and now, the EPA has finalized the RfD for PFDA, which has changed from 4×10^{-10} to 2×10^{-9} mg/kg-day. EPA’s use of PFOA’s higher RfD (which was final at the time of their assessment) is therefore unnecessary.

³⁷ Currently, this value is not final, but if finalized would be preferred over the PFOS RfD from EPA’s Office of Water using EPA’s approach to selecting toxicity values.

$$\frac{\text{Reference Dose} * \text{Body Weight}}{\text{Consumption rate}} = \text{Non-cancer screening level}$$

Figure 1: EPA's Method for Calculating Screening Levels

For example, the reference dose for PFDA (2×10^{-9} mg/kg-d) would be exceeded if a frequent fish consumer (eating 142g/d and weighing 80 kilograms) ate fish contaminated above a level of 1.13×10^{-10} mg/g (1.13 ppt)

$$\frac{2 \times 10^{-9} \text{ mg/kg-d} * 80 \text{ kg}}{142 \text{ g/d}} = 1.13 * 10^{-10} \text{ mg/g} = 1.13 \text{ ppt}$$

Figure 2: Example Calculation of an EPA Screening Level

That level, which the EPA used as a screening level, the FDA can use as an action level. Calculating action levels for food will require some basic adaptations of EPA's methodology. The changes we recommend are based on the FDA's past practices, as well as general best practices for risk assessment. Because PFAS can be harmful even at low concentrations, risk-based action levels may fall below currently quantifiable levels of PFAS, in which case the FDA can publish the action level along with the currently available detection limit.

D. Recommended Modifications of EPA's PFAS Risk Assessment Methodology.

While the EPA's method provides a strong methodological base and a reliable source of toxicity data, some accommodations will be necessary to translate the method from fish consumption to broader PFAS limits. We therefore recommend that the FDA make the following changes and additions to EPA's method.

To begin with, the target population should be expanded to include children. The EPA determined screening levels based on the fish consumption of adults, pregnant women, and frequent fish consumers. Here, the FDA should add children to that list, since they will be exposed to many of the foods the FDA has tested and are often the most sensitive to toxic chemicals like PFAS. Additionally, many of the EPA's toxicity values, such as IRIS reference doses, were calculated based on developmental endpoints in children, making children an essential population to include in risk assessments.³⁸ Using consumption rate and body weight information for children will bring the action levels in line with other FDA risk assessments, which include children.³⁹

³⁸ See e.g. Env't Protection Agency, IRIS Toxicological Review of Perfluorodecanoic Acid (PFDA) and Related Salts,

³⁹ See Food and Drug Admin. Center for Food Safety and Applied Nutrition, *Action Level for Inorganic Arsenic in Apple Juice: Guidance for Industry*, 7 (2023) <https://www.fda.gov/media/86110/download> (last accessed Nov. 15, 2024).

Another adjustment the FDA should make to the EPA’s approach is the use of a relative source contribution factor and account for other sources of exposure. This correction is widely used in risk assessment, and is necessary for the FDA to fulfill its duty to consider “the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.”⁴⁰ Using a relative source contribution factor to determine action levels lowers the screening level for a contaminant to account for the fraction of total consumption the source of exposure represents. Source contribution factors prevent risk assessments from underestimating exposure by incorrectly assuming that the food at issue is the only source of exposure. Functionally, the factor decreases the action level by whatever percentage of exposure comes from sources other than the food at issue, resulting in an updated action level calculation:

$$\text{Relative Source Contribution} * \frac{\text{Reference Dose} * \text{Body Weight}}{\text{Consumption rate}} = \text{Action level}$$

Figure 3: Updated Action Level Calculation

In the EPA’s fish advisory analysis, a relative source contribution factor was not used, but was suggested by an expert reviewer.⁴¹ But to establish PFAS drinking water standards, the EPA did use a default of 20% as a relative source contribution factor based on a finding that the scientific consensus on relative source contributions for PFAS was uncertain and other sources of exposure in addition to water are likely significant.⁴² Based on this finding, it is appropriate for the FDA to use at a maximum an 80% source contribution factor, which will reflect the upper limit of exposure from food if a single food type or group was considered the only source of exposure. Further, for each individual food group, a lower contribution should be calculated to reflect the contribution of those specific foods to total dietary intake:

$$\begin{aligned} &\text{Relative source contribution} \\ &= \% \text{ Exposure from food} * \% \text{ of food exposure from food group} \end{aligned}$$

Figure 4: Calculation of Relative Source Contribution Factor for Specific Food Item or Group

For example, if 80% of exposure to PFAS comes from food, and 20% of that exposure is from fish, then a source contribution factor of 0.16, or 16%, is appropriate in establishing action levels for PFAS in fish. While it appears that most PFAS exposure comes from food intake generally, research has not yet established a consensus as to exactly how much PFAS exposure comes from food.⁴³ There is also little research on how much PFAS comes from which foods specifically,

⁴⁰ 21 C.F.R. § 109.6(b)(2).

⁴¹ Env’t Protection Agency, *Contaminants to Monitor in Fish and Shellfish Advisory Programs: Compilation of Peer Review-Related Information A-61* (2024) <https://www.epa.gov/system/files/documents/2024-06/contaminants-monitor-fish-peer-review-package.pdf> (last accessed Nov. 14, 2024).

⁴² See Env’t Protection Agency, PFAS National Primary Drinking Water Regulation, 89 Fed. Reg. 32532, 32544-45

⁴³ Katherine Roth, et al., Diet as an Exposure Source and Mediator of Per- and Polyfluoroalkyl Substance (PFAS) Toxicity, *Frontiers in Toxicology* (Dec. 3, 2020).

though seafood, meat, and dairy are noted contributors.⁴⁴ Furthermore, food packaging and cooking materials such as PFAS-coated pans can contaminate otherwise safe foods.⁴⁵ A meta-analysis of available studies suggests that the relative source contributions vary widely.⁴⁶ As such, we believe conservative estimates are appropriate for assessing the contribution of PFAS from the diet because reliable estimates of source contributions are not available.

Another necessary change is to the confidence level used when estimating PFAS concentrations. For PFAS testing in food, the FDA has chosen to use a 99% confidence requirement,⁴⁷ since that requirement is used by the EPA in Clean Water Act permitting.⁴⁸ However, as noted by commenters, the use of a 99% confidence level is likely to result in a greater number of false negatives,⁴⁹ and EPA has only applied that level to PFAS in fish and shellfish tissues, not to other foods.⁵⁰ The FDA should instead use a 95% confidence level, as is its usual practice for environmental contaminants. For example, the FDA recommends a 95% confidence level for elemental analysis,⁵¹ and that level is used for analysis of arsenic in rice,⁵² arsenic in fruit juice,⁵³ and numerous other elements in food.⁵⁴ Given the serious risks presented by PFAS even at low levels,⁵⁵ and the difference between the FDA's goals in the foods program and the EPA's goals in the wastewater permitting program, the use of a 99% confidence level for determining PFAS exposure is less appropriate than the use of a 95% confidence level.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ Amila O De Silva et al., *PFAS Exposure Pathways for Humans and Wildlife: A Synthesis of Current Knowledge and Key Gaps in Understanding*, 40 *Env't Toxicology Chemistry* 631 (2021) <https://pmc.ncbi.nlm.nih.gov/articles/PMC7906948/> (last visited Feb. 20, 2025).

⁴⁷ Food and Drug Admin., FDA Foods Program Compendium of Analytical Laboratory Methods: Chemical Analytical Manual Method C-010.03, 20 (2024) <https://www.fda.gov/media/131510/download> (last accessed Nov. 15, 2024).

⁴⁸ Appendix B to Part 136, Title 40

⁴⁹ Tom Neltner, FDA's updated results for PFAS in food suggest progress but raise questions about its method, Environmental Defense Fund (2019) <https://blogs.edf.org/health/2019/11/20/fdas-updated-results-for-pfas-in-food-suggest-progress-but-raise-questions-about-its-method/> (last accessed Nov. 15, 2024).

⁵⁰ Env't Protection Agency, Method 1633 Analysis of Per- and Polyfluoroalkyl Substances (PFAS) in Aqueous, Solid, Biosolids, and Tissue Samples by LC-MS/MS, <https://www.epa.gov/system/files/documents/2024-01/method-1633-final-for-web-posting.pdf> (last accessed Nov. 15, 2024).

⁵¹ Food and Drug Admin., Elemental Analysis Manual for Food And Related Projects 3.2: Terminology, 4-5 (2021) <https://www.fda.gov/media/89337/download> (last accessed Nov. 15, 2024).

⁵² Food and Drug Admin., Elemental Analysis Manual for Food And Related Projects 4.11 Arsenic Speciation in Rice and Rice Products Using High Performance Liquid Chromatography- Inductively Coupled Plasma-Mass Spectrometric Determination, 17 (2012) <https://www.fda.gov/media/95197/download> (last accessed Nov 15, 2024).

⁵³ Food and Drug Admin., Elemental Analysis Manual for Food And Related Projects 4.10 High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic Species in Fruit Juice, 20 (2020) <https://www.fda.gov/media/86499/download?attachment> (last accessed Nov 15, 2024).

⁵⁴ Food and Drug Admin., Elemental Analysis Manual for Food And Related Projects 4.7 Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion, 3 (2020) <https://www.fda.gov/media/87509/download> (last accessed Nov 15, 2024).

⁵⁵ Kevin Loria, *EPA Says Even Extremely Low Levels of PFAS in Drinking Water May Be Unsafe*, Consumer Reports (2022) <https://www.consumerreports.org/water-quality/even-extremely-low-levels-of-pfas-in-drinking-water-unsafe-a1147585461/> (last accessed Nov 13, 2024).

Relatedly, we recommend that the FDA use the method limit of detection, not the limit of quantification, when applying its PFAS action level and in assessing PFAS exposure in the risk assessment process. While a limit of quantification is appropriate for assessing compliance with a tolerance, action levels and risk assessment are less sensitive to false positives and should. While tolerances come with binding legal consequences, action levels are more often used to screen products from the market and avoid contamination.⁵⁶ Because the measured concentration is the best guess of the actual concentration, detected levels of PFAS that may represent threats to human health should not be ignored. Rather, some further action such as additional testing, removal from the market, or source investigation is warranted. Relatedly if the FDA determines with 95% confidence that PFAS is present in food, the FDA should not treat that level as a non-detect in calculating exposure but instead should assume the likely truth that PFAS is present in the food.⁵⁷

We also recommend that the FDA consider the development of combined PFAS limits where toxicologically appropriate. The mechanisms underlying PFAS toxicity are complex, however, research, common sense, and the sheer number of different PFAS compounds suggest that similar PFAS may share the same toxicity pathways or endpoints in the body.⁵⁸ As has been accomplished in the European Union,⁵⁹ we recommend that the FDA create group limits on PFAS exposure where scientifically feasible. This is also legally required to fulfill the FDA's mandate to consider the effects on a consumer of "the same or related" substances in establishing action levels,⁶⁰ and as mentioned earlier is standard when FDA sets a tolerance for related substances.

Finally, the FDA will need to determine food consumption rates beyond fish consumption to calculate PFAS levels for the foods at issue here. The EPA calculated fish consumption using data from the USDA's dietary recommendations as well as from the USDA's Continuing Survey of Food Intake by Individuals (CSFII), which is now the National Health and Nutrition Examination Survey (NHANES).⁶¹ Here, we recommend that the FDA follow the latter

⁵⁶ Food and Drug Admin., *Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal* (2000) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed> (last visited Mar. 18, 2025).

⁵⁷ If the FDA is truly committed to using a 99% confidence requirement, the EPA has used several available methods for addressing potentially unquantifiable detections of a compound in risk assessments and we believe the FDA should choose to use one here. See Env't Protection Agency, *Regional Guidance on Handling Chemical Concentration Data Near the Detection Limit in Risk Assessments*.

⁵⁸ See JiaJun Hun, *A Roadmap to the Structure-Related Metabolism Pathways of Per- and Polyfluoroalkyl Substances in the Early Life Stages of Zebrafish (Danio rerio)*, 129 *Env't Health Perspectives* 077004 (2021).

⁵⁹ Commission Regulation 2023/915 of April 25, 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006, 2023 O.J. (L 119) 145.

⁶⁰ 21 C.F.R. § 109.6(b)

⁶¹ See Env't Protection Agency, Office of Water, *Contaminants to Monitor in Fish and Shellfish Advisory Programs: Compilation of Peer Review-Related Information A-8* (2024)

approach, using NHANES consumption data to estimate consumption of the foods that can be measured using the PFAS 30 method.

Tailoring the EPA’s PFAS assessment framework to the FDA’s needs in this way will ensure a robust and protective risk assessment that will produce the protective action levels needed to address the threat of widespread PFAS contamination.

E. Action levels can be set that are achievable and will not increase food prices

Achieving action levels is feasible, will not likely come at a significant cost, and will improve America’s health and agricultural economy. In the U.S. and abroad, many governments have already taken steps to remove PFAS from the environment generally and from food specifically. These measures have been successful, and are likely to continue, which will decrease the cost of compliance for PFAS action levels. The EU in particular has enacted PFAS limits on many of the foods that can be measured under the PFAS 30 method, demonstrating the feasibility of PFAS action levels. This makes action levels a clear win-win for consumers, the environment, and food producers.

Driving PFAS in our food supply closer to zero is the goal and is already happening. Both federal agencies and state governments are already taking steps to remove PFAS from food directly and indirectly.

The FDA and other federal agencies, such as the EPA, are acting to phase out PFAS use and prevent PFAS contamination of the environment.⁶² This will naturally reduce PFAS contamination of food over time. Many private companies have already voluntarily begun to phase out PFAS, reducing the amount they release into the environment.⁶³ FDA’s testing (though limited by the use of a 99% confidence interval) has found no PFAS “in over 97% (787 out of 810) of the fresh and processed foods tested.”⁶⁴ As was the case with FDA action levels set for arsenic in apple juice, this means that many companies may already be meeting health protective

<https://www.epa.gov/system/files/documents/2024-06/contaminants-monitor-fish-peer-review-package.pdf> (last accessed Nov. 14, 2024); Env’t Protection Agency, Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health, 1-12 to 1-13 (2000)

<https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf> (last visited Nov. 27, 2024).

⁶² See e.g. Env’t Protection Agency, Key EPA Actions to Address PFAS (2024) <https://www.epa.gov/pfas/key-epa-actions-address-pfas> (last visited Dec. 2, 2024).

⁶³ See 3M, 3M to phase out PFAS use by end of 2025 (2022) <https://news.3m.com/2022-12-20-3M-to-Exit-PFAS-Manufacturing-by-the-End-of-2025> (last visited Nov. 25, 2024). Shaleene Thompson, Phasing Out “Forever Chemicals”: Finding Alternatives for PFAS, Battelle (2024), <https://inside.battelle.org/blog-details/phasing-out-forever-chemicals-finding-alternatives-for-pfas> (last visited Nov. 25, 2024).

⁶⁴ See Food and Drug Admin., Per- and Polyfluoroalkyl Substances (PFAS) (2025) <https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas> (last visited Feb. 20, 2025).

levels of PFAS, and will need to take no action at all to comply.⁶⁵ Furthermore, to address PFAS in food specifically, the USDA has implemented programs designed to remediate and financially protect farmers (and therefore consumers) from remaining PFAS contamination.⁶⁶

States are also acting to address PFAS contamination. The state of Maine has regulated PFAS in agricultural sludge specifically,⁶⁷ and has established a PFAS fund to financially protect farmers.⁶⁸ Many other states have prohibited or proposed to prohibit PFAS in various consumer products and waterways.⁶⁹ This federal and state support will make it easier for farmers to reduce PFAS in their food.

Reductions of PFAS in food are feasible and have already been achieved outside the U.S. The European Union has established PFAS limits in certain foods and taken steps to limit PFAS in others. The European Food Safety Agency (EFSA) established maximum levels for PFOS, PFOA, PFNA, and PFHxS, as well as a maximum level for the sum of all four, in certain categories of foods in 2022.⁷⁰

To develop intake limits, the EFSA did what we are recommending the FDA do here: a risk assessment.⁷¹ Also as we recommend, the EFSA based their assessment on risk to children due to their heightened vulnerability to and consumption of PFAS.⁷² The EFSA calculated a tolerable weekly intake of 4.4 nanograms per kilogram of body weight per day (6.28×10^{-7} mg/kg-day) for a combination of 4 PFAS: PFOA, PFNA, PFHxS, and PFOS. The EU Commission then set both

⁶⁵ See Coral Beach, FDA adopts decade-old draft guidance for arsenic in apple juice, Consumer Reports (2024) <https://www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/> (last visited Jan. 14, 2024).

⁶⁶ U.S. Dept. of Agriculture, Per-and Polyfluoroalkyl Substances (PFAS) (2024) <https://www.farmers.gov/protection-recovery/pfas#program-support> (last visited Nov. 27, 2024); U.S. Dept. of Agriculture, Mitigation and Remediation of PFAS (2024) <https://www.ars.usda.gov/pacific-west-area/riverside-ca/agricultural-water-efficiency-and-salinity-research-unit/research/mitigation-and-remediation-of-pfas/> (last visited Nov. 27, 2024).

⁶⁷ See e.g. H.P. 1417, 130th Legislature, 2nd Regular Session, (Me. 2022). http://www.mainelegislature.org/legis/bills/display_ps.asp?id=1911&PID=1456&snum=130 (last visited Nov 25, 2024).

⁶⁸ See Maine Department of Agriculture, Conservation, and Forestry, *Fund to Address PFAS Contamination* (2024) <https://www.maine.gov/dacf/ag/pfas/pfas-fund.shtml> (last visited Dec. 2, 2024); .

⁶⁹ See Safer States, PFAS "Forever Chemicals," (2025) <https://www.saferstates.org/priorities/pfas/> (last visited Feb. 20, 2025).

⁷⁰ Originally established in 2022, see 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 OJ (L 316), the requirements were reorganized without changes in 2023, see Commission Regulation 2023/915 of April 25, 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006, 2023 O.J. (L 119) 145.

⁷¹ EFSA Panel on Contaminants in the Food Chain, *Risk to Human Health Related to the Presence of Perfluoroalkyl Substances in Food*, 18 EFSA J. 6223 (2020).

⁷² *Id.* at 7.

individual and combined legal limits for food groups to reduce exposure to that level.⁷³ The EU established limits for eggs, fish, crustaceans, bivalve mollusks, meat, and offal. These limits range from 0.2-50 µg/kg, though most are under 1 µg/kg.⁷⁴

Based on the EFSA’s recommendations, the EU Commission has also established “initiative levels” for fruits, vegetables, wild fungi, milk, and baby food. Like FDA action levels, the EU’s initiative levels are not legally binding, but are used as screening levels, the exceedance of which indicates a need for investigation into source contamination.⁷⁵

Table 2: Summary of EU regulatory and initiative levels.

PFAS Compound	Food	EU Limit (µg/kg)
PFOA	EU: Fruits and Vegetables	0.010 (initiative level)
PFNA	FDA: Lettuce, Blueberries	0.005 (initiative level)
PFHxS		0.015 (initiative level)
PFOS		0.010 (initiative level)
PFOA	Milk	0.01 (initiative level)
PFNA		0.05 (initiative level)
PFHxS		0.06 (initiative level)
PFOS		0.02 (initiative level)
PFOA	Eggs	0.3
PFNA		0.7
PFHxS		0.3

⁷³ See 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 OJ (L 316)

⁷⁴ Commission Regulation 2023/915 of April 25, 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006, 2023 O.J. (L 119) 145.

⁷⁵ Commission Recommendation (EU) 2022/1431 of August 24, 2022 on the monitoring of perfluoroalkyl substances in food, 2022 OJ (L 221)

PFOS		1.0
Total		1.7
PFOA	Salmon ⁷⁶	0.2
PFNA		0.5
PFHxS		0.2
PFOS		2.0
Total of 4 PFAS		2.0
PFOA		Clams
PFNA	1.0	
PFHxS	1.5	
PFOS	3.0	
Total of 4 PFAS	5.0	

The EU’s limitations have now been in force for two years, demonstrating the feasibility of monitoring for and preventing PFAS contamination. The EU’s experience shows that regulatory limits around at least the 1 µg/kg (ppb) mark are achievable. Importantly, all of the EU’s initiative levels (which, like action levels, are not legally binding) fall much lower, around the 50 ng/kg (ppt) level. The EU’s initiative levels both demonstrate the feasibility of very low action levels and underscore the health risks that even these very low concentrations of PFAS pose.

Costs associated with removing PFAS-contaminated products from the food supply won’t raise prices for consumers. Farm gate prices are unlikely to be impacted by the cost of cleaning up PFAS contamination.⁷⁷ The farm gate price of the raw crops ultimately eaten by American

⁷⁶ The EU allows slightly higher levels than these if the salmon is wild caught and not intended for consumptionn by infants and small children.

⁷⁷ See Yudong Xing et al., The sources and bioaccumulation of per- and polyfluoroalkyl substances in animal-derived foods and the potential risk of dietary intake, 905 *Science of the Total Environment* (2023); cf. Food and Drug Admin., Per- and Polyfluoroalkyl Substances (PFAS) (2024) (“PFAS in the environment can enter the food supply through crops and animals grown, raised, or processed in contaminated areas”).

consumers represents a small portion of overall food costs, most of which come from other aspects of the supply chain, such as transportation and processing.⁷⁸ This means that any cost of removing PFAS from food that gets passed on to consumers will represent a small portion of the price ultimately paid for the food.

Protecting our food from PFAS is not only feasible, it is financially prudent. Establishing action levels for PFAS will protect Americans' health, improve Americans' lives, and save Americans' money. As the EPA recently determined while establishing limits for PFAS in water, reducing the ingestion of toxic PFAS comes with serious health benefits.⁷⁹ Reducing PFAS ingestion will not only reduce rates of death and hospitalization but will also improve American's overall health by improving our immune systems.⁸⁰ Avoiding bad health outcomes and improving health is good in and of itself, but it also saves Americans (and the government) money on healthcare costs. Especially because PFAS in food is likely a more significant source of PFAS exposure than water, PFAS action levels are likely to come with even greater health benefits and savings.

As European restrictions tighten, the U.S. must take action to avoid becoming a dumping ground for PFAS-contaminated produce. Further regulations on PFAS compounds, including some bans, are expected in the EU.⁸¹ As these regulations tighten, not only will U.S. products increasingly fail to be marketable in the EU, but EU products not meeting regulations will be shifted to the U.S. market, further increasing Americans' levels of PFAS exposure, unless the FDA sets action levels.⁸²

III. Conclusion

The American public has made addressing the health effects of PFAS contamination a priority.⁸³

Given the health risks presented by even small exposures to some PFAS, and the scientific uncertainty as to the full extent of these health risks and the complete spectrum of risks from

⁷⁸ Jing Yi et al., Post-farmgate food value chains make up most of consumer food expenditures globally, 2 *Nature Food* 417 (2021). Economic Research Service, Price Spreads from Farm to Consumer, U.S. Dept. of Agriculture, (2024) <https://www.ers.usda.gov/data-products/price-spreads-from-farm-to-consumer/> (last visited Dec. 16, 2024).

⁷⁹ See Env't Protection Agency, Benefits and Costs of Reducing PFAS in Drinking Water (2024) https://www.epa.gov/system/files/documents/2024-04/pfas-ncdwr_fact-sheet_cost-and-benefits_4.8.24.pdf (last visited Dec. 2, 2024)

⁸⁰ See *Id.*

⁸¹ Alex Scott, *The Battle Over PFAS in Europe*, Chemical and Engineering News (2023) <https://cen.acs.org/policy/chemical-regulation/battle-over-PFAS-Europe/101/i31> (last accessed Nov. 13, 2024).

⁸² See Pat Rizzuto and Stephen Gardner, *US Food Faces PFAS Challenge as European Rules, Policies Expand*, Bloomberg Law (2023) <https://news.bloomberglaw.com/environment-and-energy/us-food-faces-pfas-challenge-as-european-rules-policies-expand> (last visited Dec. 3, 2024).

⁸³ Margo Kenyon, *Voters Are Deeply Concerned About Health Impacts of PFAS and Support Creating a Fund for Groups Impacted by Exposure*, Data for Progress (2024) <https://www.dataforprogress.org/blog/2024/8/8/voters-are-deeply-concerned-about-health-impacts-of-pfas-and-support-creating-a-fund-for-groups-impacted-by-exposure> (last accessed Nov. 19, 2024).

different PFAS, the FDA should act proactively to protect the public's health and consumer confidence in these otherwise healthful foods. To this end, we suggest the use of action levels for PFAS to protect public health while tolerances are developed. Establishing these action levels is feasible and can be accomplished swiftly using methods from the EPA's public and peer-reviewed guidance for establishing fish advisories.

EWG appreciates the opportunity to provide these comments. Thank you for your consideration. Should you have any questions about this comment, please contact Melanie Benesh, mbenesh@ewg.org.

Sincerely,

David Andrews, Acting Chief Science Officer
Melanie Benesh, Vice President for Government Affairs
Diego Huerta, Stabile Law Fellow

Environmental Working Group

1250 I Street NW, Suite 1000

Washington, DC 20005

mbenesh@ewg.org