U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

June 17, 2026

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Re: Docket Number FDA-2023-P-4826

Dear Ms. Daussin:

This letter responds to your citizen petition (Petition) on per- and polyfluoroalkyl substances (PFAS), submitted on November 1, 2023, as amended by your supplementary submission dated May 15, 2025 (Supplement).[1]

In your Petition, you requested that the Food and Drug Administration (FDA or we) "[s]et New Temporary Tolerances Under 21 CFR Subpart B – *Tolerances for Unavoidable Poisonous or Deleterious Substances*, § 109 for PFAS Residues."[2] Specifically, you asked that we "establish tolerances at the method detection limit ('MDL') . . . for residues of either twenty-six (26) or thirty (30) PFAS in a variety of foods . . . ."[3] You wrote, "Petitioners expressly and exclusively seek mandatory enforceable temporary tolerances, rather than action levels, for the PFAS indicated herein."[4]

In your Supplement, you amended your requests.[5] First, you added to the list of PFAS for which you requested that FDA establish tolerances.[6] You also made a new request in the alternative:

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[1] See Citizen Petition from Sandra Daussin, Esq., et al, submitted to the Division of Dockets Management, Food and Drug Administration, dated November 1, 2023 (FDA-2023-P-4826-0001); Supplements from AVA Law Group, dated May 15, 2025 (FDA-2023-P-4826-0013).

[2] Petition at 2.

[3] Id.

[4] Id.

[5] See Supplement.

[6] Id.

that FDA establish action levels for certain PFAS substances and commodities while establishing tolerances for others.[7]

With respect to the first change, your Supplement noted, "After the Petition was filed, FDA issued the *PFAS-30* Method as 'Method No. C-010.03' along with validation data for all 30 target PFAS analytes for all food matrices at issue, and at lower MDLs."[8] You asked that FDA now establish "temporary tolerances for all 30 target analytes in 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 at the newly lowered MDLs."[9]

With respect to the second change, your Supplement asked that "[f]or milk, salmon, [and] clams only, [FDA] establish tolerances at the MDLs, as defined in the PFAS-30 Method, for each PFOS [perfluorooctanesulfonic acid] and PFOA [perfluorooctanoic acid] and establish action levels at the method defined MDLs for the remaining 28 PFAS . . . ."[10] You also asked that "[f]or lettuce (head and leaf), blueberries, ready-to-eat bread, eggs, corn silage, and corn snaplage, [FDA] establish action levels at the method-defined MDLs for all 30 PFAS . . . ."[11]

We have carefully considered your Petition, Supplement, attachments, and a comment that we received to the docket. We share with you a common goal of protecting the public from harmful PFAS exposure, and FDA is currently considering setting action levels for PFAS in some products. However, based on the information available at this time, including the information submitted in your Petition and Supplement, there is insufficient evidence to support your request to set action levels and/or tolerances at the specific levels, for these specific PFAS, and for the specific commodities, under sections 402(a)(1) or 406 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(1) or 346).

The steps that FDA has taken and plans to take address potential PFAS contamination in food in a way that is scientifically sound and consistent with our policy goals. Addressing the potential effects of Americans' exposure to certain PFAS is an FDA priority. We are working to identify routes of PFAS exposure, understand associated safety risks, and reduce the public's dietary exposure to those PFAS that may pose safety concerns. We are also gathering data to support setting action levels for PFAS for some products in the future. Through these and other efforts, FDA is committed to addressing PFAS exposure in an agile and vigorous manner. For these reasons, and those discussed below, we are denying your requests.

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[7] Id.

[8] Supplement Part 1 at 10.

[9] Supplement Part 1 at 11.

[10] Supplement Part 1 at 13.

[11] Id.

DISCUSSION

I. Background

A. FDA's Regulation of Contaminants in Food

As part of FDA's goal to protect and promote the health and wellness of all people, we seek to reduce dietary exposure to contaminants, such as PFAS in food from environmental contamination, to as low as possible, while maintaining access to nutritious foods. A food is adulterated if it contains a poisonous or deleterious substance which may render it injurious to health.[12] For unavoidable contaminants in food, FDA may set action levels, tolerances, and regulatory limits.[13]

FDA has not set levels for most chemical contaminants in food, including PFAS. However, FDA generally has taken the approach of assessing, on a case-by-case basis, whether the type and level of the contaminant found in the food may pose a health concern, such that the food is considered to be adulterated in that the levels may render the food injurious to health.

By contrast, unlike contaminants in food, chemicals added to food through their intended use (e.g., as an ingredient or as a food contact substance that migrates into food from food packaging or food processing equipment) are regulated as food additives, as defined in section 201(s) of the FD&C Act (21 U.S.C. 321).[14] Food additives require pre-market review and authorization by FDA under section 409 of the FD&C Act (21 U.S.C. 348). A food is adulterated if it is or contains an unsafe food additive within the meaning of section 409 of the FD&C Act.[15]

B. General Information on PFAS

Per- and polyfluoroalkyl substances, or "PFAS," are a diverse group of thousands of synthetic chemicals. PFAS are used in a wide range of consumer and industrial products, previously

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[12] Section 402(a)(1) of the FD&C Act (21 U.S.C. 342(a)(1)).

[13] See 21 CFR part 109.

[14] A "food additive" is defined under section 201(s) of the FD&C Act as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, or holding food; and including any source of radiation intended for such use) . . . ."

[15] See section 402(a)(2)(C) of the FD&C Act.

including some food packaging.[16] They do not easily break down, and some types have been shown to accumulate in the environment and in our bodies. Exposure to certain types of PFAS has been linked to serious health effects, including hepatic, cardiovascular, immune, and developmental effects.[17]

Certain PFAS can enter foods through environmental contamination, such as from pollution from industrial facilities where PFAS are produced or used to manufacture other products, from the use of PFAS-containing products, and from discarded products leaching PFAS in landfills. In addition, the use of soil, water, or biosolids contaminated with PFAS to grow crops, raise animals intended for food, or raise fish or other seafood, can lead to PFAS entering the food supply. This type of contamination can occur in a specific geographic area—for example, a water well or farm near an industrial facility where PFAS were produced; or an oil refinery, airfield, or other location where PFAS were used.

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[16] While not the subject of this Petition, the specific types of PFAS that can migrate to food from food packaging go through pre-market FDA review as food additives before they enter the market to ensure that exposure levels from their intended use do not pose a health risk (see section 409 of the FD&C Act). In 2020, in response to FDA's post-market scientific review and analysis of data raising potential safety concerns about the toxicity of food contact substances containing short-chain PFAS with 6:2 fluorotelomer alcohol (6:2 FTOH), three manufacturers committed to a three-year market phase-out of these substances and to cease all sales of these substances in the U.S. market by December 31, 2023. In February 2024, FDA announced that grease-proofing substances containing PFAS are no longer being sold by manufacturers for food contact use in the U.S. market. U.S. Food and Drug Administration, "FDA Announces PFAS Used in Grease-Proofing Agents for Food Packaging No Longer Being Sold in the U.S." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-announces-pfas-used-grease-proofing-agents-food-packaging-no-longer-being-sold-us*. In January 2025, FDA announced that the 35 food contact notifications relating to PFAS-containing food contact substances as grease-proofers applied to paper and paperboard food packaging are no longer effective based on abandonment of these uses. Food Contact Notifications That Are No Longer Effective, 90 FR 653, January 6, 2025. These actions eliminate the primary source of dietary exposure to PFAS from authorized food contact uses. U.S. Food and Drug Administration, "Per- and Polyfluoroalkyl Substances (PFAS)." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas*.

[17] U.S. Agency for Toxic Substances and Disease Registry, "Toxicological Profile for Perfluoroalkyls." Accessed April 24, 2026. Available at: *https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf*; U.S. Environmental Protection Agency, "Learn About the Human Health Toxicity Assessment for PFBS." Accessed April 24, 2026. Available at: *https://www.epa.gov/chemical-research/learn-about-human-health-toxicity-assessment-pfbs*; U.S. Environmental Protection Agency, "Human Health Toxicity Assessments for GenX Chemicals." Accessed April 24, 2026. Available at: *https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals*; U.S. Environmental Protection Agency, "EPA Publishes IRIS Handbook and Final IRIS Assessment of Perfluorobutanoic Acid (PFBA) and Related Salts." Accessed April 24, 2026. Available at: *https://www.epa.gov/newsreleases/epa-publishes-iris-handbook-and-final-iris-assessment-perfluorobutanoic-acid-pfba-and*.

C. FDA Is Committed to Understanding and Addressing PFAS Exposure

Because exposure to some types of PFAS has been linked to serious health effects, we are working to better understand PFAS in foods, including those present due to environmental contamination.[18] Since 2019, we have taken the following actions, among others:[19]

- Advanced testing for PFAS in foods by:
  - Making available the first single lab validated scientific method for testing 30 different types of PFAS in a highly diverse sample of foods.
  - Optimizing our testing method for use in processed foods.
- Tested nearly 1,900 samples of foods on the U.S. market.
- Provided technical assistance to states, including testing over 400 samples from foods (not on the market) grown, raised, or processed in known areas of contamination.
- Conducted human health assessments for individual PFAS detected in foods collected by FDA from the U.S. market and foods tested as part of FDA's technical assistance to states.
- Issued a notice in the *Federal Register* requesting information on PFAS in seafood in November 2024.[20] The purpose of the notice is to gather scientific data and information from the seafood industry, academia, and state and federal agencies, as well as other interested entities, on PFAS concentrations in seafood, the surrounding environment, and processing water, as well as mitigation strategies for reducing PFAS in seafood. The request is part of FDA's continued work to increase our understanding of the potential for PFAS exposure from seafood and to reduce dietary exposure to PFAS that may pose a health concern.

When states identify foods that are grown or produced in a specific geographic area of contamination, they can contact FDA to request technical assistance. FDA may assist by analyzing samples, assessing the safety of levels of PFAS found in a food, and consulting on methodologies for testing for PFAS. We work with local and state partners, as well as other federal agencies, to determine the actions needed to address any food safety risks and, if necessary, prevent the food from entering the marketplace if determined to be a health concern.

For example, we conducted limited surveys on dairy products from certain farms in the Clovis, New Mexico area and produce from the Fayetteville, North Carolina area—specific areas with

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[18] See U.S. Food and Drug Administration, "Per- and Polyfluoroalkyl Substances (PFAS)." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas*.

[19] Id.

[20] Request for Information: Per and Polyfluoroakyl Substances in Seafood, 89 FR 91765, November 20, 2024; see U.S. Food and Drug Administration, "The FDA Issues Request for Information on PFAS in Seafood." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-issues-request-information-pfas-seafood*.

known PFAS contamination.[21] For every sample in which PFAS was detected, FDA scientists performed a safety assessment. In the case of one dairy farm in New Mexico, milk samples were determined to be a potential health concern.[22] All milk from the farm was discarded, and milk production from cattle from the farm has been suspended.[23] In the case of the produce samples that were collected from farm stands in North Carolina, the levels of PFAS detected were low. Based on our safety assessment using the best available science, the samples were determined to not likely be a health concern at the levels found through testing.[24]

We are working to better understand whether food from the general food supply is a significant source of PFAS exposure for consumers. We continue to test foods from the general food supply, with the goal of accurately estimating consumers' exposure to PFAS from foods and to inform future sampling activities. This includes ongoing testing of Total Diet Study[25] samples and conducting two surveys of bottled water. We have also conducted additional seafood testing, including a targeted sampling assignment of clams and other bivalve mollusks (e.g., oysters, mussels, and scallops), and a 600-sample survey of the top 10 consumed seafood species in the United States. To expedite our testing schedule, we are increasing our laboratory capacity by transferring analytical methods for testing PFAS in foods to additional FDA laboratories.

The results of our testing of the general food supply are summarized and posted on FDA's website as soon as they are available. If FDA finds that the level of PFAS creates a health concern, we can take action, which may include working with the manufacturer to resolve the issue and taking steps to prevent the product from entering, or remaining in, the U.S. market. For example, in 2022, two firms recalled seafood products after FDA's testing determined that

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[21] See U.S. Food and Drug Administration, "Statement on FDA's scientific work to understand per- and polyfluoroalkyl substances (PFAS) in food, and findings from recent FDA surveys." Accessed via wayback machine April 24, 2026. Available at: *https://wayback.archive-it.org/7993/20201221225810/https://www.fda.gov/news-events/press-announcements/statement-fdas-scientific-work-understand-and-polyfluoroalkyl-substances-pfas-food-and-findings*.

[22] Id.

[23] Id.

[24] Id.

[25] The FDA Total Diet Study monitors levels of contaminants and nutrients in foods that the average U.S. consumer might eat. FDA uses these data to estimate how much nutrients and contaminants the U.S. population and subpopulations consume on average each day. Total Diet Study foods are regionally and nationally distributed, are purchased at grocery stores, and represent the broad range of foods—breads, dairy, produce, meat, fish, poultry, as well as processed foods, such as macaroni and cheese and salad dressing, etc. Foods are prepared as typically eaten to provide realistic estimates of what is in the foods we eat. PFAS testing is not officially a part of the TDS program, but FDA has been utilizing foods collected for the TDS program for PFAS analysis to better understand the occurrence of PFAS in foods. To date, FDA has posted results from the analysis of over 1,350 foods, of which over 95% had no PFAS detected (see U.S. Food and Drug Administration, "Analytical Results of Testing Food for PFAS from Environmental Contamination." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/environmental-contaminants-food/analytical-results-testing-food-pfas-environmental-contamination#68517e0b97f12*).

levels of certain PFAS were a likely health concern.[26] In a follow-up to those recalls, FDA conducted a survey of both domestic and imported clams to gather more information about potential sources of contamination and ways in which PFAS concentrations in clams may be reduced.[27] The survey of imported clams resulted in three shipments of clams being refused entry into the U.S. due to elevated levels of PFAS.[28]

In March 2024, FDA issued a new import alert for human food products with levels of chemical contaminants that may present a safety concern to human health.[29] Under Import Alert 99-48, Detention without Physical Examination of Foods Due to Chemical Contamination, FDA identifies firms with a history of offering for import into the U.S. food products contaminated with human-made chemicals, including PFAS, and can prevent entry of future violative shipments.[30]

In February 2025, FDA added eight firms to Import Alert 99-48 to help prevent future entry of their shipments of processed clams into the United States, due to contamination with PFAS.[31] We detected elevated levels of PFAS, notably PFOA (perfluorooctanoic acid), in samples of clams from the firms, resulting in the products being subject to refusal of admission to the U.S. market under the FD&C Act. As FDA continues to update and enhance our approach and process for evaluating and monitoring chemicals, this Import Alert is an additional tool we can employ in our commitment to reducing harmful exposure to chemical contaminants, like certain PFAS, in the food supply. Through these and other efforts, FDA is protecting the public health and safety.

D. The Science Around Testing and Understanding PFAS Exposure and Its Effects on Human Health Is Rapidly Evolving

Although various types of PFAS have been in use in consumer and industrial products for more than 80 years, the scientific understanding of PFAS occurrence in foods and the development and improvement of technical instrumentation and analytical methods needed to test for PFAS at very low concentrations in food began only recently. FDA has been leading the science in developing

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[26] U.S. Food and Drug Administration, "FDA Shares Results on PFAS Testing in Seafood." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-shares-results-pfas-testing-seafood*.

[27] U.S. Food and Drug Administration, "FDA Shares Testing Results for PFAS in Clams." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-shares-testing-results-pfas-clams*.

[28] Id.

[29] U.S. Food and Drug Administration, "FDA Issues Import Alert for Food Products with Chemical Contaminants Including PFAS." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-issues-import-alert-food-products-chemical-contaminants-including-pfas*.

[30] U.S. Food and Drug Administration, "Import Alert 99-48." Accessed April 24, 2026. Available at: *https://www.accessdata.fda.gov/cms_ia/importalert_1180.html*.

[31] U.S. Food and Drug Administration, "FDA Adds Firms to Import Alert Due to PFAS in Clams." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-adds-firms-import-alert-due-pfas-clams*.

validated methods for testing for PFAS in increasingly diverse types of foods. We are testing for extremely low levels of these chemicals—in the parts per trillion. We have extended our testing method to increase the number of PFAS that we can test for, informed by scientific literature. We select the types of PFAS to test for based on their expected uptake by foods and the availability of the chemical standards to accurately identify their presence.

FDA is also expanding our research efforts by using high resolution mass spectrometry testing. This will allow us to determine which additional types of PFAS, beyond those we are specifically testing for with the current method, are present in foods and should be included in targeted methods going forward.

Most of our testing of the general food supply is of samples collected for the Total Diet Study.[32] No PFAS have been detected in over 95% (1,290 out of 1,352) of the fresh and processed foods tested from the Total Diet Study. At least one type of PFAS was detected in 69% (46 out of 67) of the Total Diet Study seafood samples and in 74% (60 out of 81) of the samples from our 2022 targeted seafood survey.[33] When PFAS are detected in a food sample, FDA may conduct an assessment for each type of PFAS for which there are toxicological reference values (TRVs).[34] At this time, there are ten types of PFAS[35] for which there are TRVs that are used to assess potential adverse health effects for levels found in food due to environmental contamination. Currently, FDA evaluates each PFAS detected in a food sample individually; however, we are exploring approaches for evaluating the cumulative effects from co-occurrence of multiple PFAS in a single sample.

As the science continues to evolve regarding establishing additional TRVs and on cumulative exposure assessment, our conclusions related to the potential human health concerns for certain

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[32] U.S. Food and Drug Administration, "FDA Total Diet Study." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/reference-databases-and-monitoring-programs-food/fda-total-diet-study-tds*.

[33] Recognizing the need for additional data on seafood, FDA published in the *Federal Register* a notice requesting information on PFAS substances in seafood. 89 FR 91765, November 20, 2024. Data and information that we received in response to this notice will inform FDA's future steps on PFAS in seafood.

[34] In this context, a toxicological reference value is a value that represents a concentration or dose of a contaminant, in this case in food, at which there is expected to be no observable effects. TRVs are derived from human and/or animal data and take into consideration factors such as the dosage at which no or lowest observed adverse effect level is observed in test subjects, uncertainty factors, route of exposure, length of exposure, etc.

[35] PFOA (perfluorooctanoic acid); PFOS (perfluorooctanesulfonic acid); PFNA (perfluorononanoic acid); PFHxS (perfluorohexanesulfonic acid); HFPO-DA [GenX] (hexafluoropropylene oxide dimer acid); PFBS (perfluorobutanesulfonic acid); PFBA (perfluorobutanoic acid); PFHxA (perfluorohexanoic acid); PFDA (perfluorodecanoic acid); and 6:2 FTS (6:2 fluorotelomer sulfonic acid). U.S. Food and Drug Administration, "Testing Foods for PFAS and Assessing Dietary Exposure." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure*.

levels of PFAS found in food may change.[36] The changing nature of toxicological information and the science surrounding PFAS is illustrated by the TRVs that FDA uses for assessments. For example, the TRV FDA uses for assessing PFOA levels in foods has been updated twice since 2016. The U.S. Environmental Protection Agency (EPA) published an oral reference dose (RfD) in 2016 of 20 nanograms (ng)/kilogram (kg) body weight (bw)/day,[37] which was then lowered almost ten-fold by the U.S. Agency for Toxic Substances and Disease Registry's (ATSDR) publishing of an oral minimal risk level (MRL) for PFOA of 3.0 ng/kg bw/day.[38] Most recently, EPA published an updated oral RfD of 0.03 ng/kg bw/day, nearly 700-fold less than their original RfD 8 years prior.[39] Likewise, our detection methods for analyzing PFAS in foods will likely improve over time, whether through increasing the number of compounds that can be screened, by achieving lower limits of detection, or both.

Although we have taken important steps to expand our understanding of PFAS, we are still in the process of gathering additional information, which may inform setting action levels for specific PFAS in affected foods. Gathering and assessing this information will take additional time. Furthermore, given the breadth of FDA's foods program, we must balance multiple public health and regulatory priorities.

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[36] FDA has used TRVs published by both ATSDR and EPA for assessing safe levels of PFAS in foods. ATSDR develops TRVs called MRLs for PFAS compounds when there are reliable and sufficient data on a specific route of exposure, a known specific health effect from that exposure, and the target organ of that health effect. An MRL estimates the daily human exposure to a substance that results in an unlikely risk of adverse noncancer health effects over a specified route and duration of exposure. U.S. Agency for Toxic Substances and Disease Registry, "Toxicological Profile for Perfluoroalkyls." Accessed April 24, 2026. Available at: *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*.

EPA develops TRVs called oral RfDs for PFAS compounds. An RfD is an estimate of the daily oral exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime. U.S. Environmental Protection Agency, "Research on Per- and Polyfluoroalkyl Substances (PFAS)." Accessed April 24, 2026. Available at: *https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas*

[37] U.S. Environmental Protection Agency, "Health Effects Support Document for Perfluorooctanoic acid (PFOA)." Accessed via wayback machine April 24, 2026. Available at: *https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_hesd_final_508.pdf*.

[38] U.S. Agency for Toxic Substances and Disease Registry, "Toxicological Profile for Perfluoroalkyls." Accessed April 24, 2026. Available at: *https://www.atsdr.cdc.gov/ToxProfiles/tp200.pdf*.

[39] U.S. Environmental Protection Agency, "FINAL: Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA) and Related Salts." Accessed April 24, 2026. Available at: *https://www.epa.gov/system/files/documents/2024-05/final-human-health-toxicity-assessment-pfoa.pdf*.

II. Discussion of Your Petition and Supplement

A. Your Requests

1. Your Petition

In your Petition, you requested that FDA "establish new temporary tolerances at the MDL arising from the inadvertent transfer of certain PFAS to lettuce (head and leaf), blueberries, ready-to-eat bread, milk, eggs, salmon, clams, corn silage, and corn snaplage due to the unavoidable environmental contamination of the soil, air, and water."[40] You stated that the "available data from FDA at the time of the submission of this Citizens' Petition" indicate the current MDL for these analytes in these matrices is 0.05 µg [micrograms]/kg (0.05 ppb).[41] You stated that these tolerances should be set for the 26 and 30 PFAS and "their associated free acid or salt, as applicable."[42]

Specifically, you requested that that FDA "Set Tolerances at the MDL (currently 0.05 PPB [parts per billion]) for 30 PFAS in/on Lettuce (head and leaf) and Blueberries."[43] You listed these 30 PFAS as:

1. PFBA (Perfluorobutanoic Acid)
2. PFBS (Perfluorobutanesulfonic Acid)
3. PFPeA (Perfluoropentanoic Acid)
4. PFPeS (Perfluoropentanesulfonic Acid)
5. PFHxA (Perfluorohexanoic Acid)
6. PFHxS (Perfluorohexanesulfonic Acid)
7. HFPO-DA (GenX) (Hexafluoropropylene Oxide Dimer Acid)
8. 4:2 FTS (Perfluorohexane Sulfonic Acid)
9. PFHpA (Perfluoroheptanoic Acid)
10. PFHpS (Sodium Perfluoroheptanesulfonate)
11. NaDONA (Sodium Dodecafluoro-3H-4,8-Dioxanonanoate)
12. PFOA (Perfluorooctanoic Acid)
13. PFOS (Perfluorooctanesulfonic Acid)
14. FOSA (Perfluorooctane Sulfonamide)
15. 9Cl-PF3ONS (Potassium 9- Chlorohexadecafluoro-3 Oxanonane-1-Sulfonate)
16. 6:2 FTS (Perfluorooctane Sulfonic Acid)
17. PFNA (Perfluorononanoic Acid)
18. PFNS (Perfluorononanesulfonate)
19. PFDA (Perfluorodecanoic Acid)
20. 11Cl-PF3OUdS (Potassium 11- Chloroeicosafluoro-3-Oxaudecane-1-Sulfonate)

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[40] Petition at 2.

[41] Petition at 3-4.

[42] Id.

[43] Petition at 3.

21. PFDS (Perfluorodecanesulfonate)
22. 8:2 FTS (Perfluorodecane Sulfonic Acid)
23. PFUdA (Perfluoroundecanoic Acid)
24. PFUdS (Perfluoroundecane Sulfonate)
25. PFDoA (Perfluorododecanoic Acid)
26. PFDoDS (Perfluorododecane Sulfonate)
27. 10:2 FTS (Perfluorododecane Sulfonic Acid)
28. PFTrDA (Perfluorotridecanoic Acid)
29. PFTrDS (Perfluorotridecane Sulfonate)
30. PFTeDA (Perfluorotetradecanoic Acid)

Your Petition also requested that FDA "Set Tolerances at the MDL (currently 0.05 PPB) for 26 PFAS in/on Ready-to-Eat Bread, Milk, Eggs, Salmon, Clams, Corn Silage and Corn Snaplage."[44,45] You listed these 26 PFAS as:

1. PFBA
2. PFBS
3. PFPeA
4. PFPeS
5. PFHxA
6. PFHxS
7. HFPO-DA (GenX)
8. 4:2 FTS
9. PFHpA
10. PFHpS
11. NaDONA
12. PFOA
13. PFOS
14. FOSA
15. 9Cl-PF3ONS
16. 6:2 FTS
17. PFNA
18. PFNS
19. PFDA
20. 11Cl-PF3OudS
21. 8:2 FTS

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[44] Petition at 4.

[45] You requested that FDA set tolerances at the MDL for 26 PFAS under 21 CFR part 109 (Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material). However, corn silage and corn snaplage are used as animal food and are subject to FDA's regulations under 21 CFR part 509. The criteria for setting tolerances for unavoidable contaminants in animal food under 21 CFR 509.6 are the same as the criteria for setting tolerances for unavoidable contaminants in human food under 21 CFR 109.6. Therefore, our discussion of your request to set tolerances under 21 CFR part 109 would also apply if you had requested that FDA set tolerances for corn silage and corn snaplage under 21 CFR part 509.

22. PFUdA
23. PFDoA
24. 10:2 FTS
25. PFTrDA
26. PFTeDA

You emphasized that all of the tolerances requested in your Petition "*are temporary* and must be lowered as better analytical methodology is developed and to allow lower validated MDLs. In addition, these tolerances must be revoked when there is no longer a reasonable risk of PFAS residues transferring to foods arising from environmental contamination."[46]

2. Your Supplement to the Petition

In your Supplement, you amended your original requests, and you added new requests in the alternative.

First, you amended your original requests. You wrote that "[a]fter the Petition was filed, FDA issued the *PFAS-30 Method* as "Method No. C-010.03" along with validation data for all 30 target PFAS analytes for all food matrices at issue, and at lower MDLs."[47] As such, you "update[d] the request to establish temporary tolerances for all 30 target analytes in 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 at the newly lowered MDLs."[48]

Your Supplement also included an alternative to this amendment, requesting that a subset of the requested tolerances (for two PFAS in three commodities) be set at the newly lowered MDLs: "**[f]or milk, salmon, clams only,** [FDA] **establish tolerances** at the MDLs, as defined in the *PFAS-30 Method*, for each **PFOS and PFOA** . . . ."[49] Under this alternative amendment, you requested that the remaining tolerances for the other PFAS and commodities be set at the MDLs originally specified in your petition.

Second, you added new requests in the alternative to your original requests. As additional alternatives to your primary requests relating to tolerances, your Supplement asked that FDA set action levels for certain PFAS substances and certain commodities. In particular, you asked that FDA still set *tolerances* for PFOS and PFOA in milk, salmon, and clams, but establish action levels (instead of tolerances) as follows:

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[47] Supplement Part 1 at 10 (emphasis in original).

[48] Supplement Part 1 at 11 (emphasis in original).

[49] Supplement Part 1 at 13 (emphasis in original).

- "**[f]or milk, salmon, clams only** . . . establish action levels at the method defined MDLs for the **remaining 28 PFAS** [other than PFOS and PFOA, for which you retained your request for tolerances] identified in the Petition."[50]
- , "**[f]or lettuce (head and leaf), blueberries, ready-to-eat bread, eggs, corn silage, and corn snaplage, establish action levels** at the method-defined MDLs for all 30 PFAS identified in the Petition."[51]

B. FDA Is Addressing Potential PFAS Contamination in Food

While action levels and tolerances are some of the tools that FDA uses to control levels of contaminants in food, FDA may take legal action against a product at the minimal detectable level of a contaminant if the presence of the contaminant adulterates the food, regardless of whether an established action level or tolerance exists.[52] For most foods that FDA regulates, there are no action levels or tolerances set for contaminants, yet FDA is not limited in pursuing compliance or enforcement actions on foods found to contain unsafe levels of contaminants.[53] Where no action level or tolerances have been set, FDA can pursue compliance or enforcement action if the presence of the contaminant adulterates the food even at the minimal level of detection.

When FDA does establish action levels or tolerances, we take a science-based approach, relying on extensive data to determine which commodities and at what level of contamination it is appropriate to set levels. For example, in setting action levels for inorganic arsenic in certain foods, we relied on data on toxicity, consumption patterns, and achievability, among other factors, and not solely based on method detection limits.[54]

While at this time, FDA does not find it appropriate to take the specific actions you request, as discussed above, reducing PFAS exposure in food is a priority for FDA. Through such measures as testing, data collection, and technical assistance to states, we identify sources of PFAS exposure. When we find levels of PFAS in food that may render it injurious to health, we take action, such as refusing shipments, working with firms to voluntarily recall adulterated products,

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[50] Supplement Part 1 at 13 (emphasis in original).

[51] Id.

[52] See guidance for industry *Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed* (August 2000).

[53] See, e.g., U.S. Food and Drug Administration, "Chemical Contaminants & Pesticides." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/chemical-contaminants-pesticides*.

[54] See, e.g., Guidance for industry *Inorganic Arsenic in Rice Cereals for Infants: Action Level* (August 2020); Guidance for industry *Action Level for Inorganic Arsenic in Apple Juice* (June 2023).

or listing firms on import alerts.[55] We are also gathering additional information to support setting action levels in some products.

In your Petition, you asserted that FDA has "failed to take appropriate measures," citing the presence of certain PFAS in retail milk.[56] You asserted that FDA has analyzed only 24 samples of milk between 2019 and 2022, and you speculated that it is "highly likely that adulterated milk" would have been found in stores.[57] Your Petition referred to FDA's analysis of milk in New Mexico and noted FDA's findings of certain PFAS residues in those samples.[58] In your Supplement, you added that EPA and FDA have found PFAS in fish[59] and that a Consumer Reports article reported the presence of PFAS in several other milk samples in 2024, and in infant formula in 2025.[60]

We do not disagree that certain PFAS residues have been found in some food; however, FDA has taken prompt measures in response to such findings. As discussed above, PFAS contamination is known to occur in specific geographic areas.[61] The New Mexico site that you mentioned represents a known area of PFAS contamination, where FDA has worked diligently with the state and industry to monitor safety and mitigate risk. Beyond the 24 samples that you mentioned, we

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[55] See, e.g., U.S. Food and Drug Administration, "FDA Shares Results on PFAS Testing in Seafood." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-shares-results-pfas-testing-seafood*; U.S. Food and Drug Administration, "FDA Issues Import Alert for Food Products with Chemical Contaminants Including PFAS." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-issues-import-alert-food-products-chemical-contaminants-including-pfas*; U.S. Food and Drug Administration, "Import Alert 99-48." Accessed April 24, 2026. Available at: *https://www.accessdata.fda.gov/cms_ia/importalert_1180.html*.

[56] Petition at 14.

[57] Petition at 15.

[58] Petition at 8-9.

[59] Supplement Part 2 at 7-8.

[60] Supplement Part 2 at 5-6. We note that Consumer Reports did not follow FDA's testing method in making these findings; thus, FDA has been unable to determine whether the method that Consumer Reports used was validated or not. See Consumer Reports, "We Tested 41 Baby Formulas for Lead and Arsenic." Accessed April 24, 2026. Available at: *https://www.consumerreports.org/babies-kids/baby-formula/baby-formula-contaminants-test-results-a7140095293/* (stating, "These results aren't included in the chart below because we tested only one sample from each type of formula, which isn't a robust enough test to say which products have it and which ones don't"); see also Consumer Reports, "Forever Chemicals' Are Found in Some Milk, Including Organic." Accessed April 24, 2026. Available at: *https://www.consumerreports.org/pfas/pfas-forever-chemicals-found-in-some-milk-including-organic-a1101576034/* (stating that they used methods "based on" FDA's protocols). In April 2026, FDA released the first set of test results for contaminants, including 30 PFAS, in infant formula as part of Operation Stork Speed. FDA plans to conduct further testing, including for additional contaminants; to continue to engage with manufacturers on measures to reduce the levels of contaminants to as low as possible; and to work to establish action levels for contaminants in infant formula. See U.S. Department of Health and Human Services, "FDA Releases Results from Largest-Ever Testing of Infant Formula in the U.S." Accessed June 16, 2026. Available at: *https://www.hhs.gov/press-room/fda-releases-results-largest-ever-testing-infant-formula-us.html*.

[61] See Section I.B., supra.

have tested milk samples as part of our ongoing TDS testing of the general food supply.[62] When we have tested milk from the general food supply that is not specifically from areas of known contamination, we have seen low levels of PFAS in a very limited number of samples. With respect to PFAS found in fish and other seafood, FDA conducted a seafood survey in 2022 of highly consumed seafood products, which indicated seafood may be at a higher risk for environmental contamination compared with other types of foods.[63] As a result of the survey, two firms, whose canned clams were found to contain levels of PFOA that may have rendered the clams injurious to health, issued voluntary recalls.[64] Follow-up surveys of imported canned clams, as well as a more general bivalve molluscan shellfish assignment resulted in multiple shipments being refused entry into the U.S.[65] These activities ultimately led to the first firms being added to the red list[66] for Import Alert 99-48, Detention Without Physical Examination of Foods Due to Chemical Contamination, for containing levels of PFOA that rendered the food adulterated under section 402(a)(1) of the FD&C Act.[67] In short, we have used our existing authorities to ensure that foods that represent a safety risk do not enter the market and to assist states and industry in addressing sources of PFAS exposure.

In addition to the measures described above, we are taking active steps to continue monitoring and protecting the public from potentially harmful PFAS exposure. We are reviewing EPA's PFAS National Primary Drinking Water Regulation, which establishes maximum contaminant levels for six PFAS in drinking water, for purposes of establishing an FDA regulation for PFAS in bottled water or making a determination that such a regulation is not necessary to protect public health.[68] In addition, we are actively increasing our laboratory capacity so that we can

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[62] See U.S. Food and Drug Administration, "Analytical Results of Testing Food for PFAS from Environmental Contamination." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/environmental-contaminants-food/analytical-results-testing-food-pfas-environmental-contamination#68517e0b97f12*.

[63] See U.S. Food and Drug Administration, "Testing Food for PFAS and Assessing Dietary Exposure." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure#:~:text=Targeted%20Sampling%20of%20Seafood*.

[64] See U.S. Food and Drug Administration, "FDA Shares Results on PFAS Testing in Seafood." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-shares-results-pfas-testing-seafood*.

[65] See U.S. Food and Drug Administration, "FDA Shares Testing Results for PFAS in Clams." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-shares-testing-results-pfas-clams*.

[66] Import alerts are used to protect consumers against products with a history of known violations. FDA has three different list types for import alerts. Red list refers to firms, products, and/or countries that have met the criteria for Detention without Physical Examination (DWPE) under an import alert. When FDA adds a firm, product, and/or country to the red list, FDA will detain future shipments of that product and refuse entry unless the importer can overcome the appearance of the violation(s) by demonstrating to FDA that the product does not have the violation(s) listed on the import alert.

[67] See U.S. Food and Drug Administration, "FDA Adds Firms to Import Alert Due to PFAS in Clams." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-adds-firms-import-alert-due-pfas-clams*.

[68] See section 410 of the FD&C Act (21 U.S.C. 349) ("Bottled drinking water standards; publication in Federal Register").

analyze more foods for PFAS.[69] Our research laboratories are also continuously working to update our method to include additional food matrices and PFAS analytes and to develop new methods.[70] We are reviewing information gathered through our Request for Information on PFAS in seafood,[71] which will inform future targeted sampling beyond what FDA is already doing. These and other efforts represent an approach to PFAS that is soundly based on data while being responsive to rapidly evolving science.

In your Petition, you also make several arguments regarding how FDA should evaluate the potential risks from PFAS exposure. You asserted that FDA is not aligned with other regulatory authorities in our approach to PFAS.[72] Your Petition stated that FDA is "ignor[ing]" or "refusing to assess" the cumulative risk of exposure to more than one PFAS.[73] In addition, your Petition asserted that FDA has failed to consider non-dietary sources of PFAS exposure;[74] that EPA has proposed maximum contaminant levels in water that take into account combined levels;[75] that the European Food Safety Authority considers combined exposures to PFAS;[76] and, citing no data, that there is a "reasonable inference" that the thousands of known PFAS have a common mechanism of toxicity because "they cause similar adverse effects."[77]

However, our evaluation of the potential risks from PFAS exposure is based on our statutory authority and the available science. We note that we are engaged in continual, ongoing efforts to develop our understanding of the cumulative exposure of PFAS, including from multiple

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[69] See U.S. Food and Drug Administration, "Per- and Polyfluoroalkyl Substances (PFAS)." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas*.

[70] See generally Genualdi, S., Young, W., Peprah, E. *et al.* Analyte and matrix method extension of per- and polyfluoroalkyl substances in food and feed. *Anal Bioanal Chem* 416, 627-33 (2024). https://doi.org/10.1007/s00216-023-04833-1.

[71] 89 FR 91765, November 20, 2024; see U.S. Food and Drug Administration, "The FDA Issues Request for Information on PFAS in Seafood." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/hfp-constituent-updates/fda-issues-request-information-pfas-seafood.*

[72] Petition at 9-10.

[73] Petition at 12, 15.

[74] Petition at 9-10.

[75] Petition at 9. We note that on May 20, 2026, EPA proposed to rescind parts of its 2024 rule, citing legal errors in the rulemaking process for PFHxS, PFNA, HFPO-DA, and mixtures of these three PFAS plus PFBS (91 FR 29413). EPA proposed to rescind the standards and Hazard Index associated with PFHxS, PFNA, HFPO-DA, and PFBS and retain only the maximum contaminant levels for PFOS and PFOA at 4 nanograms per liter each (id.); see also U.S. Environmental Protection Agency, "EPA Advances Comprehensive PFAS Strategy with Legally Defensible, Practical, Scientifically Sound Drinking Water Protections." Accessed May 20, 2026. Available at: *https://www.epa.gov/newsreleases/epa-advances-comprehensive-pfas-strategy-legally-defensible-practical-scientifically*; U.S. Environmental Protection Agency, "EPA Announces It Will Keep Maximum Contaminant Levels for PFOA, PFOS." Accessed April 24, 2026. Available at: *https://www.epa.gov/newsreleases/epa-announces-it-will-keep-maximum-contaminant-levels-pfoa-pfos*.

[76] Petition at 9, 16.

[77] Petition at 11.

PFAS.[78] For example, FDA is exploring approaches for evaluating samples where multiple PFAS are identified.[79] As FDA has stated, "As the science continues to evolve on establishing additional TRVs and on cumulative exposure assessments, our conclusions related to the potential human health concerns for certain levels of PFAS found in food may change."[80]

Although FDA will not be taking the specific actions you have requested at this time, we will continue to address potential PFAS contamination in food. We will continue to review the data and take action consistent with our food safety priorities, including setting action levels for PFAS where appropriate.

C. Your Specific Requests Regarding Action Levels

1. Standards Relating to Action Levels

FDA's regulations provide that "[w]hen appropriate," an action level "may be established to define a level of contamination at which a food may be regarded as adulterated."[81] Under section 402(a)(1) of the FD&C Act, a food shall be deemed to be adulterated if it bears or contains an added poisonous or deleterious substance which "may render [the food] injurious to health."

There is no requirement that FDA set action levels for a substance. Section 109.6(d) of our regulations states:

> An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b)[82] of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level for an added poisonous or deleterious substance in any food may be established at a level at

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[78] U.S. Food and Drug Administration, "Per- and Polyfluoroalkyl Substances (PFAS)." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas#:~:text=Accumulation%20of%20certain%20PFAS%20has,associated%20with%20serious%20health%20effects*.

[79] Id.

[80] Id.

[81] 21 CFR 109.4(c)(1).

[82] "Paragraph (b)" refers to 21 CFR 109.6(b), which reads, "A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met: (1) The substance cannot be avoided by good manufacturing practice. (2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances. (3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include 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."

> which the Food and Drug Administration may regard the food as adulterated within the meaning of section 402(a)(1) of the act, without regard to the criteria in paragraph (b) of this section or in section 406 of the act. An action level will be withdrawn when a tolerance or regulatory limit for the same substance and use has been established.

When it is appropriate to set levels, our regulations state that action levels (or tolerances) "are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable."[83]

In establishing action levels in the past, FDA has relied on extensive data to support the specific levels and commodities at issue. For instance, in our guidance setting action levels for lead in processed food intended for babies and young children, FDA relied on collection and analysis of lead data in various processed foods intended for babies and young children together with data-informed analyses that balanced reducing lead exposure with achievability.[84] The exposure assessment considered interim reference levels previously developed by FDA and informed by the blood lead reference value (BLRV) established by the Centers for Disease Control and Prevention.[85] It also included a quantitative component that provided estimates of reduction of dietary exposure to lead from processed food with implementation of these action levels. With respect to achievability, FDA assessed manufacturers' ability to achieve the action levels for lead in these products. FDA based the action levels on data that reflected what would be achievable under current good manufacturing practice. Our recent guidance document establishing an action level for inorganic arsenic in apple juice relied too on a sampling and analysis of data on inorganic arsenic in apple juice together with a risk assessment, an achievability assessment, and an exposure assessment.[86]

2. Your Petition Does Not Contain Facts Demonstrating That It Is Appropriate for FDA to Issue Action Levels for the Specific Commodities and PFAS, and at the Specific Levels, That You Identify in Your Petition and Supplement

We do not find it appropriate to set action levels at the specific levels and for the specific PFAS and commodities that you name at this time based on the available information in support of your requests, and taking into consideration the actions we are already taking to address potential PFAS contamination in food. We note that we do not have TRVs for some PFAS you cite, and for PFAS for which there are TRVs we do not have sufficient data to assess achievability. However, we are gathering additional information to support setting action levels for some

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[83] 21 CFR 109.7(a).

[84] See guidance for industry *Action Levels for Lead in Processed Food Intended for Babies and Young Children* (January 2025).

[85] See Flannery, B., Middleton, K. Updated interim reference levels for dietary lead to support FDA's Closer to Zero action plan. *Regulatory Toxicology and Pharmacology* 133 (2022). https://doi.org/10.1016/j.yrtph.2022.105202.

[86] Guidance for industry *Action Level for Inorganic Arsenic in Apple Juice* (June 2023).

products in the future. As more data become available, FDA will reevaluate the appropriateness of setting action levels for PFAS for specific commodities that take into account such data.

D. Your Specific Requests Regarding Tolerances

Our reasoning regarding your requests for action levels applies equally to your requests for tolerances, and vice versa to the extent the regulatory requirements overlap.[87] However, there are some distinct legal standards relating to tolerance setting. Therefore, we address your requests for tolerances separately.

1. Standards Relating to Tolerances

a) The FD&C Act Authorizes FDA to Issue Regulations Establishing Tolerances When FDA, in Its Discretion, Determines It Is Necessary for the Protection of Public Health

Section 406 of the FD&C Act authorizes FDA to issue regulations establishing "tolerances for poisonous or deleterious substances in food." Under this provision, where a "poisonous or deleterious substance" cannot be avoided, FDA "shall promulgate regulations limiting the quantity . . . to such extent as [it] finds necessary for the protection of public health . . . ."[88] Such regulations establish tolerances. A tolerance sets the level above which a substance in food would be deemed unsafe and which would make such food adulterated under section 402(a)(2)(A) of the FD&C Act. The question of whether it is necessary to establish a tolerance to protect the public health is firmly within FDA's purview.[89] Thus, while the FD&C Act provides FDA the authority to issue tolerances, there is no legal requirement that FDA do so.

b) The Food Additive Provisions of the FD&C Act and EPA's Authorities for Pesticides Do Not Apply to the Setting of Tolerances for Contaminants in Food

Your Petition asserts that a provision of the FD&C Act related to food additives requires FDA to set tolerances for the specified PFAS chemicals. Specifically, you rely on a provision in the FD&C Act, often referred to as the Delaney Clause, that prohibits FDA from issuing a regulation approving a food additive if that additive has been shown "to induce cancer in man or animal."[90] However, as explained above, contaminants in food are not regulated as food additives. Rather, food containing harmful contaminants is regulated under the adulteration provisions of the

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[87] See 21 CFR 109.6(d) ("An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section [relating to tolerances] are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future.").

[88] Id.

[89] *Young*, 476 U.S. at 981-82 (interpreting Section 406 of the FD&C Act "to give the FDA discretion to decide whether tolerance levels are necessary to protect the public health[.]"). *See also Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 376 (2024) ("the Court does not call into question prior cases that relied on the *Chevron* framework[,]" such as *Young*). *See also id.* at 395 (recognizing cases in which "the best reading of a statute is that it delegates discretionary authority to an agency[.]").

[90] Petition at 12; see section 409(c)(3)(A) of the FD&C Act.

FD&C Act related to "poisonous and deleterious substances." Therefore, as explained below, we disagree that the provisions related to food additives are relevant to setting tolerances for contaminants in food.

First, you assert that PFAS chemicals cause cancer and, as a result, FDA has no discretion in whether to set tolerances and must set such tolerances "at zero or the MDL."[91] Your Petition states, "Tolerance setting is generally at the discretion of the Secretary; however, as the U.S. Attorney General opined in 1979, that [sic] if the additive is a carcinogen no discretion can be allowed."[92] However, the opinion that you cite makes clear that its statements regarding lack of discretion are unrelated to setting tolerances for contaminants. The opinion addresses "the statutes that govern food and color additives."[93] Significantly, the opinion incorporates a memorandum from the U.S. Department of Justice's Office of Legal Counsel, which distinguishes between the approval of food additives (which is the subject of the memorandum) and the presence of a substance as a contaminant (which is the situation at issue with PFAS in your Petition). The memorandum expressly notes, "The provision permitting tolerances for substances that could not be avoided by good manufacturing practice applies to contaminants or other substances that may unavoidably be added to food in the production process . . . *and is of little relevance here*."[94] Therefore, the opinion you cite does not support your argument that FDA lacks discretion on whether to issue a regulation establishing tolerances in this situation.

Second, you cite to the Delaney clause in support of your argument that FDA must set tolerances for these PFAS chemicals at zero.[95] Similarly, citing the Delaney clause, you argue in your Supplement that "FDA cannot authorize carcinogenic food contaminants."[96] However, your Petition does not relate to the approval of these PFAS chemicals for use as food additives (such as authorizations for use in food packaging or in food processing equipment). Rather, your Petition seeks FDA action on PFAS as a contaminant "due to the unavoidable environmental contamination of the soil, air, and water."[97] FDA does not "authorize" contaminants, and the Delaney clause does not apply to your request. While you assert that PFAS residues added to

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[91] Petition at 14; see also Petition at 18; see also Supplement Part 1 at 14.

[92] Petition at 18 (citing 43 Op. Att'y Gen. 163 (1979)).

[93] See 43 Op. Att'y Gen. 163.

[94] 43 Op. Att'y Gen. 163, 12 (emphasis added) (internal citation omitted).

[95] Petition at 11-12, 14.

[96] Supplement Part 1 at 14.

[97] Petition at 11-12, 14.

food through environmental contamination are food additives if the contamination is "due to an act of man," the cases you cite to support this idea are not relevant here.[98,99]

In addition, your Petition discusses EPA's tolerance setting for pesticides, citing section 408 of the FD&C Act, the Federal Insecticide, Fungicide, and Rodenticide Act (as amended by the Food Quality Protection Act), and EPA's regulations at 40 CFR 180.5.[100] These provisions are not applicable here. Section 408 of the FD&C Act (21 U.S.C. 346a) provides the Administrator of the EPA with authority to set tolerances for pesticide residues in food. The Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq*., is the federal statute that governs the registration, distribution, sale, and use of pesticides in the United States. Its provisions relate to a different statutory and regulatory scheme than that applicable here. FDA follows the standards relevant to tolerance-setting under section 406 of the FD&C Act and 21 CFR 109.6. The standards relating to EPA's establishment of pesticide tolerances are not instructive here.[101]

c) Procedures and Regulatory Standards for Establishing Tolerances

Tolerance levels, as the Supreme Court has explained, "are set through a fairly elaborate process."[102] The FD&C Act specifies that any action for the issuance of a regulation under section 406 "shall be begun by a proposal" made by the Secretary of Health and Human Services or "by petition of any interested person, showing reasonable grounds therefor . . . ."[103] The Secretary publishes the proposal and "afford[s] all interested persons an opportunity to present their views thereon, orally or in writing," after which the Secretary "act[s] upon such proposal" by order.[104] Within 30 days of the Secretary publishing the Secretary's order, "any person who will be adversely affected by such order . . . may file objections . . . with the Secretary," specifying the objectionable provisions and requesting a public hearing on the objections.[105] The receipt of such objections "operates to stay the effectiveness of those provisions of the order to

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[98] See Petition at 17.

[99] *Gerber Products* dealt with substances that leached from a food contact surface, which are regulated as indirect food additives. *Gerber Prods. Co. v. Fisher Tank Co.*, 833 F.2d 505 (4th Cir. 1987). *Ewig Bros.* involved a pesticide-specific adulteration provision that is no longer in the FD&C Act. *United States v. Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974). *Anderson Seafood* concerned the adulteration standard under section 402(a)(1) of the FD&C Act, relating to poisonous and deleterious substances, rather than food additives. *United States v. Anderson Seafood*, 622 F.2d 157 (5th Cir. 1980).

[100] Petition at 12-13, 15.

[101] Finally, you assert that the European Food Safety Authority has established maximum levels for PFAS in foods and that by failing to set tolerances, FDA is "failing to protect international trade of agricultural goods." Petition at 16. However, you do not explain how your proposed tolerances would relate to the maximum levels established by EFSA.

[102] *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 977 (1986).

[103] Section 701(e)(1) of the FD&C Act (21 U.S.C. 371(e)(1)).

[104] Id.

[105] Section 701(e)(2) of the FD&C Act (21 U.S.C. 371(e)(2)).

which objections are made," until the Secretary takes final action on the objections.[106] The Secretary "shall by order act upon such objections and make such order public."[107]

Section 406 of the FD&C Act does not use the term "temporary" or suggest that "temporary tolerances" are a separate construct subject to different processes or requirements. The establishment of tolerances, whether styled "temporary" or not, must follow these same procedures.

To implement section 406 of the FD&C Act, FDA has issued regulations relating to tolerances. Our regulations at 21 CFR 109.4 on the "[e]stablishment of tolerances, regulatory limits, and action levels" provide:

> (a) When appropriate under the criteria of § 109.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

Subsection 109.6(b) provides:

> A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:
>
> 1) The substance cannot be avoided by good manufacturing practice.[108]
>
> 2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.
>
> 3) *No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established*. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and

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[106] Id.

[107] Section 701(e)(3) of the FD&C Act.

[108] Your Petition asserts that "environmental contamination with PFAS is widespread," but it fails to address whether the cited PFAS could be avoided above the MDL in the identified commodities. We do not discuss this criterion in detail in this response because it is not necessary to the outcome of our decision. More generally, we note that, while we are not aware of a way to remove PFAS from foods once contaminated, there are known practices that can avoid or minimize contamination. These include practices such as sourcing shellfish from uncontaminated waters. In addition, manufacturing practices such as testing raw materials for PFAS could avoid PFAS contamination in finished food products.

> anticipated studies expected to provide significant new toxicological or use data.[109]

Thus, under our regulatory framework, FDA does not establish tolerance levels for a substance unless, among other things, we anticipate that there will not be changes or advances that could affect the appropriateness of the tolerance in the near future.[110]

In the preamble to the final rule establishing 21 CFR 109.6, FDA explained the rationale for this requirement. The preamble stated, "The procedures required by section 406 of the [FD&C] [A]ct, including a public hearing and the requirement of substantial evidence to support a tolerance, contemplate ample evidence, and a relatively stable situation, in which any tolerance promulgated will be appropriate for a relatively long period of time."[111] Similarly, the preamble to the proposed rule explained:

> At times it will not be appropriate to establish a formal tolerance. The Commissioner is not required to establish a tolerance for every added poisonous or deleterious substance, as is indicated by the language of section 406 of the [FD&C] [A]ct recognizing that an adulteration charge can be made under section 402(a)(1) of the act when no tolerance is in effect. . . . When the factors required to be considered prior to promulgation of a section 406 tolerance are rapidly changing, it would be inappropriate to set such a formal tolerance. The procedures required by section 406 . . . contemplate ample evidence to consider, and a relatively stable situation where the evidence will be of more than transient significance and where the tolerance eventually promulgated will be appropriate for a relatively long period of time. For example, if industrial practices are improving so quickly that the extent to which the substance is unavoidable changes significantly from year to year, there is little justification for use of section 406 procedures. Similarly, if toxicological data are scanty or conflicting, but additional data are being developed, it would serve no good purpose to labor over an assessment of the existing data in a public hearing while ignoring the prospects of additional studies. The Commissioner therefore concludes that the structure and criteria of section 406 of the act indicate it is to be used primarily in relatively static circumstances.[112]

Given the evidentiary and procedural standards needed to establish a tolerance for a substance, it is not common for FDA to do so. FDA issued regulations establishing tolerances for one substance—our regulations on polychlorinated biphenyls (PCBs), found at 21 CFR 109.30. Recognizing the well-established data on the harm associated with PCBs, FDA first sought to

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[109] 21 CFR 109.6(b) (emphasis added).

[110] See 21 CFR 109.6(b)(3)).

[111] 42 FR 52814 at 52817, September 30, 1977.

[112] 39 FR 42743 at 42745, December 6, 1974 (internal citations omitted).

establish tolerances relating to PCBs in 1972.[113] After issuing a final order in 1973 that established tolerances for PCBs,[114] and following a series of objections, formal hearings, and litigation, FDA established the tolerance in 1983.[115] The regulation establishes "temporary tolerances for residues of PCBs as unavoidable environmental or industrial contaminants . . . for a sufficient period of time following the effective date . . . to permit the elimination of such contaminants at the earliest practicable time."[116] While FDA is not bound to maintain the same tolerance levels for PCBs—indeed, the regulation refers to the tolerances as "temporary"—any changes would undergo the same statutory and regulatory requirements as initial tolerance-setting. FDA has not amended that regulation or established tolerances for other substances.

2. Your Petition Does Not Contain Facts Demonstrating That the Regulatory Requirements for Tolerance-Setting Are Met in This Circumstance

In your Petition, you argue that there is precedent to set temporary tolerances for PFAS residues in food resulting from environmental contamination.[117] You cite our tolerances for PCBs and argue that PFAS must similarly "have post-market temporary tolerances set for residues of these chemicals in or on foods."[118] We agree with you that there is precedent for FDA to establish tolerances for environmental contaminants. However, the standards set forth in our regulations for establishing tolerances have not been met for the PFAS and commodities listed in your Petition and Supplement.

As discussed above, FDA's regulations provide that we may issue a tolerance for a contaminant when certain criteria are met.[119] As applied to the PFAS chemicals identified in your Petition, the criteria have not been met at this time. Specifically, the criteria in 21 CFR 109.6(b)(3) are not present in this case because data and methodologies relating to PFAS are in flux.

Our regulations state that FDA may establish a tolerance for an added poisonous or deleterious substance in any food when, among other things, "[n]o technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established."[120] Examples of such circumstances include "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

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[113] Polychlorinated Biphenyls, Notice of Proposed Rulemaking, 37 FR 5705, March 18, 1972.

[114] 38 FR 18096, July 6, 1973.

[115] 48 FR 37020, August 16, 1983.

[116] 21 CFR 109.30(a).

[117] Petition at 16.

[118] Id.

[119] 21 CFR 109.6(b).

[120] 21 CFR 109.6(b)(3).

data."[121] As our discussion above explains, this requirement relates to the need for "ample evidence, and a relatively stable situation, in which any tolerance promulgated will be appropriate for a relatively long period of time."[122]

Here, "technological [and] other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established."[123] The science on PFAS has evolved significantly in the last five years, and we anticipate more changes in the near future. For instance, as discussed above, there are currently ten PFAS for which there are TRVs. We anticipate further scientific advances that will update TRVs for these PFAS. Similarly, we anticipate new toxicological studies on additional PFAS and, by extension, the ability to identify TRVs for more PFAS in the near future. Updates to analytical methods, such as lower detection levels, more PFAS analytes, and more matrices, are also expected.

Neither your Petition, nor your Supplement, adequately addressed the factors in 21 CFR 109.6(b)(3). Rather, your documents align with our conclusion that the science and data around PFAS are evolving. Indeed, your Supplement changed the requests made in your Petition, citing just such advances in data and methodologies since you filed your Petition.[124] And your Petition anticipated changes of this nature, asking that the "temporary tolerances" be "lowered as new validated MDLs are achieved, and that all PFAS tolerances are revoked as soon as practicable after there is no longer any environmental contamination with PFAS."[125,126] In short, your Petition and Supplement support our determination that the "ample evidence" and "stable" scientific situation that tolerance-setting contemplates are not present in this case.[127] Accordingly, it is not appropriate to set a tolerance for PFAS at this time.[128]

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[121] Id.

[122] 42 FR 52814 at 52817.

[123] See 21 CFR 109.6(b)(3).

[124] See Supplement Part 1 at 10 (citing FDA's "Method No. C-010.03").

[125] Petition at 2-5.

[126] As discussed above, statutory and regulatory standards and processes relating to tolerance-setting are the same, regardless of whether a tolerance is styled as "temporary."

[127] See 42 FR 52814 at 52817; 21 CFR 109.6(b)(3).

[128] Citing FDA's pesticide monitoring program, your Supplement argued for a "tolerance enforcement monitoring program," asserting that the Total Diet Study is inadequate to assess risk. Supplement Part 2 at 9-13. It is unclear how this point ties to your Petition's specific requests or relates to the criteria for setting action levels or tolerances. Compliance programs, such as monitoring programs, are separate vehicles from the setting of action levels or tolerances: FDA neither requires a level to establish a compliance program nor automatically creates such a program upon establishing an action level or tolerance. FDA's pesticide residue monitoring program was not established due to the setting of an action level or tolerance; rather, it supports FDA's statutory requirement to prepare annual reports on pesticide testing. See 21 U.S.C. 1401; U.S. Food and Drug Administration, "Pesticide Residue Monitoring Program Questions and Answers." Accessed April 24, 2026. Available at: *https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-questions-and-answers*.

III. Conclusion

For the reasons explained above and in accordance with 21 CFR 10.30(e)(3), we are denying your requests.

Sincerely,

MARK A. HARTMAN -S

Digitally signed by MARK A. HARTMAN -S
Date: 2026.06.17 11:18:28 -04'00'

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