

PFAS & Food Packaging – What Franchisors and Restaurant Chains Need to Know

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August 2022

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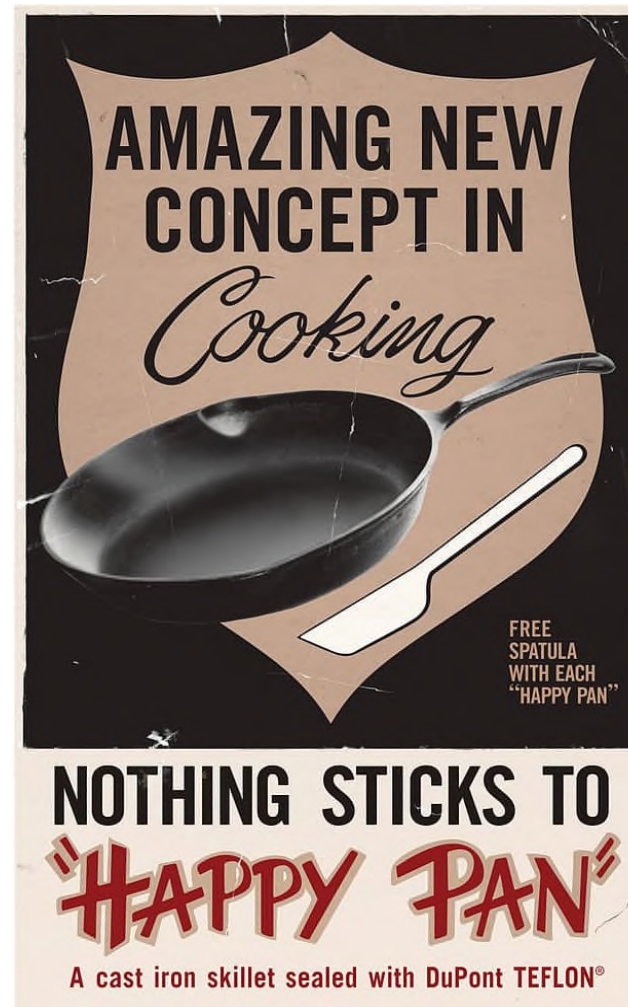
Agenda



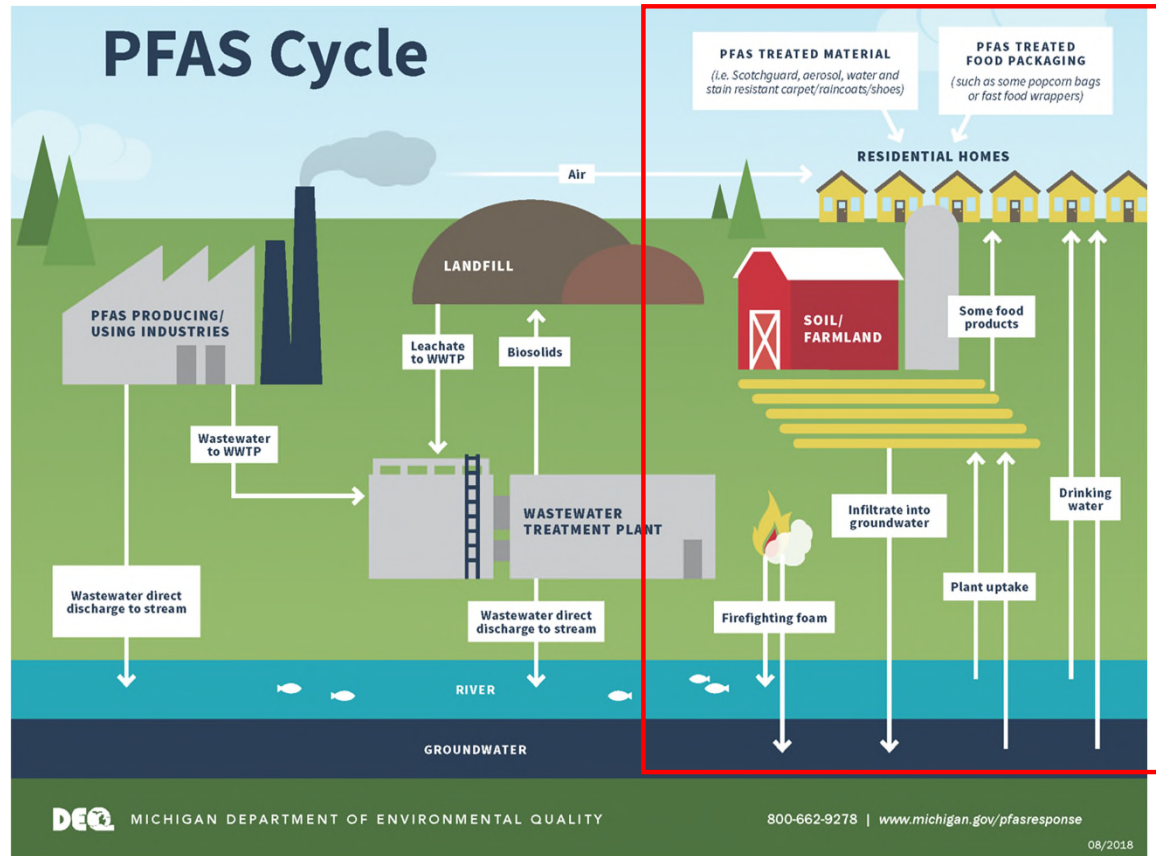
- PFAS 101
- State and Federal Regulatory Status
- Litigation Trends
- Voluntary Phaseouts
- Tips for Minimizing Risk

PFAS 101

- **Per- and Poly- Fluoro Alkyl Substances**
- Developed in 1940s
- Used for water-proofing, stain-proofing, fire resistance, and corrosion inhibition
 - Airports, military sites, fuel terminals
 - Semiconductors
 - Consumer products like cookware, textiles, clothing, carpets
- Synthetic molecules, some or all C–H bonds replaced with C–F bonds
 - C–F bond difficult to break down
- Two most widely studied are PFOA and PFOS
- Considered to be biopersistent



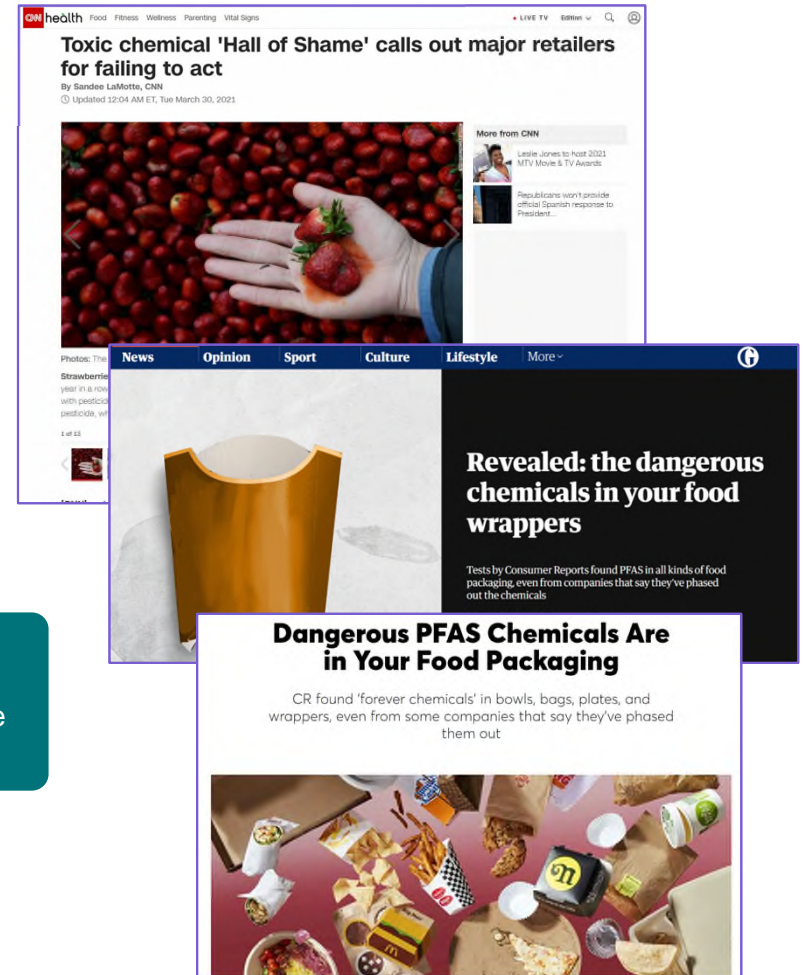
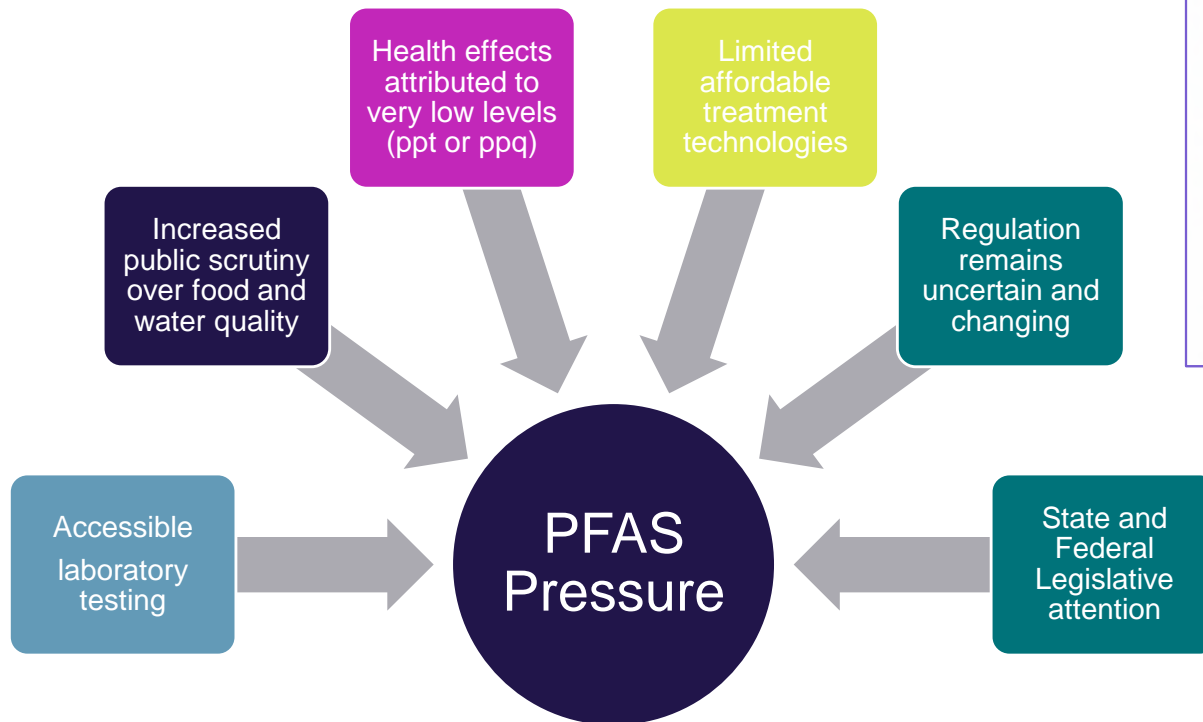
PFAS in the Food Cycle



Considerations

- Possible pathways are still not fully understood
- Not all PFAS are chemically similar
- Challenging to isolate potential exposure to a singular pathway

What's Driving Pressure





The Evolving Regulatory Environment

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Federal Regulation

Food and Drug Administration

- FDA has authorized specific PFAS for use in specific food contact applications since the 1960s
- FDA performs scientific review before approving food contact substances
 - Data on migration of the food contact substance into food
 - Expected consumer exposure to the food contact substance from its intended use
 - Other sources of dietary exposure
- When a concern is identified, FDA may:
 - Work with industry to reach voluntary market phase-out agreements
 - Revoke food contact authorizations when there is no longer a “reasonable certainty of no harm”



Federal Regulation

Food and Drug Administration

2022

- RFI on Fluorinated Polyethylene Food Contact Containers (July 19, 2022)
- Results on PFAS Testing in Seafood (July 6, 2022)

2021

- PFAS Testing Results from First Survey of Processed Foods and Nationally Distributed Processed Foods (August 26, 2021)
- Letter to Industry on Fluorinated Polyethylene Food Contact Containers (August 5, 2021)

2020

- Voluntary Agreement with Manufacturers to Phase Out Certain Short-Chain PFAS Used in Food Packaging (July 31, 2020)

2019

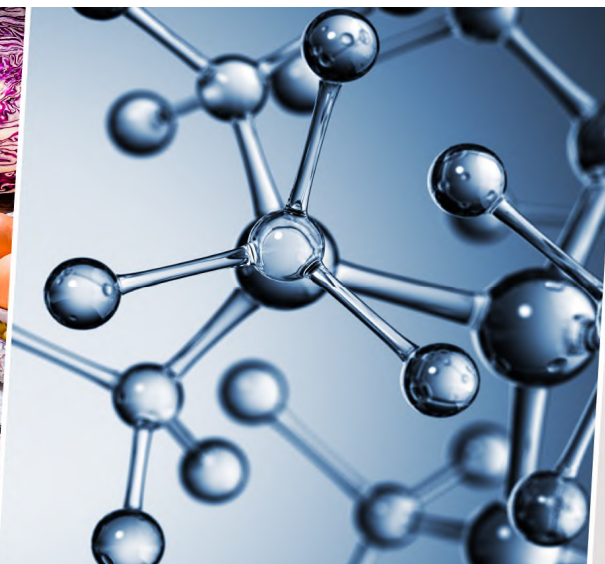
- Results from Second Round of Testing for PFAS in Foods from the General Food Supply (December 20, 2019)
- Testing Method for PFAS in Foods and Final Results from Recent Surveys (October 31, 2019)



Federal Regulation

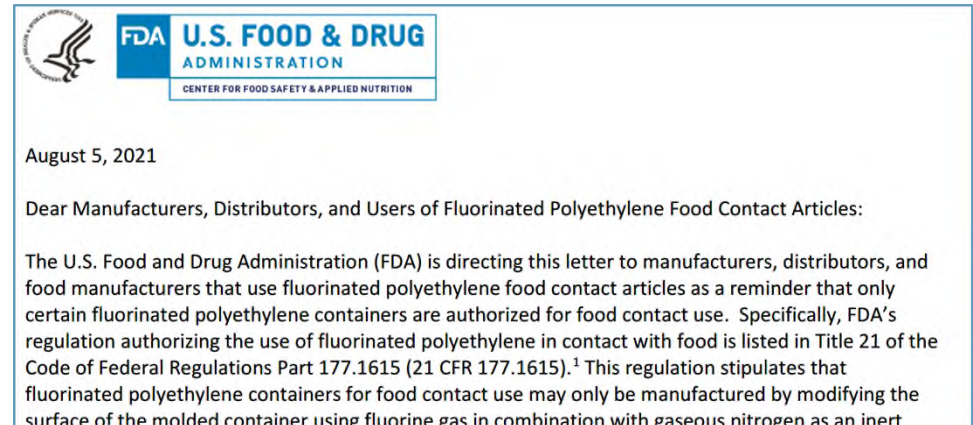
FDA Approvals and Phaseouts

- **Ban of Long Chain compounds (2016)**
 - Long chain PFAS (8 or more carbon atoms)
 - Voluntary phase out by manufacturers in 2000's
 - FDA revoked authorization by regulation in 2016
 - 2 through abandonment
 - 3 through NGO petition
- **Voluntary Phase Out of 6:2 FTOH (2021)**
 - Three manufacturers agreed to 3-year phase out of 6:2 FTOH beginning 2021
 - Up to 18 months to exhaust existing stocks of products from marketplace
 - Based on rodent studies finding biopersistence of 6:2 FTOH
- **Continued uses of PFAS in food contact applications**
 - Non-stick cookware
 - Gaskets, O-Rings, and other parts used in food processing equipment
 - Processing aids
 - Paper/paperboard food packaging
 - According to FDA, potential to leach into food because grease proofing agents are applied at lower temperatures, which are not high enough to remove residual smaller (i.e., migratable) PFAS molecules



FDA Action on fluorinated polyethylene containers

- August 5, 2021 - letter reminding industry that only certain fluorinated polyethylene containers are authorized for food contact
 - Followed EPA's testing of HDPE pesticide containers
 - FDA's regulation (21 CFR 177.1615) does not authorize fluorination of HDPE containers in the presence of water, oxygen, or gases other than nitrogen
 - Analytical studies find that PFAS cannot form in the presence of nitrogen
- July 19, 2022 – RFI on Fluorinated Polyethylene Food Contact Containers
 - FDA seeking scientific data and information on:
 - The current food contact uses of fluorinated polyethylene
 - Consumer dietary exposure that may result from those uses
 - Safety information on substances that may migrate from fluorinated polyethylene food containers



Federal Regulation

ENVIRONMENTAL DEFENSE FUND, BREAST CANCER PREVENTION PARTNERS, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY, CONSUMER FEDERATION OF AMERICA, CONSUMER REPORTS, DEFEND OUR HEALTH, ENVIRONMENTAL WORKING GROUP, GREEN SCIENCE POLICY INSTITUTE, HEALTHY BABIES BRIGHT FUTURES, LEAGUE OF CONSERVATION VOTERS

June 3, 2021

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Citizens petition requesting that the agency take more aggressive action to protect consumers from per- and poly-fluoroalkyl substances (PFAS) by banning all forms that biopersist in the human body

Dear Commissioner:

The United States is awash with per- and poly-fluoroalkyl substances (PFAS). Their widespread use and their ability to remain intact in the environment means that over time PFAS levels from past and current uses can result in increasing levels of environmental contamination, and accumulation of certain PFAS has also been shown in humans and animals.¹ Thousands of these substances have been used across various industries and goods,² including in firefighting foam,³ food packaging,⁴ and household products.⁵ People are exposed to PFAS from products we use, the food we eat, the air we breathe, and the water we drink, especially in communities near where the chemicals are produced, processed, used or disposed. As

Citizen Petition (filed June 3, 2021)

- Coalition requests:
 - Revoke FCNs for materials containing LC/SC PFAS
 - Evaluate FDA's food additive or GRAS regulations
 - Issue a regulation banning LC/SC PFAS as FCS
 - Require more information about PFAS to continue use in FCMs
 - Evaluate impacts from production, processing, use, recycling, and disposal under NEPA

Federal Regulation

FDA Testing Results

- Seafood Sampling (July 2022)
 - 81 samples of commercially available seafood
 - Much of it imported into US
 - Canned clams from China posed risk of PFOA
 - Suppliers initiated voluntary recall
- Processed Food Sampling (August 2021)
 - 164 of the 167 foods tested had no detectable levels of the PFAS
 - Detectible levels in: Fish sticks (PFOS and PFNA), canned tuna (PFOS and PFDA), and protein powder (PFOS)
 - “FDA has no scientific evidence that the levels of PFAS...indicate a need to avoid any particular foods in the general food supply”



Pending Federal Legislation



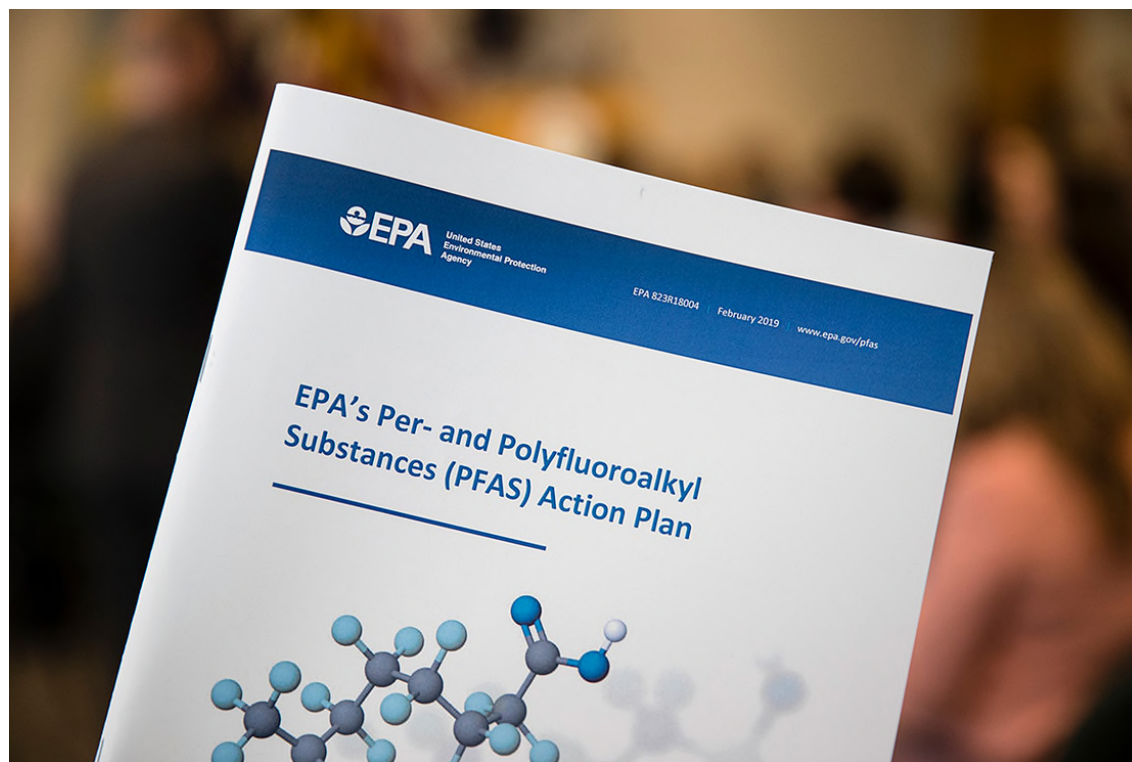
- PFAS Action Act of 2021 (H. R. 2467)
 - Would create a voluntary labeling system for cookware manufactured using PFAS and revise safer choice standard to identify requirements for cooking equipment
 - Referred to the Committee on Environment and Public Works July 2021
- The Keep Food Containers Safe from PFAS Act (S.3169)
 - Approved by the Senate Health, Education, Labor and Pensions Committee on June 14
 - Amendment would ban the use of intentionally added PFAS in food packaging beginning on January 1, 2024
 - On July 19, 2022, over 100 environmental and health NGOs sent a letter to Congress supporting the ban

State Regulation of Food Packaging

State	Type of Limit	Effective Date
California	<ul style="list-style-type: none"> Bans sale or distribution of intentionally added PFAS and more than 100 ppm of PFAS substances as TOF Requirement to list ingredients in food packaging 	January 1, 2023
Colorado	<ul style="list-style-type: none"> Banning sale or distribution of intentionally added PFAS 	January 1, 2024
Connecticut	<ul style="list-style-type: none"> Banning sale or distribution of intentionally added PFAS 	December 31, 2023
Hawaii	<ul style="list-style-type: none"> Banning sale or distribution of intentionally added PFAS 	December 31, 2023
Maine	<ul style="list-style-type: none"> Prohibits the sale of PFAS-containing food packaging if safer alternatives are available Requires manufacturers of products containing intentionally added PFAS to notify Maine DEP of such products and uses beginning January 1, 2023 	2022 or 2 years if alternatives available, 2030 unless unavoidable use
Maryland	<ul style="list-style-type: none"> Banning sale or distribution of intentionally added PFAS 	January 1, 2024
Minnesota	<ul style="list-style-type: none"> Banning sale or distribution of intentionally added PFAS 	January 1, 2024
New York	<ul style="list-style-type: none"> Banning sale or distribution of intentionally added PFAS 	December 31, 2022
Vermont	<ul style="list-style-type: none"> Banning sale or distribution of intentionally added PFAS 	July 1, 2023
Washington	<ul style="list-style-type: none"> Ban on PFAS in food packaging for which WDOE can identify a safer alternative Flat serveware, open-top containers, closed containers, bags and sleeves, and bowls (May 2024) Paper wraps and liners, food boats, pizza boxes, and plates (Feb 2023) 	2 years after alternatives identified
Iowa, Massachusetts, Michigan, Pennsylvania, Rhode Island	<ul style="list-style-type: none"> Various restrictions on sale or distribution of intentionally added PFAS 	Proposed

Biden Plan to Combat PFAS Pollution

- Cornerstone is EPA's PFAS Roadmap but also:
 - The Department of Defense to conduct PFAS cleanup assessments at nearly 700 installations
 - The Food and Drug Administration to expand its testing of food in order to estimate potential dietary exposure to PFAS
 - The Department of Agriculture to support research on PFAS in the food system
 - The Department of Homeland Security to investigate and remediate PFAS at its facilities
 - The Department of Health and Human Services to review “the rapidly evolving science” surrounding PFAS exposure
 - The Federal Aviation Administration to conduct research on the use of firefighting foam containing PFAS



Federal Regulation

Environmental Protection Agency

- Drinking Water Health Advisories
 - Non-enforceable, non-regulatory
 - Only applies to drinking water, not to ingestion of food
 - In absence of standards, used as benchmark
 - “Below the level of both detection (determining whether or not a substance is present) and quantitation (the ability to reliably determine how much of a substance is present)”
 - Two lawsuits filed against EPA challenging new HALs
- Final Regulatory Determinations for PFOS and PFOA in drinking water issued in Feb 2021
 - Determined that PFOA and PFOS require primary drinking water standards
 - Proposed standard anticipated by end of 2022, final rule by end of 2023

Chemical	2016 Lifetime Health Advisory Level (ppt)	2022 Lifetime Health Advisory Level (ppt)	Minimum Reporting Level UCMR 5 (ppt)
PFOA	70	0.004 (Interim)	4
PFOS	70	0.02 (Interim)	4
GenX Chemicals	--	10 (Final)	5
PFBS	--	2,000 (Final)	3

Federal Regulation

Environmental Protection Agency

- **Chemical:** Utilized TSCA Subpoena authority to investigate pesticide manufacturer using fluorinated HDPE containers
 - March 16, 2022 open letter addressed to manufacturers, processors, users and disposers of fluorinated HDPE containers
 - Any PFAS in those materials introduced by the fluorination process could violate the 2020 TSCA SNUR for long chain PFAS
 - Cooperation with the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA)

