FDA Regulatory Updates on Per- and Polyfluoroalkyl Substances (PFAS) in Food Contact Uses

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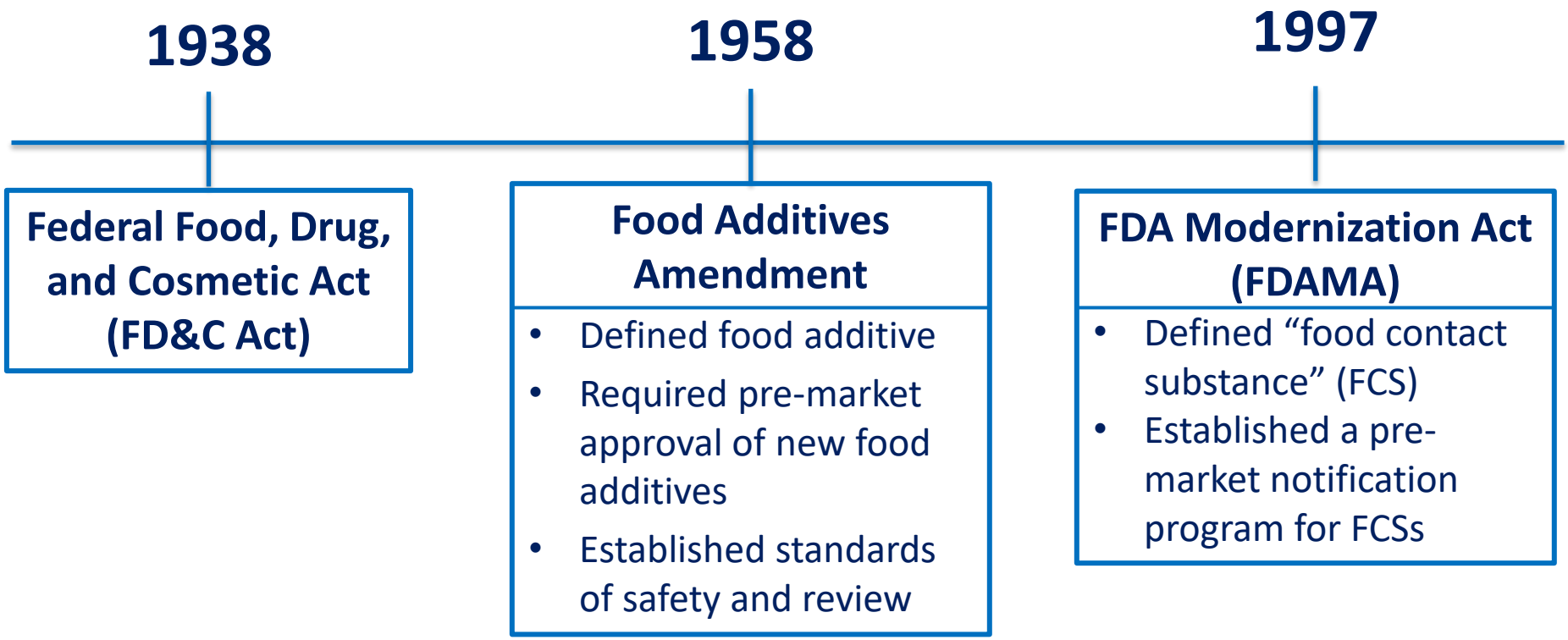
Outline

- Food Contact Regulatory Mechanisms
- PFAS containing Food Contact Substances
- Short Chain-PFAS Phase-Out
- PFAS in Resin Uses
- Fluorinated Polyethylene
- Summary

U.S. FDA Legal Authority



Food Additive

- The term “food additive” means:
  - “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.” *FD&C Act §201(s)*

Food Contact Substance (FCS)

"Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food."

- 1997 Food and Drug Administration Modernization Act (FDAMA) 21 U.S.C 348(h) (Section 409(h) of the FD&C Act)
- Requires pre-market authorization – Food Contact Substance Notification
- Effective FCNs listed on FDA Website:

https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-effective-food-contact-substance-fcs-notifications

Regulatory Pathways for Food Additives

Comparison of Mechanisms for Food Additives: Food Additive Petition, FCN, Threshold of Regulation Exemption (TOR)			
	Petition	**FCN**	**TOR**
Allowed exposure	Dietary Concentration: **> 3000 µg/p/d (1 ppm)**	Dietary Concentration: **< 3000 µg/p/d (1 ppm)**	Dietary Concentration: **< 1.5 µg/p/d (0.5 ppb)**
Required Safety Data	Case-by-Case (Usually > than FCN requirement)	Specific requirements based on exposure tiers (see Guidance)	Carcinogenicity only
Are study reports provided?	Required	Required	Literature search only
Environmental Review?	Required	Required	Required
Is submission to FDA required before marketing product?	Required	Required	Required
Who can utilize result?	Any manufacturer	Listed manufacturer only	Any manufacturer

Final Rule to Amend 21 CFR 170.105

- Final rule to amend 21 CFR 170.105 published on March 22, 2024.
- Final Rule:
  - Federal Register Volume 89, Number 57, 20306-20317, March 22, 2024
  - https://www.federalregister.gov/documents/2024/03/22/2024-05802/food-additives-food-contact-substance-notification-that-is-no-longer-effective#print
- Constituents Update:
  - https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-final-rule-revise-procedures-and-update-reasons-revoking-authorizations-food-contact

DEPARTMENT OF HEALTH AN HUMAN SERVICES
Food and Drug Administration 21 CFR Part 170
[Docket No. FDA–2021–N–0403] RIN 0910–AI01
Food Additives: Food Contact Substance Notification That Is No Longer Effective

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its regulations relating to the procedures for determining that a premarket notification for a food contact substance (FCN) is no longer effective. The final rule provides additional reasons that could form the basis for FDA to determine that an FCN is no longer effective. The final rule also ensures that manufacturers or suppliers have the opportunity to provide input before we determine that an FCN is no longer effective. We are making these changes to allow FDA to respond better to new information on the safety and use of food contact substances (FCSs), as well as manufacturers' business decisions, and also improve the efficiency of the premarket notification program.

DATES: This rule is effective May 21, 2024.

Per- and Polyfluoroalkyl Substances (PFAS)

Summary of Key Exposure Pathways throughout the PFAS Lifecycle

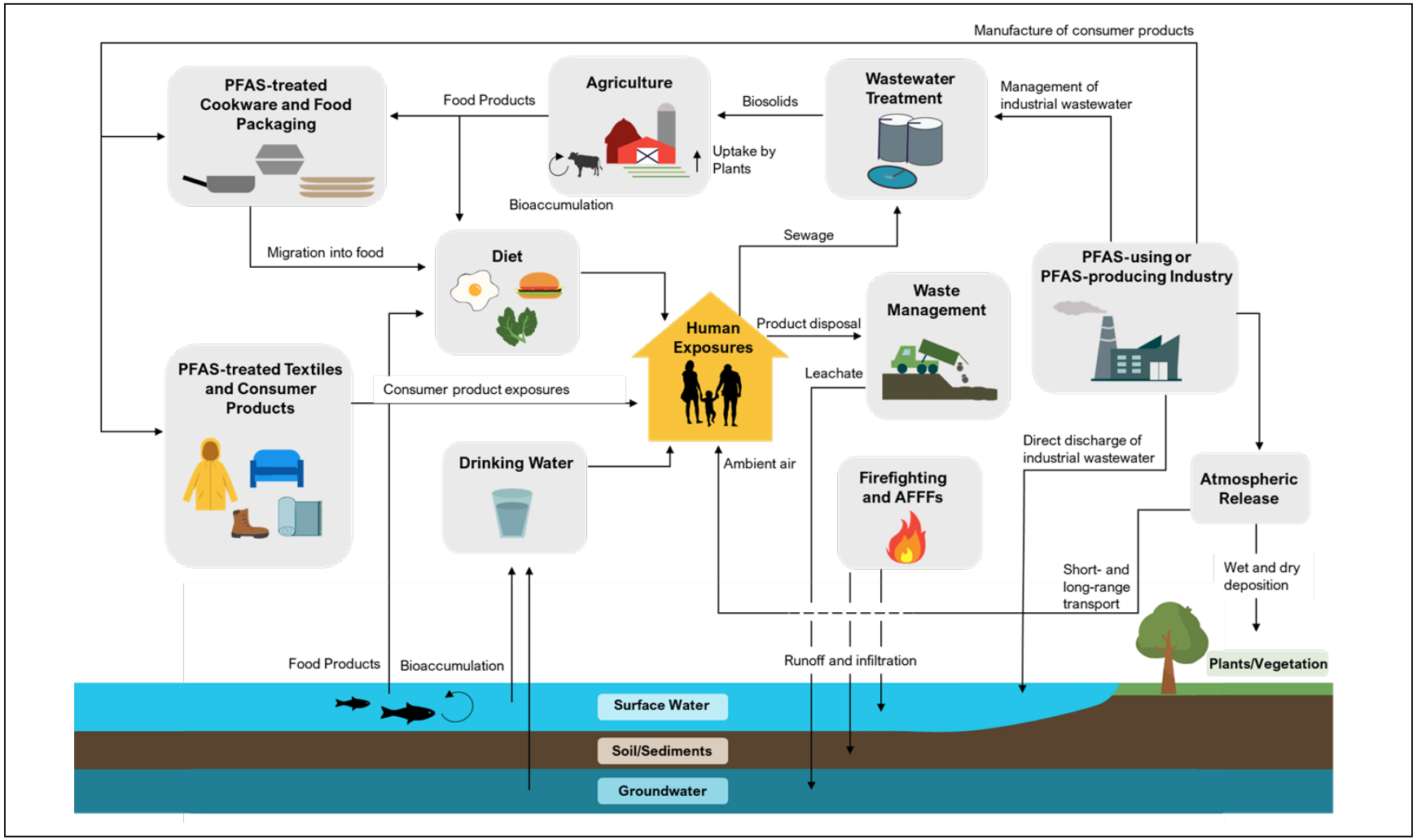
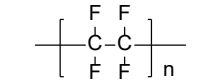


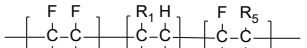
Image taken from "Characterizing PFAS Chemistries, Sources, Uses, and Regulatory Trends in the U.S. and International Markets," June 2023, RTI prepared for CPSC.

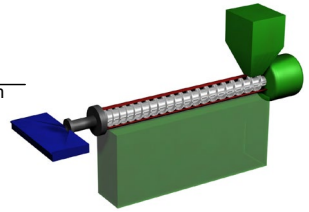
Historical Uses of PFAS in Food Contact

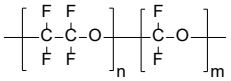
Authorized & Intended Use	Migration Potential
1. Non-Stick Applications Pots & Pans	Negligible
2. Rubber O-Rings & Gaskets Food Processing Equipment	Negligible
3. Manufacturing / Processing Aids Added to other food contact polymers	Negligible
4. Grease-Proofing Agents Used on paper/paperboard	Migration expected under certain conditions of use

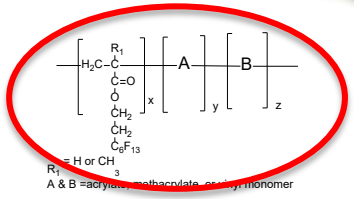


Polytetrafluoroethylene









FDA's Postmarket Assessment

Grease-Proofing Agents

- Removed food contact substances containing long-chain PFAS through:
  - 2011: voluntary commitment letters received for 7 effective FCNs from 3 PFAS manufacturers.
  - 2016: removal of authorizations in 21 CFR 176.170 of three LC-PFAS authorizations due to safety concerns, and removal of two LC-PFAS authorizations based on abandonment.
- The postmarket assessment for short-chain (SC) PFAS - initiated review of published scientific information raising potential concerns for biopersistence of the 6:2 fluorotelomer alcohol.

Conclusions from Postmarket SC-PFAS Assessment Indicate Datagaps

- Scientific gaps exist around the safety of 6:2 FTOH.
- Recent scientific review of existing data indicate that 6:2 FTOH biopersists in the tissues of rodent models.
- The biopersistence amplifies toxicity (e.g., immunotoxicity, developmental and reproductive toxicity, and possibly carcinogenicity).

Regulatory Actions to Remove SC-PFAS from U.S. Market

- Chemours provided voluntary commitment letter stating the cessation of their food contact substances containing SC-PFAS in August 2019.
  - Ceased sales in June 2019, and expected supply chain exhaustion in June 2020.

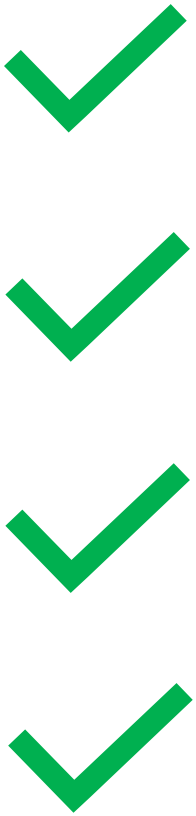
- Three PFAS manufacturers, Daikin, AGC, Archroma, provided voluntary commitment letters to phase-out their food contact substances containing SC-PFAS

Joint FDA Commissioner and CFSAN Center Director Statement: https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-agreement-manufacturers-phase-out-certain-short-chain-pfas-used-food

PFAS Constituent Update: https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-voluntary-phase-out-industry-certain-pfas-used-food-packaging

Phase-Out Status for FCNs that contain 6:2 FTOH

PFAS Manufacturer	Status
Chemours (3 FCNs)	Completed June 2019
Archroma (1 FCN)	Completed January 2022
Daikin (7 FCNs)	Completed April 2023
AGC (4 FCNs)	Completed December 31, 2023



OTHER GREASE-PROOFING AGENTS

Other PFAS Grease-Proofing Agents (Do not lead to 6:2 FTOH exposure)

PFAS Manufacturer	Status
Solvay (6 FCNs)	Completed July 2022
Solenis (6 FCNs)	Completed 2021
Archroma (1 FCN)	Completed 2015

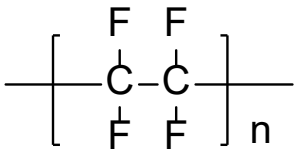
Summary: PFAS Grease-Proofing Agents

- 35 Food Contact Notifications deemed no longer effective.
  - Federal Register :: Food Contact Notifications That Are No Longer Effective (90 FR 653, January 6, 2025).
- FDA is the only regulatory agency in the U.S. and world-wide who has taken steps to remove exposure to 6:2 FTOH.
- FDA completed a sampling plan for surveillance in 2025 – collection of paper/paperboard products.
  - FDA has a validated method for paper sampling testing to determine presence of 6:2 FTOH
  - FDA completed surveillance collection and sampling

OTHER PFAS USES

PFAS Use: Non-Stick Applications

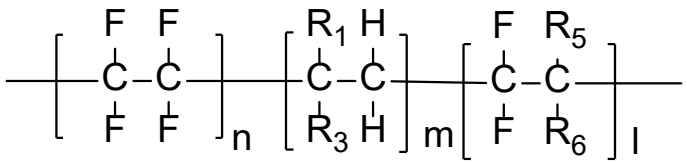
- Examples: pots & pans
- PFAS molecules (e.g., polytetrafluoroethylene) are polymerized and applied to surface of cookware at high temperatures
  - High molecular weight food contact substance
  - Leads to tightly bound polymer coating on cookware surface.
- Migration potential = negligible



Polytetrafluoroethylene

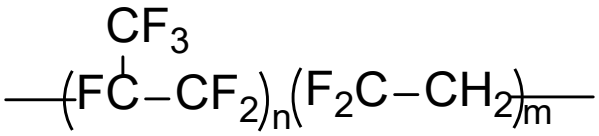
PFAS Use: Rubber Articles

- Examples: O-rings and gaskets used in food processing equipment.
  - These are typically repeat use articles
- PFAS molecules are polymerized resulting in high molecular weight resins that are made into parts.
- Migration potential = negligible



PFAS Use: Manufacturing / Processing Aids

- Examples: added to improve polymer properties and to reduce build-up on manufacturing equipment.
- PFAS molecules are high molecular weight polymers added to conventional polymers.
- Migration potential = negligible



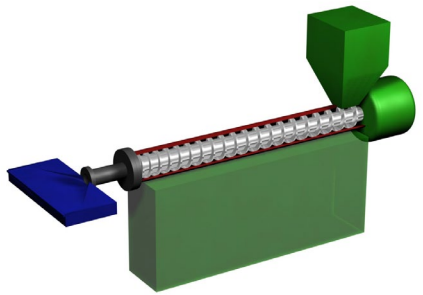


Image courtesy of Mikeeg555

Fluorinated Polyethylene

- On August 5, 2021, FDA issued a letter reminding industry that only fluorinated polyethylene containers produced in compliance with specifications listed in 21 CFR 177.1615 were appropriate for food contact.
- On July 20, 2022, FDA issued a Request for Information (RFI) for fluorinated polyethylene containers used for food contact. The comment period closed on October 18, 2022.

https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-letter-industry-fluorinated-polyethylene-food-contact-containers

https://www.federalregister.gov/documents/2022/07/20/2022-15455/fluorinated-polyethylene-containers-for-food-contact-use-request-for-information

Summary

- FDA amended 21 CFR 170.105 allowing removal of effective FCNs for reasons beyond safety such as abandonment.
- FDA determined 35 FCNs no longer effective in January 2025. These include all PFAS uses as grease-proofing agents in paper and paperboard.
- FDA conducted a sampling plan for surveillance of the market phase-out of PFAS-based grease-proofing agents.
- FDA is reviewing new scientific developments around other food contact PFAS uses including those that form in authorized fluorinated polyethylene containers used for food contact.

Questions

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Online Resources

- Packaging & Food Contact Substances Guidance
  - https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm
- Inventory of Effective FCNs
  - https://www.accessdata.fda.gov/scripts/fdcc/?set=fcn
- FDA PFAS Webpage
  - https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas


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