



Per- and Polyfluoroalkyl Substances (PFAS): From Molecules to Regulations

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- Tim Sowecke, Shareholder, GableGotwals
- Environmental and Energy litigation and regulatory compliance
- **** Subsequent information should not be understood as, or considered a substitute for, specific legal advice. For inquiries, please contact Tim Sowecke, or another licensed attorney.**
 - **** PFAS regulatory landscape is changing fast!**

Roadmap



PFAS Headlines!

What are PFAS?

Regulatory Nexus

Response Measures

Headlines: Read All About It!



PFAS chemicals in turnout gear may release by wear and tear, study says

By Vivien Leigh | News Center Maine | January 26, 2024

New Zealand to ban PFAS in cosmetics; what are 'forever chemicals' and how do they damage health?

By [Parmita Uniyal](#) , New Delhi

Explainer

“Forever Chemicals” Called PFAS Show Up in Your Food, Clothes, and Home

These toxic chemicals are so common in consumer products and manufacturing that they're everywhere—including inside our bodies.

April 12, 2023

 The Portland Press Herald

A forever farm is no match for forever chemicals

A fourth-generation farmer running an organic dairy farm in Fairfield lost his livelihood when his milk and lands tested hot for PFAS...

Jun 11, 2023

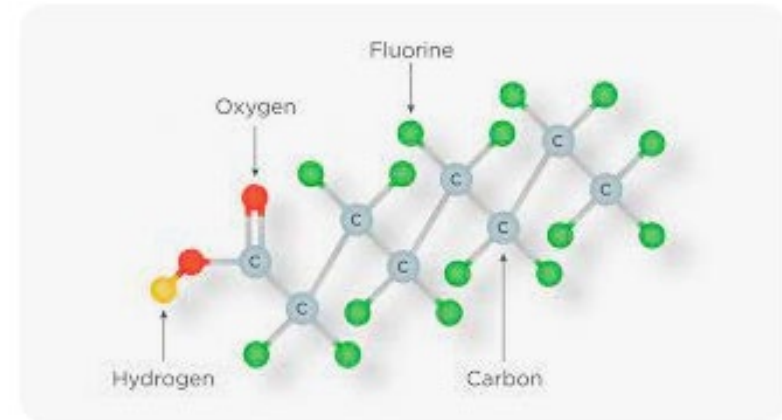
Connecticut suing 28 companies for PFAS in products

25 Jan 2024 | wtnh

What Are Per- and Polyfluoroalkyl Substances (“PFAS”)?



- **Class of compounds first developed in the 1930s, and used in countless industrial and consumer applications.**
 - **1938:** First perfluorinated compound (PFC) – tetrafluoroethylene resin – created while working with Dupont’s freon refrigerants.
 - Synthetic fluoropolymer Polytetrafluoroethylene (PTFE) was introduced 10 years later under trader name “Teflon.” Heat resistant and no stick!
 - Dupont Chemical plant – Washington Works, in West Virginia uses perfluorooctanoic acid (PFOA) in its manufacturing process.
 - **More applications:** E.g., 1950s development by 3M of perfluorooctanoic sulfonate (PFOS) generally-commercially known as “Scotchguard.” No stains!
 - **1963:** United States Navy begins to work with 3M to develop aqueous film-forming foams (AFFF).
- **Broad class of chemicals**
 - Short- and long-chains of carbon with fluorine attached = VERY STRONG
 - Very strong chemical bonds!
 - Hydrophobic tail (repels/does not mix with water)
 - Hydrophilic head (affinity for/mixes with water)
 - Lipophobic (“afraid of fat” – not soluble in lipids)
 - Oleophobic (“afraid of oil” – property of being repelled from oil)
 - Wide use in industrial and consumer products – resistant to water, heat and stains



American Water Works Association
PFAS | American Water Works Association

What Are PFAS? (cont).



Those durable qualities that give PFAS such a high utility for industrial and consumer applications also make them persistent and mobile in the environment (e.g., soil and water) and human body, hence the nickname, “Forever Chemicals.”

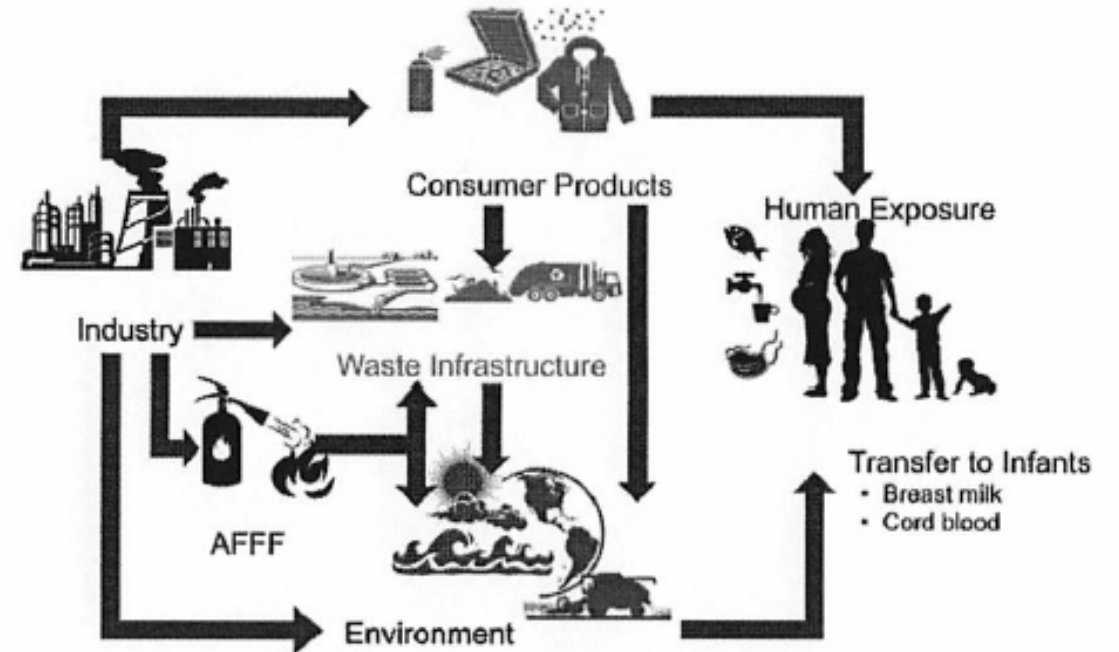


Figure 1 from Sunderland et al. (2019) *Journal of Exposure Science & Environmental Epidemiology* 29(2). doi:10.1038/s41370-018-0094-1

What are PFAS: Toxicology



- According to EPA, current peer-reviewed scientific studies have shown that exposure to certain levels of PFAS may lead to:
 - Reproductive effects such as decreased fertility or increased high blood pressure in pregnant women.
 - Developmental effects in children, including low birth weight, accelerated puberty, bone variations, or behavioral changes.
 - Increased risk of some cancers, including prostate, kidney and testicular cancers.
 - Reduced ability of the body's immune system to fight infections, including reduced vaccine response.
 - Interference with the body's natural hormones.
 - Increased cholesterol levels and/or risk of obesity.

What are PFAS: Toxicology (cont.)



- However, still considerable uncertainty:
 - There are thousands of PFAS with potentially varying effects and toxicity levels and fate and transport in environment, yet most studies focus on a limited number of better known PFAS compounds, e.g., PFOA, PFOS.
 - People can be exposed to PFAS in different ways and at a different stages of their life.
 - The type and uses of PFAS change over time, which makes it challenging to track how exposure to these chemicals occurs and how they affect human health.



Regulatory Nexus

Cross-eyed and painless, Road to Nowhere,
Burning Down the House, This Must Be the
Place

Cross-eyed and Painless: Early Regulatory Efforts



- **UCMR 2012:** Safe Drinking Water Act require that once every five years EPA issue a new list of unregulated contaminants, and in 2012 under UCMR 3, EPA identified six PFAS for further investigation and evaluation in Public Water Systems (PWS).
 - Footnote: litigation had started approximately 2001 in West Virginia class actions, “In Dark Waters,” medical monitoring.
- **May 2016:** EPA issued estimated lifetime drinking water level of 70 parts per trillion (“ppt”) to provide Americans with a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water. The health advisory level is not a binding regulation, but is designed to give state, local, tribal governments information to better protect human health and environment.
- **February 2019:** EPA Action Plan “describes the EPA’s approach to identifying and understanding PFAS, approaches to addressing current PFAS contamination, preventing future contamination, and effectively communicating with the public about PFAS,” including:
 - Evaluate need for maximum contaminant level (MCL) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS);
 - Begin necessary steps to propose designating PFOA and PFOS as “hazardous substances” through one of the available federal statutory mechanisms, e.g., CERCLA, RCRA, TSCA, CWA, CAA.

Cross-eyed and Painless: Early Regulatory Efforts



- **February 2019:** EPA Action Plan “described the EPA’s approach to identifying and understanding PFAS, approaches to addressing current PFAS contamination, preventing future contamination, and effectively communicating with the public about PFAS,” including (cont.)
 - Develop groundwater cleanup recommendation for PFOA at contaminated sites.
 - Develop toxicity values or oral reference doses for various PFAS.
 - Develop new analytical methods and tools for understanding and managing PFAS risk.
 - Promulgate significant new use rules under the Toxic Substances Control Act that require EPA notification before chemicals are used in new ways that may create human health and ecological concern, and in some instances ban the use or import of such chemicals.
 - Use enforcement actions to help manage PFAS risk.
- **Early Development of Analytical Methods:** Validated method for testing certain PSA in drinking water, EPA Method 533 (Validation December 2019) to include multiple short-chain PFAS that cannot be measured by Method 537.1. (18 analytes) (Validation 2018/2020 no technical changes).

Cross-eyed and Painless: Early Regulatory Efforts (cont'd)



- **March 3, 2021:** EPA published its Final Regulatory Determination (i.e., endangerment determination), in which it determined:
 - Two most widely used, studied, and regulated PFAS thus far;
 - Perfluorooctanoic acid (PFOA); and
 - Perfluorooctane Sulfonic acid (PFOS)
- That PFOA and PFOS may have adverse health effects;
- That PFOA and PFOS occur in Public Water Systems (PWS) with a frequency and at levels of public health concern; and
- Specifically, EPA noted the following health effects caused by PFOA and PFOS:
 - Development effects to fetuses during pregnancy or to breast-fed infants;
 - Cancers (e.g., testicular; kidney);
 - Immune effects (e.g., inhibits antibody production and immunity);
 - Other effects, including cholesterol changes.

Road to Nowhere: EPA's PFAS Roadmap



- **October 18, 2021:** EPA Publishes its “PFAS Strategic Roadmap” – outlined coming regs.
- **Targets for regulation:**
 - Ongoing nationwide monitoring for PFAS in drinking water (Ongoing)
 - Establish a national primary drinking water regulation for PFOA and PFOS (proposed rule in Fall 2022 and final rule pending)
 - Restrict PFAS discharges from industrial sources through Effluent Limitations Guidelines (ELGS) (Ongoing)
 - Leverage National Pollution Discharge Elimination Systems (NPDES) permitting to reduce PFAS discharges to waterways. (Winter 2022) *See Enforcement Action at Washington Works Manufacturing Facility, April 2023.*
 - Publish updates to PFAS analytical methods to monitor drinking water (Fall 2024)
 - Publish final recommended ambient water quality criteria for PFAS (Winter 2022 and Fall 2024)
 - Propose to designate certain PFAS as CERCLA hazardous substances (Spring 2022 and final rule pending)
 - Disposal and destruction: *See December 2020, *EPA Interim Guidance on Destruction and Disposal*; see also Department of Defense Memorandum, *Interim Guidance on Destruction or Disposal of Materials Containing Per- and Polyfluoroalkyl Substances in the United States* (July 11, 2023).

Burning Down The House: CERCLA or Superfund Act



- **September 6, 2022:** EPA published a proposed rule to designate two PFAS – PFOA and PFOS – as hazardous substances under the Superfund Act.
- **Broad Implications:**
 - Any release of a reportable quantity of 1lb. In 24-hour period.
 - Requires Dept. of Transportation to regulate PFOA and PFOS as hazardous materials under DOT regulations, e.g., pipeline, trucking.
 - Apparent issues: Property valuations, transfers, due diligence (e.g., Phase I Environmental Assessments).
 - Will give EPA and private parties the ability to clean up PFOA and PFOS on certain properties and recover compensation from potentially responsible parties (e.g., past and present owners, operators and arrangers).
 - Strict Liability – no finding of “fault” is necessary.
 - Joint and Several liability – any potentially responsible party could be held accountable for entire cost, even if other entities responsible.

Burning Down The House: Safe Drinking Water Act (SDWA)



- **May 2016:** EPA issued estimated lifetime drinking water level of 70 parts per trillion (“ppt”) to provide Americans with a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water. **The health advisory level is not a binding regulation**, but is designed to give state, local, tribal governments information to better protect human health and environment.
- **June 2022:** EPA issued updated health advisories for four different PFAS:
 - Perfluorooctanoic Acid (“PFOA:”) = 0.004 PPT
 - Perfluorooctane Sulfonate (“PFOS”) = 0.02 ppt
 - GenX chemicals, i.e., replacement for PFOA = 10 ppt
 - Perfluorobutane Sulfonate (“PFBS”) = 2,000 ppt
- **March 2023:** EPA proposed National Primary Drinking Water standards for six (6) PFAS
 - Monitoring and treatment of public water supplies for specified MCLs.
 - 4 PPT MCL for PFOA and PFOS; pushing detectable limits.
 - 1ppt “health index” risk-based standards for PFHxS, HFPO-DA, PFNA, and PFBS.

Burning Down The House: Toxic Substances Control Act (TSCA)



- October 2023: Reporting and Recordkeeping Rule (effective November 13, 2023)
 - “EPA is requiring persons that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011, to submit information to EPA regarding PFAS uses, production volumes, byproducts, disposal, exposures, and existing information on environmental or health effects.”
 - PFAS manufacturers have 12 months from the effective date of the rule to collect the information.
 - This is followed by a six-month reporting period.
 - Small manufacturers that are reporting solely on imported PFAS contained in manufactured articles have an additional six months to report.
 - Persons who have only processed, distributed in commerce, used, and/or disposed of PFAS are not required to report under this rule, unless they have also manufactured (or imported) PFAS for a commercial purpose.
 - Merely receiving PFAS from domestic suppliers or other domestic sources is not, in itself, considered “manufacturing PFAS for commercial purposes” under the rule.

Burning Down The House: TSCA (cont'd)



- Check TSCA Inventory and EPA’s definition of PFAS under the rule.
 - From the known TSCA universe, EPA has identified at least 1,462 PFAS that meet the definition.
- Reporting Standard: “to the extent known or reasonably ascertainable” (i.e., all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know)
 - No reporter exemption to this rule
 - No minimum volume or concentration exemption – any amount of PFAS known to be manufactured is reportable.
 - Some data elements may be duplicative of information previously submitted under the Chemical Data Reporting Rule, Toxics Release Inventory, or Greenhouse Reporting Program.

Burning Down The House: Toxic Release Inventory (TRI)



- **October 2023:** Final Rule on Reporting
- Authorization under Section 313 of the Emergency Planning and Community Right to Know Act (EPCRA)
- Adds all PFAS included in the Toxics Release Inventory (TRI) to the list of "chemicals of special concern" to TRI reporting (total number of PFAS under TRI is 196).
- Includes removal of exemption for "chemicals of special concern" including a de minimis exemption.
- Effective November 30, 2023, and applies as of January 1, 2024 for reporting year 2024 (reports due July 1, 2025).

Burning Down The House: RCRA



- **February 2024:** Two proposed rules from EPA under Resource Conservation and Recovery Act (RCRA): (1) add nine (9) PFAS to list of hazardous constituents and (2) amendment of Definition of Hazardous Waste Applicable to Corrective Action for Releases from Solid Waste Management Units:
- Nine PFAS (hazardous constituent designation does not trigger hazardous waste management and disposal requirements)
 - 1) Perfluorooctanoic acid (PFOA)
 - 2) Perfluorooctanesulfonic acid (PFOS)
 - 3) Perfluorobutanesulfonic acid (PFBS)
 - 4) Hexafluoropropylene oxide-dimer acid HFPO-DA or GenX)
 - 5) Perfluorononanoic acid (PFNA)
 - 6) Perfluorohexanesulfonic acid PFHxS)
 - 7) Perfluorodecanoic acid (PFDA)
 - 8) Perfluorohexanoic acid (PFHxA)
 - 9) Perfluorobutanoic acid (PFBA)
- **Important: First step towards regulation as hazardous waste.**
- **Effect: Broaden scope of corrective action programs.**

This Must Be the Place: Disposal and Destruction



- **December 2020:** EPA *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances*
 - Interim storage feasibility issue (2 – 5 years)
 - Deep well injection (Disposal)
 - Permitted Hazardous Waste Landfills (RCRA Subtitle C)
 - Solid Waste Landfills (RCRA Subtitle D)
 - Thermal Treatment Products of Incomplete Combustion (PIC), E.g., Carbon Reactivation Units
- ****Environmental Justice**
- **July 2023:** Department of Defense, *Interim Guidance on Destruction or Disposal of Materials Containing Per- and Polyfluoroalkyl Substances in the United States*

This Must Be the Place: Analytical



- EPA Method 537.1 (Drinking Water)
 - Method for measuring 18 PFAS in drinking water
- EPA Method 533 (Drinking Water)
 - Method for measuring 25 PFAS in drinking water
- EPA Method 1633 (Non-potable Water and Other Media)
 - Method for measuring 40 PFAS in wastewater, surface water, groundwater, soil, biosolids, sediment, landfill leachate, and fish tissue.
- Other Test Method (OTM) – 45 (For Air Emissions)
 - Method for measuring 50 PFAS in air emissions from stationary sources.
- Other Test Method (OTM) – 50 (For Air Emissions)
 - Method for measuring 30 PFAS in air emissions

This Must Be the Place: Analytical



- EPA Method 1621

“[D]eveloping analytical methods for each individual PFAS compound is impractical, if not impossible. Therefore, this project pursued validation of a procedure to determine an aggregate measure of organofluorine substances in aqueous materials as a proxy for PFAS and other fluorinated pesticides and pharmaceuticals, known as AOF.” Multi-laboratory validation study report for Method 1621: Determination of Adsorbable Organic Fluorine (AOF) in Aqueous Materials by Combustion Ion Chromatography (CIC) (January, 2024)

- Shows chain lengths between Cr-C8, as well as non-PFAS fluorinated compounds.
- Sensitive to contamination
- Reasonable method, capable of consistent application across labs.

This Must Be the Place: States Are Establishing MCLs



- Many states have begun the process of regulating PFAS in drinking water and in soil and have adopted enforceable standards or Maximum Contaminant Levels (MCLs) for PFAS in their state.
- E.g., drinking water MCLs for several states:

	PFOA	PFOS	PFNA
New Jersey	14 ppt	13 ppt	13 ppt
Connecticut	16 ppt	10 ppt	12 ppt
Michigan	8 ppt	16 ppt	6 ppt

This Must Be the Place: States Are Passing Legislation



- Many states have also legislated prohibitions against “intentionally adding” PFAS, or otherwise banning certain consumer goods containing PFAS.
 - Focused on manufacturers of PFAS and intentional users of PFAS.
 - For example, in July 2021 Maine banned PFAS in nearly all products, stating that as of January 1, 2030, “a person may not sell, offer for sale, or distribute for sale” in Maine products where PFAS has been “intentionally added” except in cases of “unavoidable use.” 38 M.R.S. § 1614.
 - Under the Maine law, “Intentionally added PFAS” means PFAS added to a product or one of its product components to provide a specific characteristic, appearance or quality or to perform a specific function. The plain language of the statute shows that the PFAS must be intentionally added and furthermore, have a specific function within the product.
 - In some cases, exemptions provided where alternative unavailable.



Response Measures: Take me to the River

Take Me to the River: What Should Businesses Be Doing?



- Because of prevalence of products containing PFAS and inevitable wave of federal and state regulations, businesses must take proactive steps to identify PFAS in business:
 - **Investigate! Informal/formal audits:** Are you a source of PFAS, using PFAS?
 - Conduct facility-wide inventory for PFAS and PFAS-containing products, including supply chain.
 - Are there other sources in the area that may be the actual source, e.g., emissions, groundwater contamination, soil migration;
 - Does your site pose an exposure risk through drinking water, aquifers, surface water?
 - Consider audit privileges and any reporting obligations.
 - Consider commenting on proposed rules and regulations!
 - Retain good attorney and experts!
 - Consider removal and replacement chemicals and other forms of mitigation of PFAS associated risks.
 - Check your drinking water and wastewater discharges, and all permits for PFAS nexus.

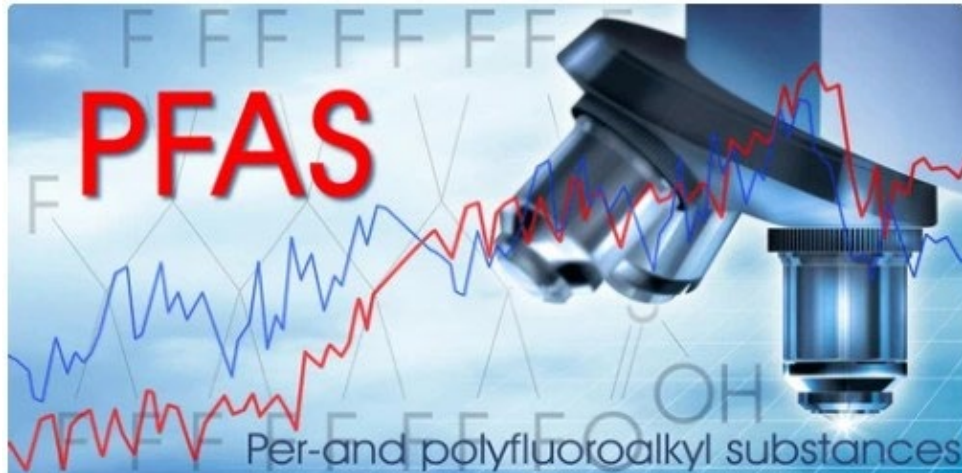
Take Me to the River: Businesses (cont'd)



- Check insurance coverage.
 - Because of pollution exclusions, coverage more likely under 1986 policies.
 - Cover claims for property damage and bodily injury.
 - Environmental claims are generally considered claim for property damage.
 - Duty to defend is broad and generally requires carrier to defend as long as there is potential for coverage.
- Consider privileges and safe harbor of environmental audit**
- If you receive any type of order or request from an agency, contact a good environmental regulatory attorney and enlist the right environmental consultant
 - Negotiate response with entity issuing order.

Stay up to date on regulations – PFAS regulations are fast changing!

Thank You!



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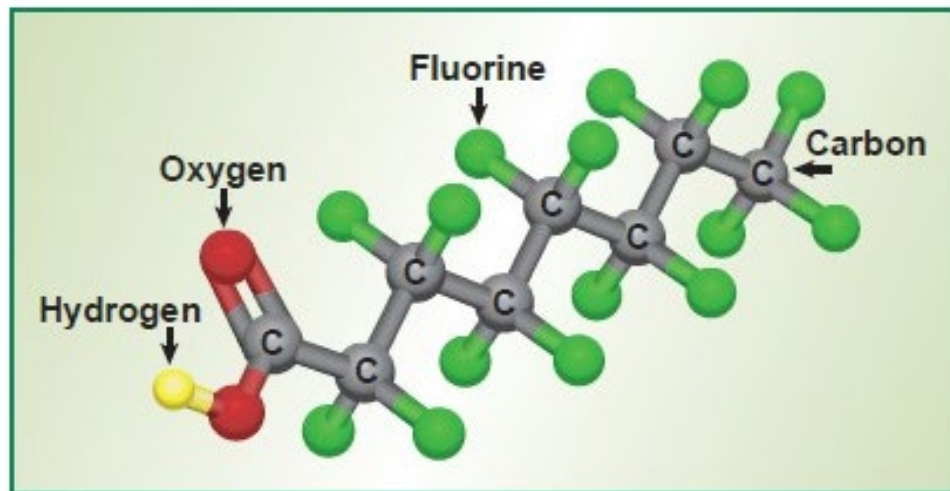


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