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PFAS 2024 Update: Regulatory and Scientific Developments, Increasing Litigation, Insurance Issues

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Holland & Knight

Regulatory Updates

1. CERCLA: PFAS as a “Hazardous Substance”
2. Toxic Substances Control Act (TSCA): Massive Data Call & More
3. Drinking Water: NPDWR Finalized & Promptly Challenged
4. RCRA: Proposed Rules Emerge from Litigation
5. Toxics Release Inventory (TRI): Ongoing Efforts
6. Stormwater/Wastewater: More to Come in 2025
7. Air Emissions: EPA Starts with Data Collection Proposal
8. Biosolids: Litigation May Move this Along
9. State Regulation: It’s Hard to Keep Up

EPA's Strategic Roadmap Updates

- October 2021: EPA Publishes its [PFAS Strategic Roadmap](#)
 - Commitments to Action 2021-2024
 - Research, Restrict & Remediate
- November 2022: EPA Publishes its [One Year Review](#)
 - [National Testing Strategy](#)
 - Drinking Water
 - Remediation
 - Funding
- December 2023: EPA Publishes its [Second Annual Progress Report](#)
 - TSCA & TRI Enhancing Chemical Safety
 - Drinking Water & Water Quality
 - Remediation & Holding Polluters Accountable

CERCLA

- EPA's initial 2019 PFAS Action Plan committed to listing PFOA and PFOS as “hazardous substances”
- Final Rule Finally Here: Effective July 8, 2024
 - [Biden-Harris Administration Finalizes Critical Rule to Clean up PFAS Contamination to Protect Public Health | US EPA](#)
 - [Published](#) May 8, 2024
 - Proposed Rule [Published in the Federal Register](#) [September 6, 2022](#)
 - [Docket EPA-HQ-2019-0341](#)

CERCLA

- Releases of one pound or more in a 24-hour period must be reported.
- Evaluation of PFOA and PFOS in Superfund 5-year Review of NPL sites
- All Superfund powers and provisions for EPA & Private Parties
 - Order investigations
 - Recover costs
 - Private party contribution actions
 - Impacts on federal facilities & transfers of federal properties
- Compliance with the “All Appropriate Inquiry” rule, 40 C.F.R. Part 312, will require consideration of PFOA and/or PFOS to qualify for CERCLA Landowner Liability Protections
- [PFAS Enforcement Discretion and Settlement Policy Under CERCLA | US EPA](#)
- Petition Challenging Regulation filed June 10, 2024

Toxic Substances Control Act (TSCA)

- NDAA Section 7351: Amended Section 8 reporting requirements
- [Final Rule](#) Effective November 13, 2023
 - EPA [Proposed Rule](#) June 2021
 - Regulations.gov [Docket EPA-HQ-OPPT-2020-0549](#)
- Requires persons that manufacture (including import) or have manufactured PFAS (broadly defined) in any year since January 1, 2011 thru December 31, 2022, to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards.
 - New regulations, [40 C.F.R. Part 705](#)
 - Detailed reporting requirements will generate voluminous (largely) publicly available data
 - Reporting Deadline: May 8, 2025 (Nov. 10, 2025 for small entities)

TSCA Data Call – Key Issues

- Very broad inclusion of PFAS compounds
 - List is illustrative only
 - Defined by combination of carbon and fluorine atoms
 - More than 1,000 substances identified by EPA
- Very broad inclusion of entities subject to reporting
 - Manufacturers for any commercial purpose, including test marketing, R&D, etc.
 - Includes byproducts, impurities, chemical transformation during use or aging
 - Includes importers
 - Includes “articles” (products) as well as chemical substances
 - No exemption for small businesses or de minimis quantities
- Very broad search of records and information required
 - “Known or reasonably ascertainable” – all information in possession or control, plus a reasonable person what might be expected to possess, control or know
 - [TSCA Section 8\(a\)\(7\) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances | US EPA](#)

More TSCA Developments

- EPA [announced](#) elimination of Low Volume Exemptions (LVEs) for new PFAS compounds (April 21, 2021)
- [Significant New Use Rule \(July 2020\)](#)
 - prohibits companies from manufacturing, importing, processing, or using certain long-chain PFAS without prior EPA review and approval
 - Includes foreign articles which use/contain identified PFAS compounds (e.g., surface coatings)
- [PEER Petition](#) to Regulate PFOA, PFNA and PFDA Manufactured during Plastic Fluorination: [EPA grant](#) July 10, 2024
 - Latest in ongoing litigation after 5th Circuit defeat Mar. 21, 2024 in the Inhance Technologies case

Drinking Water - History

- [EPA Health Advisory](#) (May 2016)
 - PFOA 70 ppt
 - [EPA Preliminary Regulatory Determination](#) (March 2020) (PFOA & PFOS)
 - [EPA Final Regulatory Determination](#) (March 2021) (PFOA & PFOS)
- [2022 Interim Updated PFOA and PFOS Health Advisories](#) (June 15, 2022)
 - Interim updated Health Advisory for PFOA = 0.004 parts per trillion (ppt)
 - Interim updated Health Advisory for PFOS = 0.02 ppt
 - “The updated advisory levels, which are based on new science and consider lifetime exposure, indicate that some negative health effects may occur with concentrations of PFOA or PFOS in water that are near zero and below EPA’s ability to detect at this time.”

“New” PFAS EPA Health Advisories & More

- [June 15, 2022 New Health Advisories](#) for different PFAS compounds
 - Final Health Advisory for GenX chemicals = 10 ppt
 - Final Health Advisory for PFBS = 2,000 ppt
- [Contaminant Candidate List 5](#)
 - [Federal Register Notice](#) (November 14, 2022)
 - Contaminants which might be subject to regulation in the future
 - Includes expanded group of PFAS
- [Fifth Unregulated Contaminant Monitoring Rule](#) (March 2021) (added 29 PFAS compounds to measure in public water systems broadly defined)
 - Data collection began in 2023
 - [PFAS Q&A](#)

Final NPDWR

- EPA [announced](#) the National Primary Drinking Water Regulation ([NPDWR](#)) on April 10, 2024
- Established Maximum Contaminant Levels (MCLs) and nonbinding MCL Goals for 6 PFAS Compounds
 - perfluorooctanoic acid (PFOA)
 - perfluorooctane sulfonic acid (PFOS)
 - perfluorononanoic acid (PFNA)
 - GenX chemicals: hexafluoropropylene oxide dimer acid (HFPO-DA)
 - perfluorohexane sulfonic acid (PFHxS)
 - perfluorobutane sulfonic acid (PFBS)

PFAS Compound	Final Legally Enforceable Maximum Contaminant Level (MCL)	Final MCL Goal
PFOA	4 parts per trillion (ppt)	0
PFOS	4 ppt	0
PFNA, PFHxS, PFBS, GenX Chemicals	10 ppt	10 ppt
Mixtures containing two or more of PFHxS, PFNA, HFPO-DA, and PFBS	Hazard Index (unitless) of 1	Hazard Index (unitless) of 1

Final NPDWR

- Requirements Phased In
 - Public water systems have 3 years to begin testing
 - Large systems (over 10,000 people) 4 times per year
 - Small systems 2 times per year
 - Within 5 years systems must notify residents of results and take action to achieve MCLs
- Legal Challenges filed June 7 and June 10 consolidated in the D.C. Circuit Court of Appeals as Docket Nos. 24-1188 (24-1191 & 24-1192)
 - Issues include whether unitless “hazard index” is legal, whether regulation of mixtures is legal, whether levels are feasible, especially related to costs, and whether proper reliance on occurrence data

Drinking Water - States

- Many states already regulating drinking water and PFAS contamination potentially impacting drinking water aquifers
 - [Maine](#), [Massachusetts](#), [Michigan](#), [New Hampshire](#), [New Jersey](#), [New York](#), [Pennsylvania](#), [Rhode Island](#), [Vermont](#), [Washington](#) and [Wisconsin](#)
 - [Delaware](#) and [Virginia](#) are in the process
 - [Connecticut](#), [Maryland](#), and [Oregon](#), have established non-enforceable "action levels" or drinking water guidelines
 - [California](#) and [Utah](#) have begun monitoring programs
- [Persistent Chemicals: EPA Should Use New Data to Analyze the Demographics of Communities with PFAS in Their Drinking Water | U.S. GAO \(2022 Report\)](#)
 - 6 states (Illinois, Massachusetts, New Hampshire, New Jersey, Ohio and Vermont)
 - 18% of systems tested had at least two PFOA or PFOS above detection limits (2022 Health Advisories)
 - Serving approximately 9.5 million people

RCRA

- Feb. 8, 2024, Resource Conservation Recovery Act (RCRA) [proposal](#)
 - Add nine PFAS compounds, their associated salts and structural isomers to a list of hazardous constituents considered in the [RCRA Corrective Action Program](#)
- Feb. 8, 2024 [proposal](#) to expand the scope of hazardous waste requiring corrective action
 - to include chemicals that meet the statutory definition but may not be explicitly defined by RCRA regulations
 - change will allow the agency to enforce RCRA corrective action requirements as was intended in the law
 - grant EPA the authority to address PFAS and other emerging contaminants that have not yet been explicitly defined as hazardous waste at RCRA-permitted treatment, storage and disposal facilities
- EPA's [Spring 2024 Agency Rule List](#) - EPA [expects](#) to finalize these rules in December 2024

Toxics Release Inventory (TRI) Reporting

Background

- Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), [42 U.S.C. 11023](#)
- Based upon SIC and NAICS Codes, [40 C.F.R. 372.23](#)
- Supplier Notification, [40 C.F.R. 372.45](#) (Safety Data Sheet)
- Guidance: [EPA TRI Guide with Updates NAICS Codes](#)
- Guidance: [EPA PFAS Reporting Guidance](#)

Toxics Release Inventory (TRI) Reporting

- Historic Reporting began in 2020
 - Limited Data reported because *de minimis* exemption allowed facilities that report to TRI to disregard certain minimal concentrations of chemicals in mixtures or trade name products
- 2022 Proposed Rulemaking to correct reporting deficiencies
 - [December 5, 2022 Federal Register Notice](#)
 - Proposal to list PFAS as chemicals of special concern
 - Would eliminate the use of the *de minimis* exemption and the option to use Form A and would limit the use of range reporting for PFAS
 - Would remove the availability of the *de minimis* exemption for purposes of the Supplier Notification Requirements for all chemicals on the list of chemicals of special concern
- [Final rule](#) published October 31, 2023
 - [EPA Explanation](#): Implementation over reporting years 2023 & 2024

Stormwater/Wastewater Discharges

- National Pollutant Discharge Elimination System (NPDES):
 - [April 28, 2022](#) and [December 5, 2022](#) Memos to permit writers
 - Recommends adopting the full suite of [PFAS monitoring techniques](#)
 - EPA's [Spring 2024 Agency Rule List](#) - EPA [expects](#) to issue a proposed rule in June 2025 to update NPDES application regulations, 40 C.F.R. 122.21
- Effluent Guidelines Program Plan 15 ([Plan 15](#))
 - Multi-industry study of PFAS discharges: [Textile Mills Industry](#) (40 CFR part 410), [Concentrated Animal Feeding Operations](#) (40 CFR part 412), [Landfills](#) (40 CFR part 445), [Pulp, Paper, and Paperboard Category](#) (40 CFR part 430)
 - EPA's [Spring 2024 Agency Rule List](#) - EPA [expects](#) to issue a proposed rule (ELG) revising the existing Organic Chemicals, Plastics, and Synthetic Fibers ELG (40 CFR Part 414) by September 2024
- Update Clean Water Act Part 136 monitoring methods
 - to incorporate multi-laboratory validated [methods for analyzing PFAS](#) in January 2025

Air Emissions

- No federal regulation yet, but potential Clean Air Act jurisdiction if EPA acts
- Clean Air Act 111(b)(1)(A), [42 U.S.C. 7411](#), a compound that “contributes significantly to air pollution which may reasonably be anticipated to endanger public health or welfare”
- Clean Air Act 112, [42 U.S.C. 7412](#), “Hazardous Air Pollutant” the compound provides a “threat of adverse human health effects” or other “adverse environmental effects.” (b)(2)
- EPA Office of Research and Development (ORD): [EPA PFAS Air Emission Measurements: Activities and Research | Science Inventory | US EPA](#) (June 2019) (ORD technical support to states in measuring emissions)
- Proposed Rule [published](#) August 9, 2023 to initiate data collection from point sources beginning in 2027
 - Seeks comment on how to handle PFAS, including whether to adopt program similar to TRI reporting requirements

Biosolids

- Wastewater residual (sludge) used for land application
- Regulated under Clean Water Act, Section 405, [33 U.S.C. 1345](#)
- [PowerPoint Presentation \(epa.gov\)](#) (PFAS Treatment in Biosolids – State of the Science, 9/23/20)
- [40 CFR 503](#) (PFAS not specified yet)
- [Biennial Reviews of Sewage Sludge Standards | Biosolids | US EPA](#) EPA requirement to review & identify additional toxic pollutants that occur in biosolids and set regulatory standards
 - PFAS included in most recent reports, [No. 8](#) & [No. 9](#)
- [EPA Risk Assessment Underway](#): Completion by December 2024
- PEER [litigation](#) filed June 6, 2024 to compel EPA to act

State by State Regulations & Guidance

- Despite the simplicity of a color-coded maps, every state is different
- Enforceable regulations vs. advisory/guidance
- PFOA/PFOS vs. broader group (PFAS6, 20, Gen-X)
- What's being regulated?
 - Drinking water (public & private wells)
 - Groundwater (source of drinking water?)
 - Soil (Exposure & Protection of GW & DW)
 - Release notification
 - Remediation
 - Products & Packaging (registrations & bans)
- Constantly changing

PFAS and Beyond – Final Thoughts

- All emerging contaminants present regulatory and litigation risk
- Even non-binding governmental pronouncements can have cascading effects
- Litigation theories are just as emerging as the contaminants themselves
 - No longer traditional remediation claims (although those still exist)
 - Natural Resource Damages (NRD) claims likely to rise as science improves, including analytical methods & toxicology for compounds beyond PFOA/PFOS
 - Class actions will increase, even for plaintiffs who are never sickened
 - False representation and similar “marketing” claims will increase due to public perception of harm
 - Record-keeping burdens will increase & will provide a road-map to liability

Questions?

Thank you

Additional References (2024 Articles)

- [Product Importers: Are You Ready for the New PFAS Reporting Requirements Under TSCA? | Insights | Holland & Knight \(hklaw.com\)](#) (June 26, 2024)
- [FAA Reauthorization Act Creates PFAS Replacement Program for Airports | Insights | Holland & Knight \(hklaw.com\)](#) (June 5, 2024)
- [EPA Finalizes PFAS Drinking Water Regulations](#) *Pratt's Energy Law Report* (June 2024)
- [The FDA's New Pre-Harvest Agricultural Water Rule: Impacts on PFAS-Contaminated Groundwater? | Insights | Holland & Knight \(hklaw.com\)](#) (May 16, 2024)
- [EPA Designates 2 PFAS Compounds as Hazardous Substances | Insights | Holland & Knight \(hklaw.com\)](#) (April 26, 2024)
- [EPA Finalizes PFAS Drinking Water Regulation | Insights | Holland & Knight \(hklaw.com\)](#) (April 17, 2024)
- [EPA Exceeds Statutory Authority in PFAS Fluorination Case | Insights | Holland & Knight \(hklaw.com\)](#) (April 16, 2024)

Additional References (2024 Articles)

- [Senate Committee Convenes Hearing to Examine PFAS as Hazardous Substances | Insights | Holland & Knight \(hklaw.com\)](#) (April 5, 2024)
- [FDA Ramps Up Actions on PFAS | Insights | Holland & Knight \(hklaw.com\)](#) (April 3, 2024)
- [EPA Proposes RCRA Corrective Action Expansions Targeting PFAS | Insights | Holland & Knight \(hklaw.com\)](#) (February 14, 2024)
- [PFAS in Products: 2024 Is Off to a Busy Start in Many States | Insights | Holland & Knight \(hklaw.com\)](#) (February 5, 2024)
- [2023 PFAS Year in Review: EPA Policy and Aqueous Film-Forming Foam Litigation Updates | Insights | Holland & Knight \(hklaw.com\)](#) (January 16, 2024)
- [EPA Takes Action Against Inhance Technologies LLC on Fluorinated HDPE Containers | Insights | Holland & Knight \(hklaw.com\)](#) (January 11, 2024)

Additional References (2023 Articles)

- [Continuing an Annual Tradition, the NDAA Contains PFAS Provisions of Note | Insights | Holland & Knight \(hklaw.com\)](#) (December 19, 2023)
- [What Affordable Housing Developers Should Know About Emerging Contaminants| Housing Finance Magazine](#) (November 2, 2023)
- [EPA Publishes Comprehensive PFAS Reporting Rule Under TSCA | Insights | Holland & Knight \(hklaw.com\)](#) (October 17, 2023)
- [Preparing for the Legal Effects of PFAS Legislation and Litigation on Your Business | Insights | Holland & Knight \(hklaw.com\)](#) (September 27, 2023)
- [Navigating PFAS Compliance With FDA, Emerging State Laws - Law360](#) (September 21, 2023)
- [FDA, PFAS and Food Packaging: More to Come? | Insights | Holland & Knight \(hklaw.com\)](#) (September 13, 2023)
- [EPA Seeks Comment on Air Pollutant Reporting for PFAS | Insights | Holland & Knight \(hklaw.com\)](#) (August 10, 2023)

Additional Resources (2023 Articles)

- [EPA Publishes Semiannual Agenda Previewing PFAS-Related Agency Actions | Insights | Holland & Knight \(hklaw.com\)](#) (August 3, 2023)
- [Minnesota Joins Maine in Enacting Comprehensive PFAS Reporting Requirements | Insights | Holland & Knight \(hklaw.com\)](#) (July 27, 2023)
- [PFAS Food Packaging Regulations Boil Over: Time to Develop a Compliance Plan | Insights | Holland & Knight \(hklaw.com\)](#) (June 29, 2023)
- [EPA's Latest CERCLA Action on PFAS | Insights | Holland & Knight \(hklaw.com\)](#) (April 12, 2023)
- [EPA Publishes Proposed PFAS Drinking Water Regulation | Insights | Holland & Knight \(hklaw.com\)](#) (March 29, 2023)
- [Year in Review: 2022 PFAS Regulatory Updates | Insights | Holland & Knight \(hklaw.com\)](#) (January 9, 2023)

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[Dianne R. Phillips](#) is an attorney in Holland & Knight's Boston office who concentrates her practice in litigation, regulatory, energy and environmental law. As former assistant general counsel for Suez LNG North America LLC and its wholly owned subsidiary, Distrigas of Massachusetts LLC, Ms. Phillips was involved in all aspects of regulatory compliance for the nation's oldest, continuously operating liquefied natural gas (LNG) import terminal located in Everett, Mass., including safety and security. Her LNG experience includes advising clients with respect to specialized regulatory compliance under 49 C.F.R. Part 193 and NFPA 59A.

Ms. Phillips' environmental practice focuses on brownfields redevelopment and remediation, including former military installations, former manufactured gas plants (MGPs) per- and polyfluoroalkyl substances (PFAS) sites, and vapor intrusion sites. She regularly advises developers, lenders and investors in real estate transactions involving contaminated property, enforcement defense, regulatory compliance, due diligence, and complex project development and permitting matters, including those under the National Environmental Policy Act (NEPA) and the National Pollutant Discharge Elimination System (NPDES), among others.

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