



Morgan Lewis

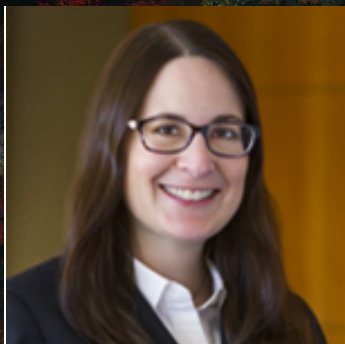
**2023  
EARTH DAY  
WEBINAR SERIES**

**Regulation and Litigation on the (PFAS)t  
Track in 2023**

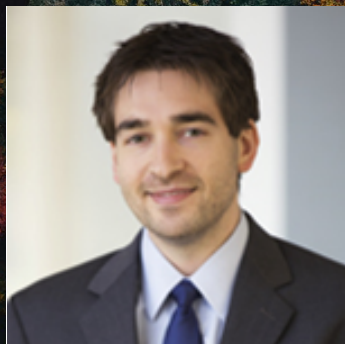
April 18, 2023



# Presenters



**Stephanie R. Feingold**  
Partner | Princeton



**Jeremy Esterkin**  
Partner | Los Angeles



**Kathryn E. Deal**  
Partner | Philadelphia



**Drew Cleary Jordan**  
Associate | Washington, DC

**Morgan Lewis**



# Upcoming Earth Day Webinars

- **EPA's Chemicals Regulatory Agenda – Testing, Reporting, Rulemaking, and Litigation**

April 19, 2023 | 1:00 – 2:00 PM ET

– Presenters: John McGahren, Debra Carfora

- **Environmental Justice and the E in ESG**

April 20, 2023 | 1:00 – 2:00 PM ET

– Presenters: Duke McCall, Rick Rothman, Gina Waterfield (Berkeley Research Group)

*Recording and slides available:*

- **Evolving Environmental Laws: Endangered Species Act and WOTUS Under the Clean Water Act**

April 17, 2023

– Presenters: Doug Hastings, David Brown





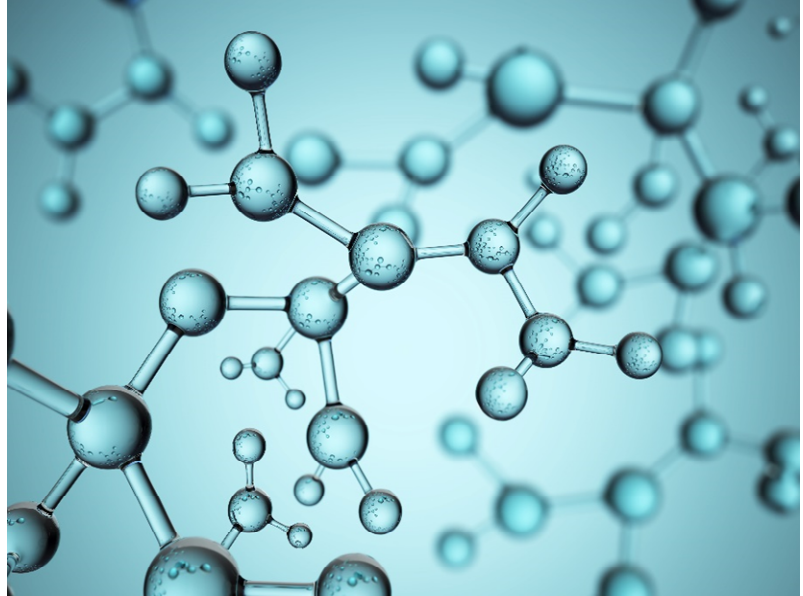
# PFAS – Overview

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# What Are PFAS and Why Do They Matter?

- Chain of carbon and fluorine atoms
- Valuable properties
  - Very durable
  - Moisture repellent
  - Heat resistant





# What Are PFAS and Why Do They Matter?

- Common applications:
  - Fabric treatments
  - Firefighting foam
  - Paper coating
  - Cosmetics
  - Cleaning products
  - Electrical insulation





# What Are PFAS and Why Do They Matter?

- PFAS in the environment
  - Persistent
  - Mobile
  - Tendency to bioaccumulate and biomagnify



# PFAS Toxicity?

The logo for the Agency for Toxic Substances and Disease Registry (ATSDR) is displayed in a large, blue, sans-serif font.

National Institute of  
Environmental Health Sciences

*"At this time, **scientists are still learning** about the health effects of exposures to mixtures of different PFAS.... **Additional research may change our understanding** of the relationship between exposure to PFAS and human health effects."*

*"Human health effects from exposure to low environmental levels of PFAS are uncertain.... **More research is needed** to assess the human health effects of exposure to PFAS."*

*"When looking for possible human-health effects of chemical compounds, it is important to understand **that they are hard to study, especially with thousands of variations in PFAS chemicals**.... While knowledge about the potential health effects of PFAS has grown, **many questions remain unanswered**."*





# Selected US Regulatory Developments

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# Pending CERCLA Regulation of PFAS

- Proposed Rule to designate PFOA and PFOS as hazardous substances under CERCLA
  - Proposed rule published Sept. 6, 2022; Final rule expected August 2023
  - Over 600 comments published
- ANPRM seeking public input on whether to designate seven other PFAS (PFBS, PFHxS, PFNA, HFPO-DA, PFBA, PFHxA, and PFDA); precursors to PFOA, PFOS, and certain other PFAS; and/or categories of PFAS as hazardous substances under CERCLA
  - Published April 13, 2023
  - Comments due by June 12, 2023





# Significance of CERCLA Listing of PFOA/PFOS

- First designation of a chemical as a hazardous substance under CERCLA by rulemaking
- Potential impacts to a broad range of companies and industries
- Inclusion of PFAS in RI/FS process at Superfund sites
  - Possible addition of new PRPs to sites
  - Addition of new sites to NPL based on PFAS contamination
  - Possible reopener under 5-year-review process
- Triggers release reporting requirements under CERCLA and EPCRA
- Cost recovery and contribution claims (= more litigation)

# Practical Considerations

- EPA Listening Sessions - March 14 and 23, 2023
- EPA Proposed Enforcement Discretion Policy
  - Community water utilities
  - Publicly owned treatment works
  - Publicly owned/operated municipal solid waste landfills
  - Farms that apply biosolids to their lands
  - State, tribal or municipal airports and tribal or local fire departments
  - EPA may consider equitable factors to identify other entities
- State standards as ARARs



# Challenges

- Limits on testing/lab capacity
- Lag in development of approved methods for disposal/destruction of PFAS remediation wastes
  - Currently no clear guidance
  - Updated guidance due by December 2023
- Environmental Justice considerations



# Safe Drinking Water Act: National Primary Drinking Water Regulations

- The Safe Drinking Water Act (SDWA) was established to protect the quality of drinking water in the United States.
  - SDWA authorizes EPA to establish minimum standards to protect drinking water
- The National Primary Drinking Water Regulations (NPDWR) are legally enforceable primary standards and treatment techniques that apply to public water systems.
- In setting NPDWR, EPA considers whether:
  - the contaminant may have adverse health effects;
  - the contaminant is found or substantially likely to be found in public water systems with frequency and at levels of concern; and
  - there is a meaningful opportunity for health risk reduction through a national drinking water regulation.



# EPA's Proposed PFAS NPDWR

- EPA published its proposed NPDWR establishing legally enforceable Maximum Contaminant Levels (MCLs) and health-based, non-enforceable Maximum Contaminant Level Goals (MCLGs) for six PFAS
- Proposed PFAS MCLs seek to regulate:
  - PFOA and PFOS as individual contaminants, and
  - Perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), perfluorobutane sulfonic acid (PFBS), and hexafluoropropylene oxide dimer acid and its ammonium salt (HFO-DA) (more commonly known as GenX chemicals) as a PFAS mixture
- Proposed MCLGs for these six PFAS:
  - MCLG is the level of a contaminant in drinking water below which there is no known or expected risk to health.
  - MCLGs allow for a margin of safety and are non-enforceable public health goals.

# Proposed MCLG and MCL Levels

Compound	Proposed MCL (enforceable)	Proposed MCLG (non-enforceable)
<b>PFOA</b>	<b>4.0 parts per trillion (ppt)</b>	<b>0 ppt</b>
<b>PFOS</b>	<b>4.0 ppt</b>	<b>0 ppt</b>
<i>For the following PFAS individually or any mixture containing one or more of each:</i>		
<b>PFNA</b>	<b>1.0 (unitless) Hazard Index</b>	<b>1.0 (unitless) Hazard Index</b>
<b>PFHxS</b>		
<b>PFBS</b>		
<b>HFPO-DA (GenX Chemicals)</b>		



# Hazard Index

- Hazard Index is a tool used to evaluate possible health risks of simultaneous exposure to mixtures of related chemicals
  - The HI considers the combined toxicity of PFNA, GenX Chemicals, PFHxS, and PFBS in drinking water
  - Does not include PFOA and PFOS (regulated individually)
- Water systems to monitor and compare the amount of each PFAS in drinking water to its associated Health-Based Water Concentration (HBWC).
  - HBWC is the level below which no health effects are expected for that PFAS

## Proposed HBWCs

Compound	Proposed HBWC
<b>PFNA</b>	10.0 ppt
<b>PFHxS</b>	9.0 ppt
<b>PFBS</b>	2,000 ppt
<b>GenX Chemicals</b>	10.0 ppt

# Monitoring, Compliance, & Treatment Technologies

Under EPA's proposed rule, public water systems will be required to:

- Monitor for these six PFAS;
- Notify the public if levels exceed MCLs; and
- Reduce exposure levels of the the PFAS if they exceed MCLs
  - Treatment Technologies: Granular Activated Carbon, Anion Exchange, and High-Pressure Membrane Technologies

Estimated 66,000 public water systems to be subject to this rule

Estimated 3,400-6,300 public water systems exceed one or more PFAS MCL

Estimated compliance costs of \$772 million to \$1.2 billion

Federal funding availability





# PFAS Reporting Rule: TSCA Section 8(a)(7)

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# The Objective

“Not later than **January 1, 2023**, the Administrator shall promulgate a rule in accordance with this subsection requiring **each person who has manufactured a [PFAS] chemical** ... in any year **since January 1, 2011**, to submit to the Administrator a report that includes, for each year since January 1, 2011, the information described in subparagraphs (A) through (G) of paragraph (2).”

# The Draft Rule

## Key Issues:

1. **Who** is required to report?
2. **What** information is required?
3. **How** does the proposed rule define PFAS?



# The Draft Rule: Who is required to report?

“...each person who has manufactured a [PFAS] chemical  
... in any year since January 1, 2011...”

- “The term ‘manufacture’ means to **import** into the customs territory of the United States..., **produce**, or **manufacture**.” *15 U.S.C. § 2602(9)*
- “For the purposes of this proposed rule, **articles** containing PFAS, including imported articles containing PFAS (such as articles containing PFAS as part of surface coatings), **are included in the scope of reportable chemical substances**.”
- “This proposed rule under TSCA section 8(a)(7) **does not exempt small manufacturers** from reporting and recordkeeping requirements.”

# The Draft Rule: What information is required?

## Report Contents (per PFAS chemical, per year)

- Basic chemical info
- Categories of use
- Total volume manufactured
- Description of byproducts
- “All existing environmental and health effects information of such substance or mixture”
- Number of persons exposed at work
- Disposal practices and volumes

# The Draft Rule: What information is required?

## What if information is unavailable?

- Research required
- Make reasonable estimates
- Document efforts



## The Draft Rule: How is PFAS defined?

“Per- and polyfluoroalkyl substances or PFAS, for the purpose of this part, means any chemical substance or mixture that structurally contains the unit  $R-(CF_2)-C(F)(R')R''$ . Both the  $CF_2$  and  $CF$  moieties are saturated carbons. None of the R groups (R, R' or R'') can be hydrogen.”

# The Draft Rule

## Key Issues:

### 1. **Who** is required to report?

- Manufacturers, importers, producers
- Articles, not just raw supply
- No small business exemptions

### 2. **What** information is required?

- Numerous categories
- Broken out annually and per-chemical
- Requirements if data cannot be obtained

### 3. **How** does the proposed rule define PFAS?

- Complex definition
- No finite list

# How Did We Get Here?

<b>June 2021</b>	Notice of Proposed Rulemaking
<b>June-December 2021</b>	Public Comment Period
<b>February 2022</b>	EPA announces formation of Small Business Advocacy Review Panel (SBAR)
<b>August 2022</b>	SBAR publishes its report
<b>November 2022</b>	EPA issues Initial Regulatory Flexibility Analysis and Updated Economic Analysis
<b>January 2023</b> <b>March 2023</b>	Final Rule publication date

# ...Isn't It April?

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## View Rule

[View EO 12866 Meetings](#) [Printer-Friendly Version](#) [Download RIN Data in XML](#)

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**EPA/OCSP** **RIN:** 2070-AK67 **Publication ID:** Fall 2022

**Title:** TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances

**Abstract:**

EPA published a proposed rule on June 28, 2021, addressing reporting and recordkeeping requirements for Per- and Polyfluoroalkyl Substances (PFAS) under section 8(a)(7) of the Toxic Substances Control Act (TSCA). In accordance with obligations under TSCA section 8(a), as amended by section 7351 of the National Defense Authorization Act for Fiscal Year 2020, persons that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011, would be subject to the reporting and recordkeeping requirements. In addition to fulfilling statutory obligations under TSCA, EPA expects that the final rule will enable EPA to better characterize the sources and quantities of manufactured PFAS in the United States. EPA solicited additional public comments on an Initial Regulatory Flexibility Analysis (IRFA) following the completion of a Small Business Advocacy Review (SBAR) Panel addressing the proposed PFAS reporting and recordkeeping requirements.

**Agency:** Environmental Protection Agency(EPA) **Priority:** Other Significant

**RIN Status:** Previously published in the Unified Agenda **Agenda Stage of Rulemaking:** Final Rule Stage

**Major:** No **Unfunded Mandates:** No

**CFR Citation:** [40 CFR 705](#)

**Legal Authority:** [15 U.S.C. 2607\(a\)\(7\) Toxic Substances Control Act](#)

**Legal Deadline:**

Action	Source	Description	Date
Final	Statutory	TSCA section 8(a), as amended in December 2019 by section 7351 of the National Defense Authorization Act for Fiscal Year 2020 (NDAA).	01/01/2023

**Timetable:**

Action	Date	FR Cite
NPRM	06/28/2021	<a href="#">86 FR 33926</a>
NODA	11/25/2022	<a href="#">87 FR 72439</a>
NODA Comment Period End	12/27/2022	
<b>Final Rule</b>	<b>03/00/2023</b>	



# What Changed?

	<b>Initial (June 2021)</b>	<b>Revised (Nov 2022)</b>
<b>Industry Costs</b>	\$10,800,000	\$876,000,000

# Possible Changes to the Final Rule

- Exempt small entities
- Exempt impurities, byproducts and/or low PFAS concentrations
- Provide guidance, training and webinars
- Give small entities additional compliance time
- Clarify scope of covered entities
- Provide a definitive PFAS list
- Implement a phased approach to reporting





# PFAS Bans

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# PFAS Bans – United States

- Most common: States banning “intentionally added PFAS” in packaging and food-contact materials
- States restricting or banning PFAS/“intentionally added PFAS” in consumer products
  - Carpets and rugs
  - Textiles and apparel
  - Cookware
  - Cosmetics
  - Juvenile products
  - Maine – all products with intentionally added PFAS
- Certifications
- Supply Chain Impacts
- Voluntary Phase-Outs

# PFAS Bans – Europe

- European Union (EU) Proposed PFAS Ban (REACH)
  - Covers chemicals, mixtures and articles with 25 ppb or more of a specified PFAS or 250 ppb of a combination of PFAS
  - Broad reach could impact anyone exporting products to the EU
  - Final restrictions expected 2025
  - Phase-out would begin 18 months after the rule is finalized
    - Derogations allow phase-outs to take place over five- or 12-year periods
  - Affected business may need to reexamine the composition and design of thousands of products
- Could prompt additional US state bans, federal legislation





# PFAS Consumer Products Litigation

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# Public Testing and Class Actions: The Basics

Who?	What?	Where?	How?
Consumers performing independent testing	Challenging labeling practices and pursuing alleged economic losses for allegedly undisclosed presence of PFAS in products	Across industries, including: <ul style="list-style-type: none"><li>• apparel,</li><li>• cosmetics,</li><li>• food and beverage,</li><li>• personal care,</li><li>• pet food,</li><li>• cleaning supplies</li></ul>	Putative class claims based on alleged labeling omissions or misrepresentations, deceptive marketing practices, and state consumer protection laws



# Public Testing and Class Actions: Claims and Damages

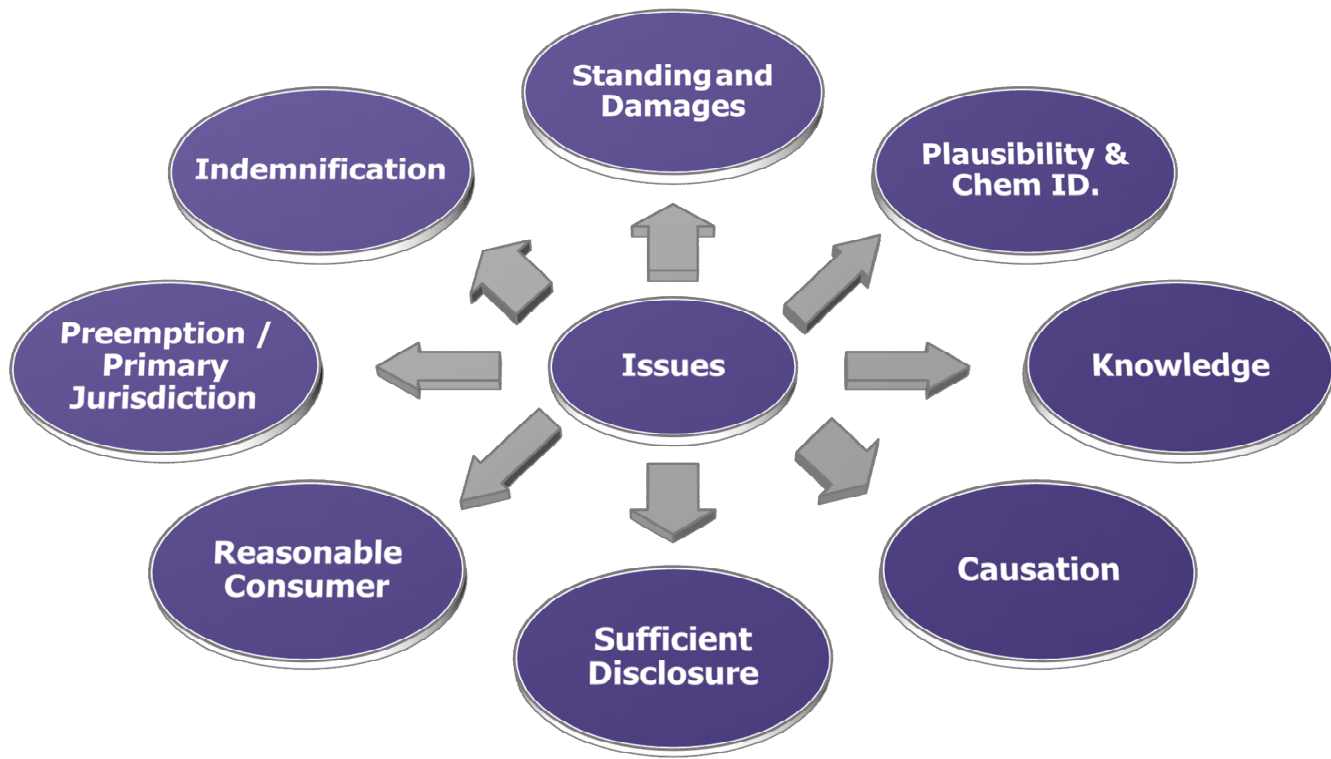
## Types of Alleged Claims:

- PFAS in food, beverages, and personal care products labeled as “natural” or “all natural”
  - *Esquibel et al. v Colgate-Palmolive Co. & Tom’s of Maine, Inc.*, 1:23-cv-00742 (S.D.N.Y., Jan. 27, 2023)
  - *Toribio v. The Kraft Heinz Co.*, 1:2022-cv-06639 (N.D. Ill., Nov. 29, 2022)
- PFAS in waterproof products including clothing and cosmetics
  - *Lupia v. Recreational Equipment Inc.*, No. 3:22-cv-02510 (N.D.Cal., April 25, 2022)
  - *Hicks v. L’Oreal USA, Inc.*, No. 22-cv-01989 (S.D.N.Y. March 2022)
- PFAS in food packaging with anti-grease or microwaveable qualities
  - *McDowell v. McDonald's Corp.*, No. 1:22-cv-01688 (N.D. Ill., March 2022)
  - *Richburg v. Conagra Brands, Inc.*, No. 22-cv-02420 (N.D. Ill. May 2022)

## Types of Alleged Damages:

- Benefit of the Bargain Theory
- Price Premium Theory

# Public Testing and Class Actions: Potential Defenses



# What's Next?

- Tip of the Iceberg
- Risks of potential non-compliance as new regulations fall into place
- Continued increase in PFAS litigation
- Bans impacting manufacture and distribution of products

## Bottom Line:

- Know what PFAS are in your products, processes, and waste streams.
- Develop strategies to manage PFAS risks and ensure compliance with new regulations, now and over the long term

# Biography



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Stephanie represents clients in litigation and dispute resolution with a focus on environmental issues, and provides environmental and regulatory counseling. Her work spans investigations, cost recovery and contribution actions, and enforcement actions brought by and against environmental agencies and government authorities, as well as private party actions, under both federal and state environmental laws. She defends major corporations and businesses in toxic tort actions, commercial litigation, and product liability litigation.

Stephanie also counsels clients in matters involving drinking water contamination and emerging contaminants, including per- and polyfluoroalkyl substances (PFAS) and 1,4-dioxane. Stephanie also works with potentially responsible parties (PRPs) in connection with contaminated sites, including working closely with consultants and experts, and negotiating with regulatory agencies.



# Biography



## **Jeremy Esterkin**

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With more than a decade of practice focused on environmental, mass tort, and product liability matters, Jeremy counsels clients facing complex environmental litigation and regulatory compliance challenges involving contaminant migration, hazardous substance exposure, and property damage claims. He has been at the forefront of some of the most high-profile environmental litigation in the country, including the Aliso Canyon gas leak, the Deepwater Horizon oil spill, and the Anadarko-Tronox spinoff. Jeremy leverages his experience with environmental modeling, contaminant fingerprinting, and analysis of historical records to deliver tangible and cost-effective results for clients.

# Biography



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Kate, a former federal prosecutor, defends clients at trial and in aggregate litigation, including class actions, mass actions and arbitrations, mass torts, multidistrict litigation, and parallel government proceedings throughout the United States. Over the past two decades, Kate has secured trial and arbitration wins for Fortune 100 clients in complex disputes; managed and favorably resolved portfolios of putative class, mass, and government proceedings; and investigated and prosecuted a variety of economic crimes and complex frauds. As a partner to clients facing aggregate litigation exposure, Kate has obtained early litigation victories through efficient investigation, strategic motion practice, and a practical and proactive approach to risk mitigation and compliance.

# Biography



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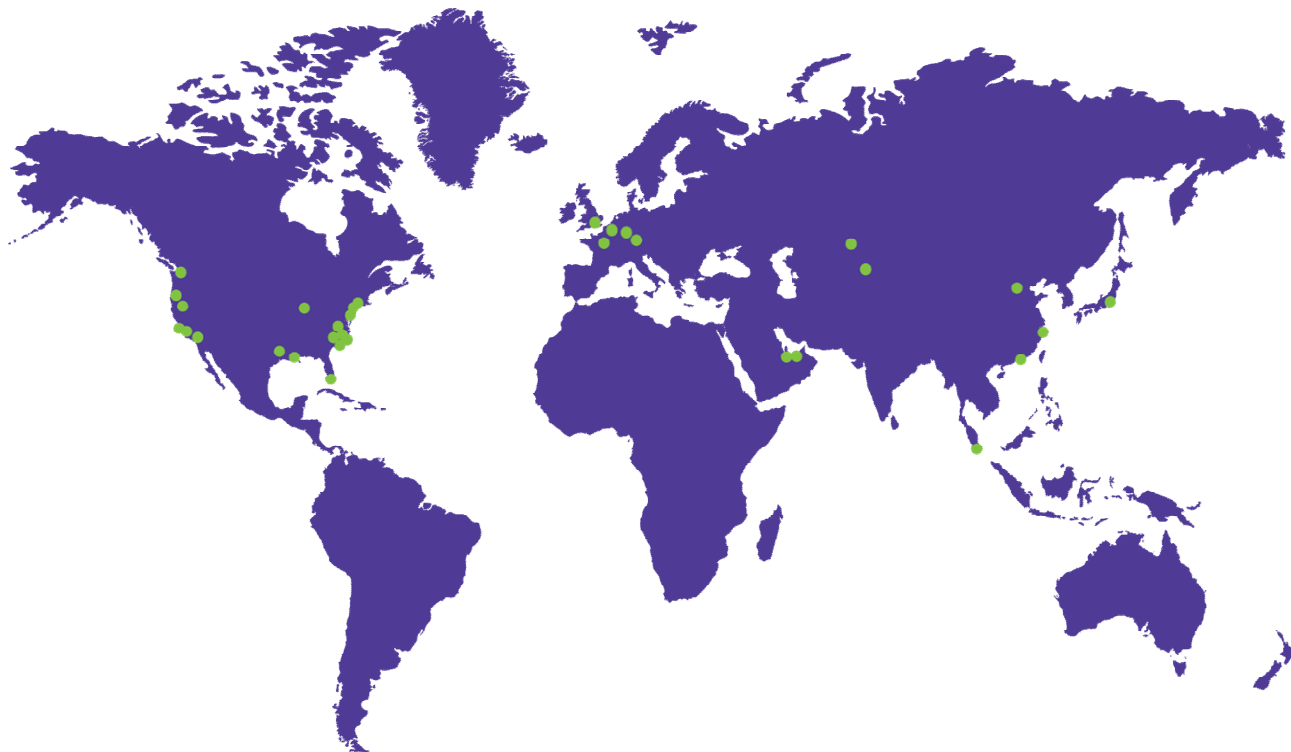
Drew represents national and international clients in complex litigation and crisis management, focusing on environmental, mass and toxic tort, class action, product liability, and commercial matters before US federal and state courts, including appellate courts. Drew's environmental practice includes representing and counseling clients in connection with enforcement litigation and investigations, regulatory compliance, due diligence, and contribution and cost recovery claims under state and federal environmental statutes and related common law causes of action. He also counsels clients in matters involving emerging contaminants, including per- and polyfluoroalkyl substances (PFAS).

## Our Global Reach

Africa  
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Latin America  
Middle East  
North America

## Our Locations

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