PFAS Reporting in the United States

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Note: Global regulations around PFAS chemicals are rapidly evolving. The regulations listed in this presentation do not represent the entirety of regulatory activity or requirements. This presentation is for information only and should not be construed as legal advice.
PFAS, a family of synthetic chemicals, has been in widespread use since the 1940s.

- Tight carbon-fluorine bonds provide certain properties to materials, including oil-, water-, temperature- chemical- and fire-resistance, and electrical insulating properties.
- There are thousands of PFAS chemicals, making it challenging to study and assess the potential health and environmental risks.

The same tight chemical bonds responsible for these properties also earn these substances the nickname "forever chemicals" due to their resistance to degradation over time.

A great primer on PFAS from Vox:
You probably have “forever chemicals” in your body. Here’s what that means.
Why Use PFAS?
Performance Attributes Guide PFAS Use in Products

- Water repellent and anti-condensation
- Oil and stain repellent
- Chemically inert and biocompatible
- Non-stick and slippery
- High temperature stability
- Electrically insulating and flame retardant
- Resistant to ultraviolet (UV) light
Common Uses of PFAS

Electronics - batteries, PCB’s, conformal coatings, flame retardants
Wires & Cables
Hoses & Tubing
Lubricants
Gaskets, Seals, O-Rings
Plastic Parts - mold release agents in resins and dies
Coatings - powder, e-coats, lacquer, paints
Inks - shipping labels, pad printed parts
Tape and Adhesives
Plastic packaging - foods, beverages, solvents, pesticides

Most of these materials could be impacted not only for use in products but also as indirect materials in manufacturing operations, including maintenance!
PFAS in Operations

Due to their desirable material properties, PFAS are also widely used in manufacturing operations. A few examples:

- Chemical processes like mist suppressant in electroplating operations
- Employee PPE
- Fire-fighting systems
- MRO materials for machine repair and maintenance
  - lubricants, grease, cutting fluids
  - rust preventative coatings
  - floor cleaners and waxes
US EPA PFAS Roadmap

EPA’s Commitments to Action 2021–2024

Research
Invest in research, development and innovation to increase understanding of PFAS and effective interventions

Restrict
Pursue a comprehensive approach to proactively prevent PFAS from entering air, land and water at levels that could impact human health and the environment

Remediate
Broaden and accelerate the cleanup of PFAS contamination to protect human health and ecological systems

In October 2023, the EPA published a long-awaited rule under TSCA section 8(a)(7) which requires reporting and recordkeeping for per- and polyfluoroalkyl substances (PFAS)

- The rule was first published as a draft in June 2021
- The rule was mandated by Congress under the National Defense Authorization Act (NDAA) for FY 2020
- Reporting for most manufacturers will be required between November 12, 2024 and May 8, 2025

The final rule requires submission of PFAS manufacturing and importing data from 2011 forward, including PFAS that are incorporated into imported articles.

- Under the rule, articles containing PFAS, including imported articles containing PFAS (such as articles containing PFAS as part of surface coatings), are included in the scope.
- Applies to everyone who has “manufactured” or imported a PFAS in any year between 2011 - 2022.
- Manufacturers or importers of PFAS are required to provide detailed data within 18 months (by May 8, 2025).
- Substances in scope of reporting are those that meet a definition provided by the EPA (rather than a fixed substance list).
- Distributors and contract manufacturers are also in scope if they import materials containing PFAS.
No Two Laws Are the Same!
Regulators Can’t Agree on How to Define PFAS

U.S. TSCA Reporting Rule
PFAS is defined as including at least one of these three structures:
- \( R-(CF2)_{n}-CF(R')R'' \), where both the CF2 and CF moieties are saturated carbons
- \( R-CF2OCF2-R' \), where \( R \) and \( R' \) can either be F, O, or saturated carbons
- \( CF3C(CF3)R'R'' \), where \( R' \) and \( R'' \) can either be F or saturated carbons

State of Maine Reporting & Restriction Rule
"Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" means substances that include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.

EU REACH Restriction Proposal
Per- and polyfluoroalkyl substances (PFASs) defined as: Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it), or two or more contiguous perfluorinated methylene groups (\(-CF2\)-).

UK Regulatory Management Options Analysis (RMOA)
PFAS are defined as fluorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), or two or more contiguous perfluorinated methylene groups (\(-CF2\)-).
EPA PFAS Lists - Narrow the Scope to Limit Supplier Fatigue

**TSCA Section 8(a)(7)**

EPA estimates that at least 11,409 substances* meet the definition of PFAS in the regulation...

HOWEVER

Most of those defined substances are not considered “active” in the “known TSCA universe”, which includes substances listed on the TSCA Inventory or have been listed with a Low-Volume Exemption (LVE) claim (i.e. registered for use in commerce in the US)

**EPA PFAS Master (aka “CompTox”)**

All known substances - whether active or not - that are considered as “PFAS” by the EPA. Not specifically linked to section 8(a)(7)

Whether those substances are currently used in commerce is irrelevant - 10,000+ PFAS substances are NOT listed on the TSCA Inventory and they are not known to be used in commerce

**EPA lists** at least 11,409 substances that meet the definition in 8(a)(7)

In the final rule, EPA estimates that only 1,462 of these are “active” - listed on the TSCA Inventory or have LVE claims

EPA has only provided a partial list - 1,224 of the of the “1462” substances they say meet the definition

The total number of impacted substances is likely greater than 1,462 since all substances which meet the definition must be reported, even if not on the Inventory or LVE claim lists

*Per EPA, this list includes substances beyond the known TSCA universe to provide as comprehensive a list as possible to potential reporting entities. It is not exhaustive and does not contain polymers or UVCBs which may be covered by the rule
Who Is Required to Report?

“Importers of PFAS in articles are considered PFAS manufacturers” –EPA

Anyone who has produced, manufactured, or imported PFAS for a commercial purpose in any year since 2011 is covered by this rule.

- This includes importing a PFAS into the customs territory of the United States, whether on its own, in a mixture, or incorporated into an article.
- This includes coincidental manufacture of PFAS as byproducts or impurities.

The owner of a product or design that includes PFAS is not necessarily the responsible party to report if they are sourcing it within the U.S.

- Simply receiving PFAS from domestic suppliers (including distributors) is not considered “manufacturing PFAS” under this rule.
- Distributors and contract manufacturers may be in scope of this reporting rule if they are importing PFAS.
Who DOESN’T Need to Report?

Exceptions

There is no *de minimis* threshold exempting small businesses or companies that manufacture or import small amounts.

However, small manufacturers **may** be allowed an additional six months (for a total of 24 months) to submit reports.

- This only applies if they would report *exclusively* as “article importers” for this rule.
- Manufacturers who meet this definition will be allowed to submit reports through November 10, 2025

What’s NOT exempt from this rule:

- fluoropolymers
- recycled materials
- article importers
- substances that meet the PFAS definition but are not listed on the TSCA Inventory
- PFAS imported / manufactured for non-product purposes
Unlike the proposal, the final rule provides manufacturers and importers with three different reporting options:

- There is a full version of reporting for substances and mixtures
- **There is a streamlined reporting option for article importers to provide data**
- There is another streamlined option available for R&D substances manufactured below 10 kg

Reporting is done for each chemical, for each year - 2011 - 2022 (reporting is NOT completed for each individual product SKU)

Data will need to be entered into the EPA’s Central Data Exchange system, the same one that is used for quadriannual CDR reporting

**The portal will open in November 2024**
Not Known or Reasonably Ascertainable

“Information must be submitted to the extent the submitter knows or can reasonably ascertain.”

“Known to or reasonably ascertainable by” means 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.

Possession or control means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner.) Information is included within this definition if it is:

(1) In files maintained by submitter's employees who are:

   (i) Associated with research, development, test marketing, or commercial marketing of the chemical substance in question; and/or

   (ii) Reasonably likely to have such data.

(2) Maintained in the files of other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question in the course of their employment as such agents.
Due Diligence Obligations

This standard requires manufacturers to conduct a “reasonable inquiry,” which may also require inquiries outside the organization to fill gaps in knowledge. **Such activities may include phone calls or email inquiries to upstream suppliers or downstream users.**

The final rule specifically addresses:

- Manufacturers with partial data
  - “…this rule is not a product testing requirement” – EPA
- Manufacturers who haven’t been able to identify any PFAS in their materials

The EPA encourages manufacturers to **document their activities** to provide evidence of due diligence. Additionally, companies may want to retain documentation of reasons for their conclusion that they were *not* subject to reporting requirements (e.g. supplier declarations that indicate “no PFAS”).
Due Diligence Obligations

While the EPA provides various examples of due diligence in action, they stress that because the standard applies on a case-by-case basis, these examples cannot substitute for a complete analysis of a submitter’s particular circumstances.

Scenario:

Example Company O imports stain-resistant garments. They do not know specifically what chemical is used to impart stain resistance, but they do know that chemicals used to impart stain resistance are often fluorinated chemicals and could meet the definition of PFAS.

For more hypothetical scenarios, please refer to the TSCA PFAS Reporting Instructions, Chapter 4 Instructions for Reporting PFAS Under TSCA Section 8(a)(7) October 2023 at section 4.2 - “Reporting Standard”
PFAS Regulations
US States
PFAS in the States: Nearly every U.S. State taking action

**Forty-six states have passed or proposed PFAS legislation**
- Actions include restrictions or reporting requirements.

**Processes & Products Affected**
- PFAS legislation increasingly applies to a wider range of products
- Several states, led by Maine and Minnesota, are beginning to legislate PFAS requirements for all products

**Trends to watch — expansion of:**
- **Scope:** From specific products to all products
- **Requirements:** From registration to disclosure to prohibition
- **Substances:** From specific chemicals to entire family

Source: Bloomberg Industry Group
https://public.flourish.studio/visualisation/12740251/
State Reporting Requirements

Maine

38 M.R.S. §1614: Products Containing PFAS

The new law requires manufacturers of all products with intentionally added PFAS to report those products to the department beginning January 2025. Fee payment is also required.

Effective January 2030, any product containing intentionally added PFAS may not be sold in Maine unless the use of PFAS in the product is specifically designated as a “currently unavoidable use.”

Note: These dates are different than in the original law, which was amended in June 2023.

<table>
<thead>
<tr>
<th>Data Point</th>
<th>Details Required</th>
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<tbody>
<tr>
<td>A brief description of the product, including an estimate of the total number of units of the product sold annually in the State or nationally</td>
<td>Product description and Total number of units sold annually (state or nationally)</td>
</tr>
<tr>
<td>The purpose for which PFAS are used in the product, including in any product components</td>
<td>Application / use of PFAS</td>
</tr>
<tr>
<td>The amount of each of the PFAS, identified by its chemical abstracts service registry number or in the absence of this number a description approved by the department, in the product, reported as an exact quantity, or as the amount of total organic fluorine if the amount of each PFAS compound is not known, determined using commercially available analytical methods or based on information provided by a supplier as falling within a range approved for reporting purposes by the department</td>
<td>Amount of PFAS (exact quantity OR as the amount of total organic fluorine) AND CAS number OR a description approved by the department</td>
</tr>
<tr>
<td>The name and address of the manufacturer, and the name, address and phone number of a contact person for the manufacturer</td>
<td>Manufacturer information</td>
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Minnesota passed the nation's most comprehensive PFAS restrictions as part of the 2023 omnibus environment, natural resources, climate, and energy finance and policy bill. Product registration is due January 2026 and full restrictions in 2032 unless designated as a “currently unavoidable use”. The prohibitions do not apply to prosthetic or orthotic devices or to any product that is a medical device or drug regulated by the US FDA, but registration is still required.

“This will be the strongest PFAS legislation in the nation,” said Rep. Sydney Jordan of Minneapolis. “Minnesota invented PFAS. By passing this, Minnesota is going to invent the solution.”

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<tr>
<td>A brief description of the product, including a universal product code (UPC), stock keeping unit (SKU), or other numeric code assigned to the product</td>
<td>Product description and Product Identifier (SKU, catalog number, etc.)</td>
</tr>
<tr>
<td>The purpose for which PFAS are used in the product, including in any product components</td>
<td>Application / use of PFAS</td>
</tr>
<tr>
<td>The amount of each PFAS, identified by its chemical abstracts service registry number, in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the commissioner</td>
<td>Amount of PFAS (exact quantity OR as a range) AND CAS number</td>
</tr>
<tr>
<td>The name and address of the manufacturer and the name, address, and phone number of a contact person for the manufacturer</td>
<td>Manufacturer information</td>
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PFAS in the States

A few examples of ongoing state efforts

**Colorado SB 81**
No provision for critical/unavoidable use exemption.

**California SB 903**
Bans all products with PFAS by 2030 unless use is "unavoidable”

**Illinois SB 2705**
Basically a duplicate of the Minnesota PFAS bill.

**Indiana HB 1399**
Sponsored by the Indiana Manufacturing Association.

**New Hampshire HB 1649**
Proposal contains PFAS product labeling requirements.

**NEWMOA - Northeast Waste Management Officials Association (8 NE states)**
Has proposed model legislation to lower PFAS contamination through reporting requirements and phase-outs

**New Jersey AB 1421**
Registration and restriction proposal with a $1,000 fee.

SaferStates anticipates that at least 35 states will introduce policies in 2024 around PFAS

Source: Safer States 2024 Analysis of State Legislation Addressing Toxic Chemicals and Plastics
Timeline of Major US Milestones

- **October 11, 2023**: TSCA Final Rule is published in the Federal Register
- **November 11, 2023**: The final EPA PFAS rule is effective
- **November 12, 2023**: The submission period into the EPA's Central Data Exchange begins
- **November 12, 2024**: State of Maine "PFAS in Products" reporting is due
- **January 1, 2025**: The TSCA section 8(a)(7) submission period for most manufacturers closes (still open for "small manufacturers")
- **May 8, 2025**: The TSCA submission period for "small manufacturers" closes
- **November 10, 2025**: 3M discontinues manufacture of all PFAS, including ~25,000 products which contain PFAS chemicals
- **December 31, 2025**: State of Minnesota "PFAS in Products" reporting is due
- **January 1, 2026**:
PFAS poses multidimensional risk that is unprecedented for complex manufacturers

- Vast Scope & Pervasiveness
  - Impacts all industries
  - 1,400–14,000+ substances

- Complex Regulatory Landscape
  - United States - federal and state
  - Europe
  - Canada
  - Evolving
  - Different requirements, thresholds, timing, consequences

- Disruptive PFAS & Part Obsolescence
  - Product redesign and recertification
  - Supply chain disruption
  - Obsolescence risk (e.g., 3M)
  - Operation shut-down

- Products & Processes are at Risk
  - Parts
  - Finished products
  - Process chemicals
  - Facility

- Overwhelming Pressure From All Around
  - Regulators
  - Customers
  - Investors
  - Insurers
  - Consumers, NGOs
  - Competitors
What Does This Mean for You?

Even if you’re exempt from some regulations or if don’t make PFAS chemicals yourself, other business drivers from customers, insurers, suppliers, and investors will drive every manufacturer to need to answer the question “do we use PFAS in our processes or products?”

How to Get Started

▶ Understanding where you have PFAS in purchased materials, and what they’re used for, is urgent
  ▶ These are high-performance substances, and are often used to provide specific capabilities, so look for those features first
  ▶ Don’t forget about MRO materials used in your operations, even if they’re not part of the final product!
Identifying PFAS in Materials

Safety Data Sheets

- **Very limited information, extremely manual process**
  - PFAS are unlikely to be listed on most SDS due to current hazard classifications. They may be “held back” as proprietary
  - Most purchased materials will not be provided with an SDS since SDS are not required by law for the majority of “articles”
  - Where data IS available on the SDS, extensive manual work is required to collect, analyze, and map the data to regulations

Chemical Testing

- **Expensive and time consuming, still incomplete**
  - Test methods have only been developed for a few specific PFAS chemicals to detectable thresholds
  - Lab availability is limited; complex articles are difficult to test
  - Lower limits on detection levels are incompatible with regulations that restrict ALL levels of PFAS.
    - The EPA’s drinking water proposal set limits for PFOA/PFOS higher than the “health advisory levels” due to the fact that testing methods couldn’t detect levels <4 ppt

Supply Chain Query

- **Universally-accepted approach**
  - The part level approach is already internationally-recognized for materials compliance regulations (e.g. IEC 63000)
  - The U.S. EPA recognizes in the Section 8(a)(7) PFAS Reporting proposal that manufacturers’ attempts to gather reporting data may “include phone calls or email inquiries to upstream suppliers”
  - Last year the state of Maine amended their PFAS reporting rule to accept supplier-provided data

Poor results

Some data

Best results
Take Action!

Where do you need more data?

**Product Design**
- Review product performance requirements for PFAS properties (e.g. waterproof, non-stick, etc).
- Where these properties are identified, contact manufacturers for specific composition information regarding PFAS
- Where PFAS materials are confirmed, evaluate alternatives, especially if it's one of the individually-restricted substances

**Purchased Materials**
- Review purchased materials where you may pay a premium for PFAS performance.
- Educate suppliers on what PFAS are, where they may be located, and the impact of regulations
- Query suppliers on the presence of PFAS in purchased parts and materials
- Supplier-Level Survey (more generic and easier for suppliers, but can't match data to an individual product)
- Part-specific declarations (can be translated to a BOM)
Resources
TSCA Section 8(a)(7)
Supporting & Related Material

AEM Resources for TSCA PFAS Reporting:
Available soon!
Check AEM website for updates!

EPA Resources for TSCA PFAS Reporting:
TSCA 8a7 Reporting Instructions 9-28-23
Data Elements included in the TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for PFAS
Partial List of PFAS Substances ID'd by the EPA
TSCA 8a7 Small Entity Compliance Guide
Final Rule Response to Comments

Supporting & Related Materials for TSCA 8a7
Common PFAS Uses and Resources

Resources are continually being developed to help manufacturers identify their highest risk areas for PFAS. Some useful links:

ChemSec PFAS Guide
An overview of the uses of per- and polyfluoroalkyl substances (PFAS)
Historical and current usage of per- and polyfluoroalkyl substances (PFAS): A literature review
PFAS free - PFAS in our products
PFAS in Building Materials

Adhesives
Building and construction industry
Ceramics and nanostructures synthesis
Cleaning products
Coatings - especially for water-, oil-, stain-, grease-, electrical- and temperature-resistance
Cookware
Dry cleaning
Electronics industry (including batteries)
Electroplating
Engine compartment wirings & gauges
Etching
Explosives, propellants, and ammunition
Fabric
Fire-fighting foam
Fuel system seals & hoses
Medical equipment
Metal plating and finishing
Mining industry

Oil and gas industry
Packaging, paper, and cardboard
Paints, varnishes and sealants
Pesticides and fertilizers
Photography and lithography industries
Plastics, resins, and rubber
Recycling and material recovery
Refrigerants
Safety equipment
Scientific, general use
Semiconductor industry
Solar panels
Textiles
Transportation industry
Identifying PFAS in Applications

Swedish Chemicals Agency PRIO tool can be used to search for chemicals used and support in prioritizing substances for substitution.

KEMI PRIO Tool

Keep one step ahead with PRIO

The PRIO tool helps you to find and replace hazardous substances in your articles or chemical products. By replacing hazardous substances, you will take care of your employees, your customers, and the environment. It also allows your products to be recycled and reused providing the basis for the development towards a non-toxic circular economy.

In PRIO you will find both substances that are banned and substances that are still allowed to be

About PRIO

- Analyse chemicals risks in your business
- Background – PRIO
- How to search in PRIO
Identifying PFAS in Applications

ChemSec’s “PFAS Guide” provides a starting point for identifying common applications by industry/sector, as well as suggesting possible alternatives for some applications.