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# Materials Compliance

*(PFAS Continued...)*

Neil Smith & Bruce Jarnot

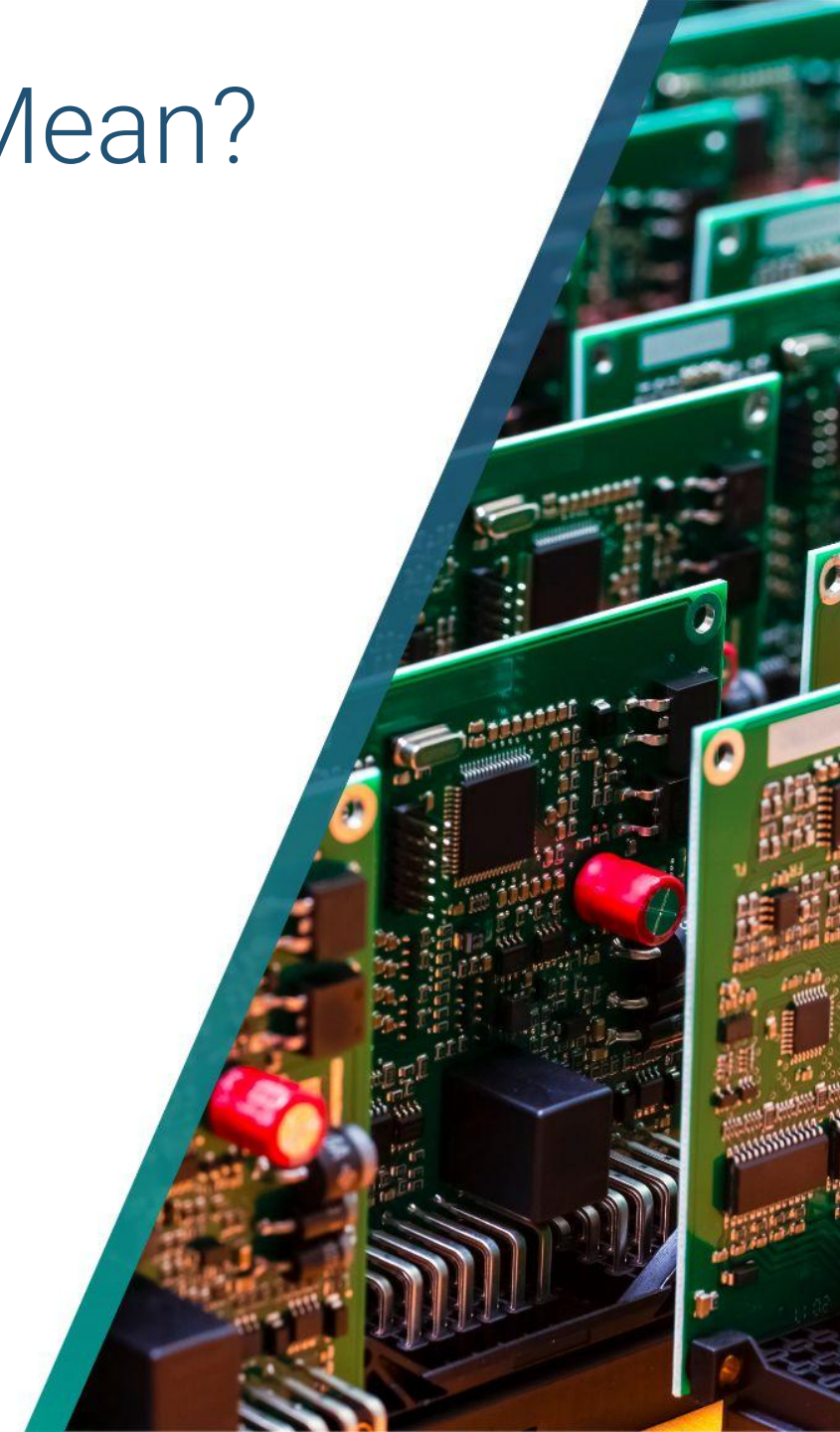


# What Does Materials Compliance Mean?

- ▶ Product compliance — constantly evolving and challenging
- ▶ Global legislation — continuously changing
- ▶ Essential for manufacturers, retailers, and suppliers to respond quickly to ensure their products are compliant
- ▶ Successful product compliance management is critical

## Why Should You Care?

- ▶ Product compliance is a **legal requirement**
- ▶ Products could be denied **market access**
- ▶ You could face **finances** and other **penalties**



# Materials Compliance Requirements

## Examples from the EU & US



Registration, Evaluation,  
Authorisation, and Restriction of  
Chemicals  
EU (REACH) Regulation



EU Waste  
Framework Directive  
& SCIP



EU Restriction of  
Hazardous Substances  
(RoHS) Directive



California  
Proposition 65



US Toxic Substances  
Control Act (TSCA)



Conflict Minerals  
Reporting



Uyghur Forced Labor  
Prevention Act

And many more  
globally!



# Regulatory Authorities

## The European Chemicals Agency (ECHA)

Oversees the EU's chemical legislation that protects human health and the environment.



## Environmental Protection Agency (EPA)

An independent executive agency of the U.S. federal government tasked with environmental protection.



## Office of Environmental Health Hazard Assessment (OEHHA)

CalEPA OEHHA's mission is to protect and enhance public health and the environment in California through scientific evaluation of the risks posed by hazardous substances.



## Other Government Bodies/ Enforcement Agencies







# Regulatory Authorities

## What Do They Do?

- ▶ Protect human health and the environment
- ▶ Ensure chemicals are used safely
- ▶ Aggregate information on chemicals
- ▶ Restrict high-risk substances
- ▶ Enforce compliance with legislation
- ▶ Control market access

# Product Safety Documentation

## What Is a Technical File?

- ▶ Full record of proof of compliance with appropriate local rules and regulations
- ▶ Required for key product compliance legislation around the world, including:



Conformité Européenne (CE)  
Europe



Korea Certification (KC)  
Korea



UK Conformity Assessment (UKCA)  
Great Britain



Norma Oficial Mexicana (NOM)  
Mexico



Regulatory Compliance Mark (RCM)  
Australia & New Zealand

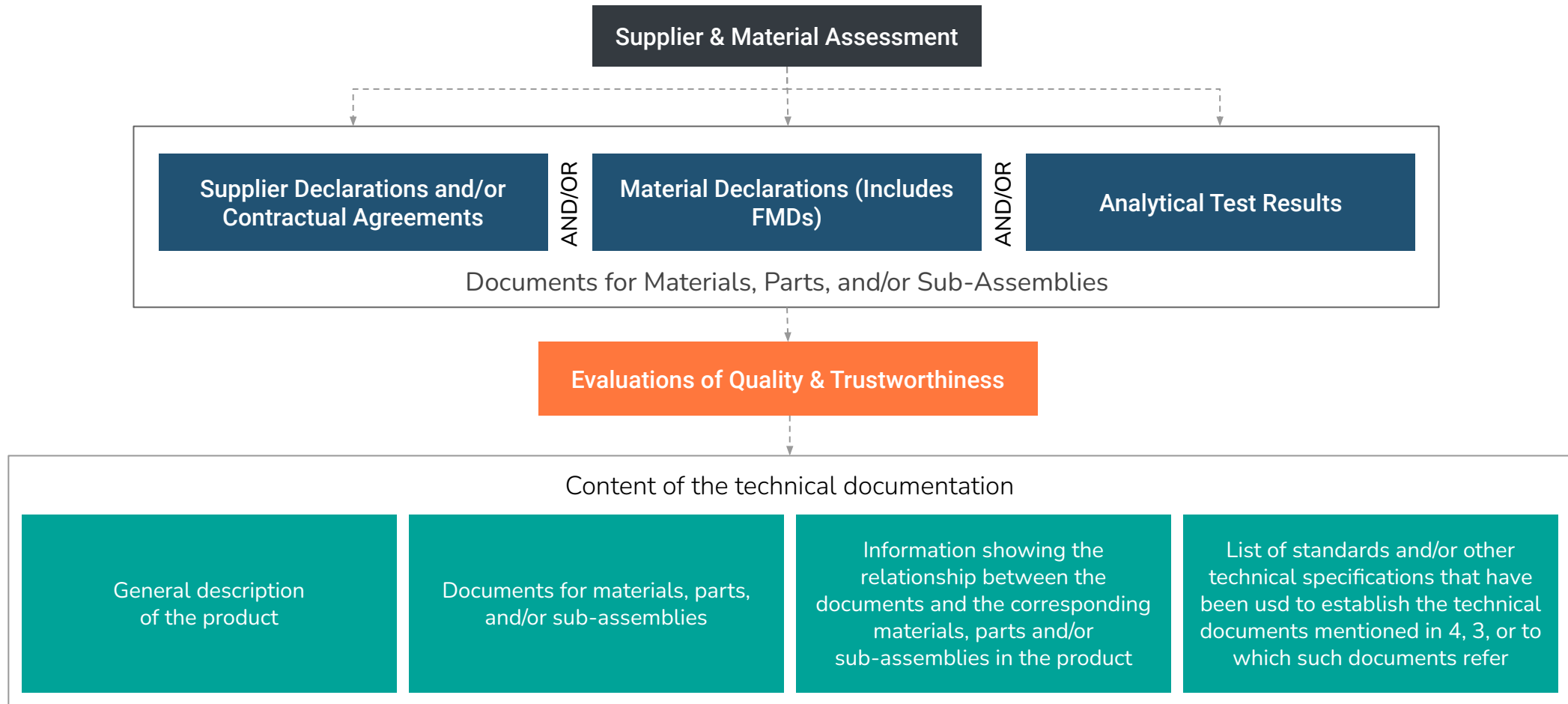


Federal Communications Commission (FCC)  
United States



# Building a Technical File

## IEC 63000 — Demonstrating Due Diligence Through Presumption of Conformity



IEC 63000. (2016). *Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances*: Figure 1 – Schematic representation of process to create the technical documentation. Retrieved from <https://www.sis.se/api/document/preview/8022787/>

# Enforcement

## What Happens?

- ▶ Published enforcement cases are **not common**, particularly in Europe
- ▶ **However**, the scarcity of high-profile case studies is a strong indication that enforcement has been **effective**
- ▶ EU member states and U.S. authorities have powers to impose **severe penalties** and take companies to **court** where breaches of the laws are discovered
- ▶ But in lots of instances, enforcement agencies are working with companies on a **collaborative** basis and products are staying on the market







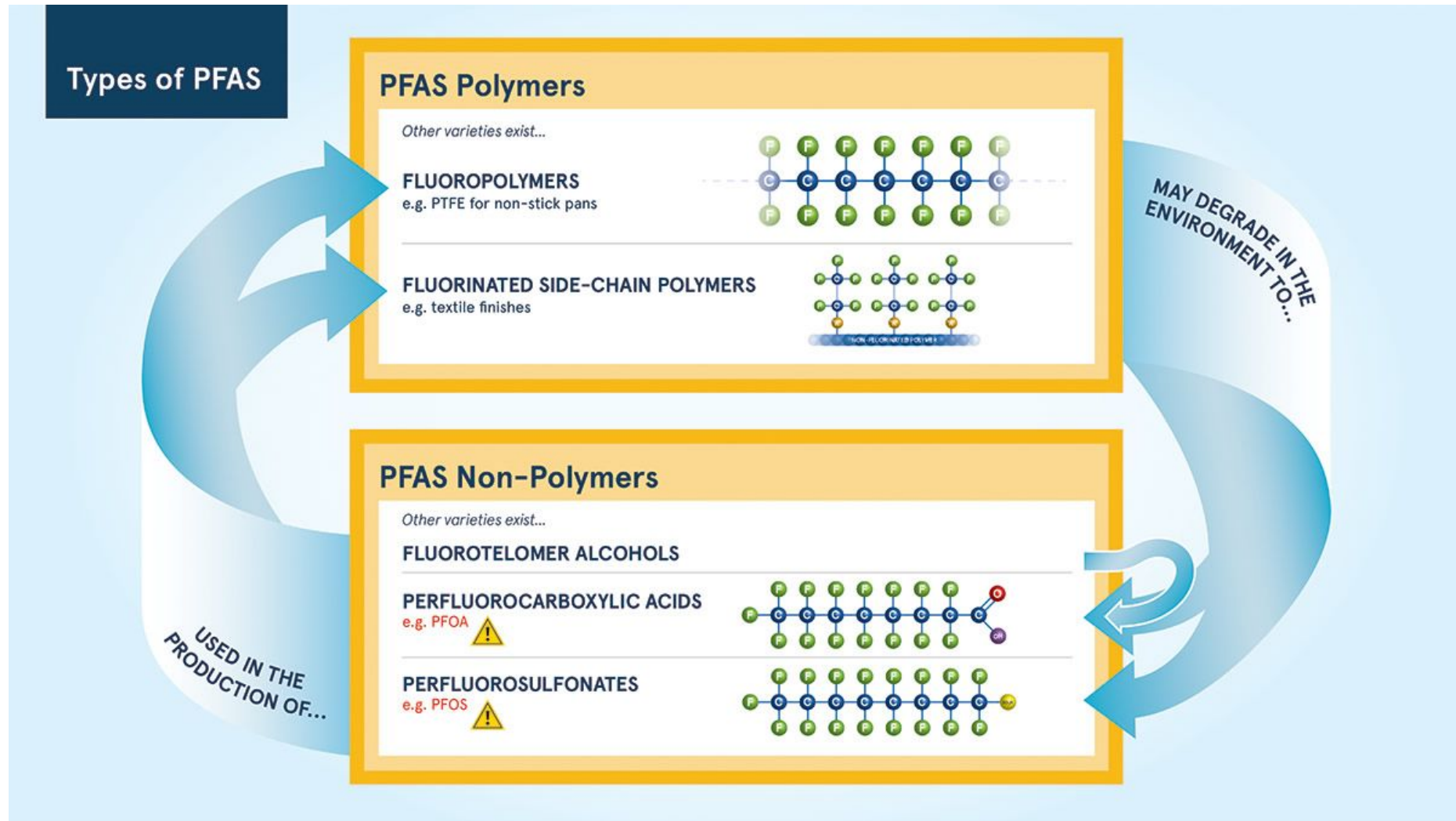
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# Materials Compliance - PFAS Fluorocarbons





# PFAS Families



Source: Fidra

<https://www.pfasfree.org.uk/about-pfas/pfas-science-the-basics>



# What are PFAS Fluorocarbons?

## PFAS Have Performance Attributes That Guide Their Use in Products



- ▶ **Fluorinated polymers, elastomers, and fluids**
  - ▶ Chemically inert and biocompatible
  - ▶ Non-stick and slipper (low-friction)
  - ▶ High temperature stability
  - ▶ Electrically insulating and flame retardant
  - ▶ Often transparent to ultraviolet (UV) light
- ▶ **Fluorinated coatings**
  - ▶ Fluorinated plastic packaging (foods, beverages, solvents, pesticides)
  - ▶ Water repellent and anti-fogging (hydrophobic)
  - ▶ Oil and stain repellent (lipophobic or oleophobic)



# PFAS Materials

## Commonly Used PFAS

**PTFE** (polytetrafluoroethylene) such as Teflon<sup>®</sup>, Hyflon<sup>®</sup>, Fluon<sup>®</sup>, or Polyflon<sup>®</sup> resins

**ePTFE** (expanded PTFE) such as Gore-Tex<sup>®</sup>, VIRTEK<sup>®</sup>, or Durapore<sup>®</sup> membranes

**PVDF** and **PVF** (polyvinylidene or polyvinyl fluoride) such as Kynar<sup>®</sup>, Solef<sup>®</sup>, Hylar<sup>®</sup> or Tedlar<sup>®</sup> resins

**PCTFE** (polychlorotrifluoroethylene) such as Kel-F<sup>®</sup> or Voltalef<sup>®</sup> resins

**PFA** (perfluoroalkoxy) and **FEP** (fluorinated ethylene-propylene) such as Neoflon GP<sup>®</sup> or Everflon<sup>®</sup> FEP resins

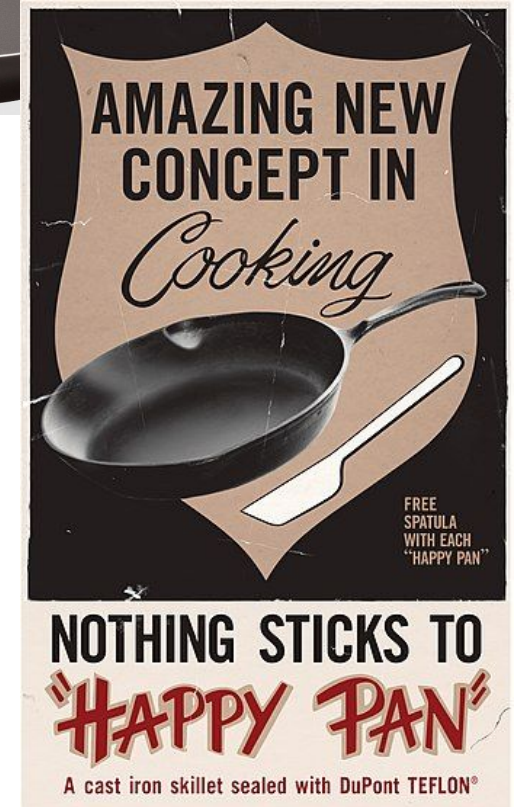
**Fluorosilicones** such as FSR, FVMQ, or Silastic<sup>™</sup> compounds

**Fluoroelastomers** such as FKM, FPM, Viton<sup>®</sup>, Kalrez<sup>®</sup>, AFLAS<sup>®</sup>, or Fluonox<sup>®</sup> compounds

### How Teflon Works

Teflon is the brand name for polytetrafluoroethene. It is a carbon-fluorine polymer.

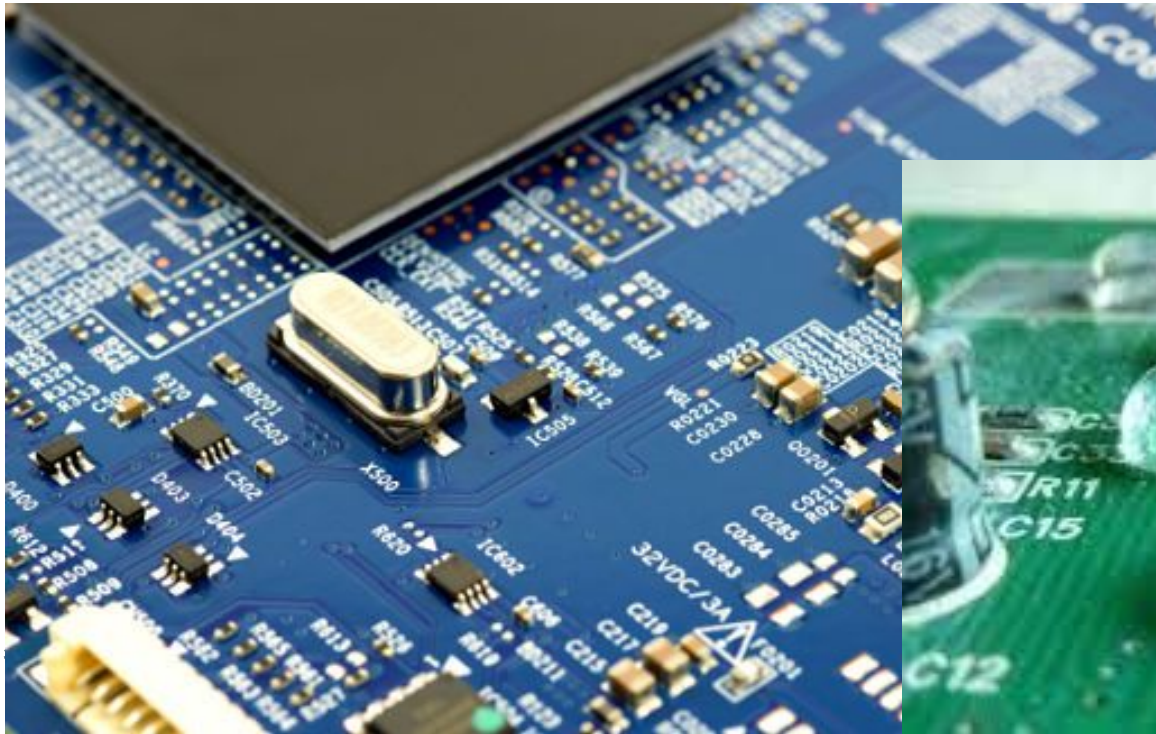
- The carbon and fluorine atoms stick to each other, but not to food or other substances.
- Roughing the pan surface helps Teflon stick to it.
- Sometimes chemical treatments on the pan change Teflon touching it, so it sticks.





# PFAS in Electronics

- ▶ PTFE-insulated wires and cables can be used in harsh environments and as a dielectric where high-volume data transmission is required, such as medical equipment
- ▶ Fluoropolymers can be found in rigid, flexible, and hybrid printed circuit boards
- ▶ PTFE is used as a dielectric in thin-film capacitors
- ▶ PFAS are used in conformal coatings on PCBAs
- ▶ Fluoroelastomer gaskets are used to seal enclosures

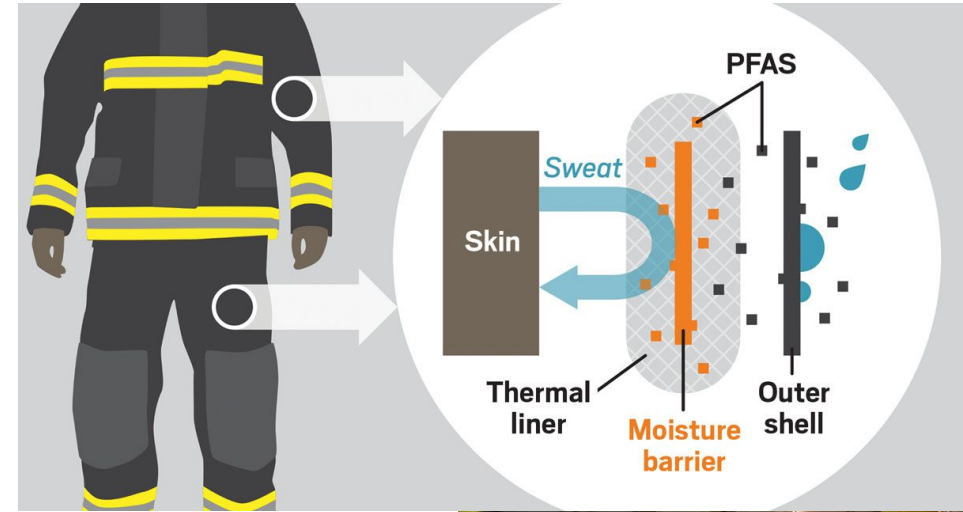


# PFAS in Operations

Widely used in manufacturing processes

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

- ▶ Mist suppressant in electroplating operations
- ▶ Employee PPE
- ▶ MRO materials for machine repair and maintenance
- ▶ Fire-fighting systems where water cannot be used





# PFAS Reporting Under TSCA

In June 2021, the EPA proposed PFAS reporting requirements under Section 8(a)(7)

The EPA will likely publish their federal PFAS reporting requirement by September 2023

- ▶ Under the 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
- ▶ There is no "de minimis" threshold that would exempt small companies or those that only use small amounts. This could pose an additional challenge for small suppliers
- ▶ For this proposed rule, the EPA has identified at least 1,346 chemical substances and mixtures that are PFAS and would potentially be subject to reporting under the final rule

## Some products are exempt from TSCA:

pesticides (EPA under FIFRA); tobacco, firearms & ammunition (ATF);  
specified nuclear material (NRC);  
food, food additives, drugs, **medical devices**, and cosmetics (FDA)



*In accordance with obligations under TSCA, as amended by the National Defense Authorization Act for Fiscal Year 2020, EPA proposes to require persons that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2012, to **electronically report information** regarding PFAS uses, production volumes, disposal, exposures, and hazards.*

Source: EPA. (n.d.). TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for PFAS.

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-8a7-reporting-and-recordkeeping>



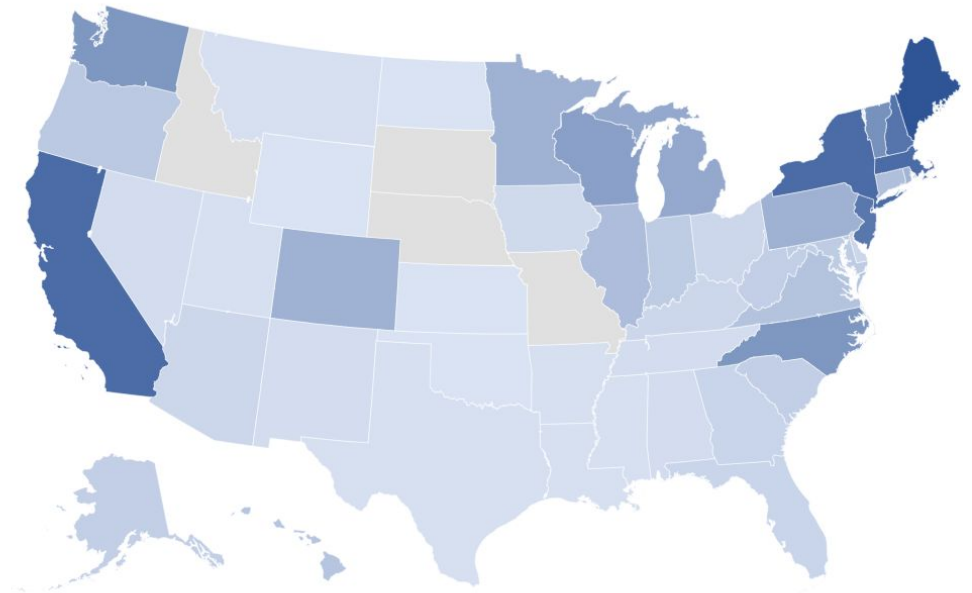
# PFAS in the States

46 US states with PFAS actions

46 states have passed or proposed PFAS legislation. Actions include restrictions or reporting requirements.

## Processes and Products Affected

- ▶ PFAS legislation initially focused on processes that could affect drinking water. But it is increasingly being applied to a wider range of products, including finished **articles**
- ▶ Common products impacted by legislation have been fire fighting foam, food packaging, cookware, furniture, carpets, personal care products, clothing, cosmetics, children's products
- ▶ Several states, led by Maine and Minnesota, are beginning to legislate PFAS requirements for "all products"



Source: Bloomberg Industry Group  
<https://public.flourish.studio/visualisation/12740251/>

## 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





# EU REACH PFAS Restriction

## Expected Addition to Annex XVII

The national authorities of Denmark, Germany, the Netherlands, Norway, and Sweden have submitted a proposal to ECHA to restrict ~10,000 PFAS under REACH, the EU's chemicals regulation

### The EU PFAS restriction proposal:

- ▶ Seeks to prohibit the use of over **10,000 PFAS** types (*manufacture, placing on the market, use*)
  - ▶ The only exclusion being a sub-class of PFAS that have been deemed “fully degradable”
- ▶ Applies to PFASs themselves, as a constituent in other substances, in mixtures, and in articles.
- ▶ Different concentration limits apply depending on the PFAS type



Sources: ECHA. (n.d.).

ECHA receives [PFASs restriction proposal](#) from five national authorities.

[ECHA publishes PFAS restriction proposal](#)



# Other EU PFAS Activity



## REACH

- ▶ There are 13 entries for PFAS substances on the **REACH SVHC List** and 6 PFAS chemicals on the **Annex XVII Restricted List**
- ▶ Restrictions have been proposed for **PFHxS** & **PFHxA**
- ▶ All **PFAS** used in firefighting foams have been proposed for restriction



## STOCKHOLM CONVENTION

## Persistent Organic Pollutants (POPs)

- ▶ **PFOS, PFOA** and **APFO** are already included in the Stockholm Convention and is already restricted under POPs
- ▶ **PFHxS** was added to the Stockholm Convention in 2022 and is being proposed for addition to POPs



## Classification, Labelling and Packaging (CLP)

- ▶ A few PFAS are already in scope, including **PFOA, APFO, PFNA, PFDA**
- ▶ **PFHpA** is under evaluation



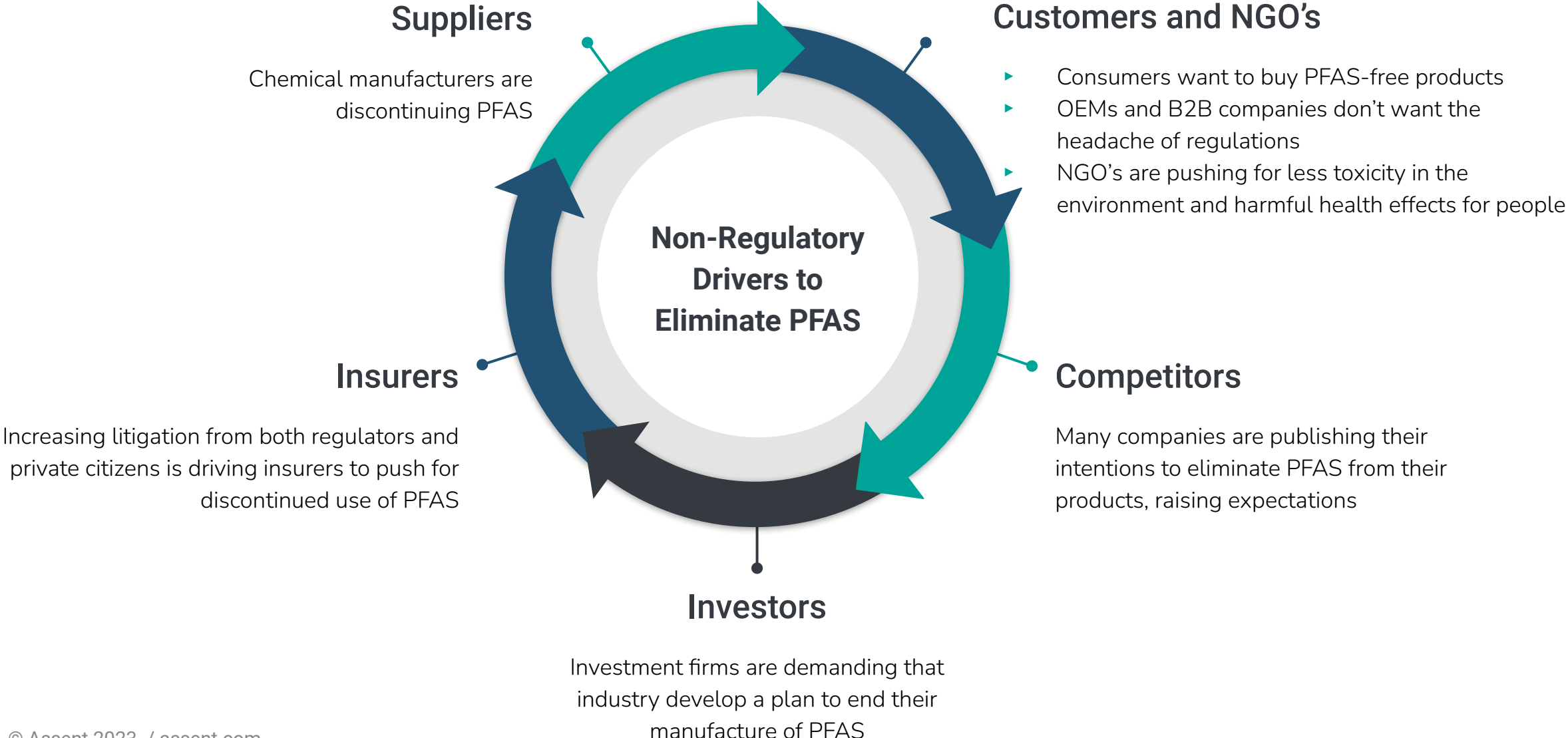
## Drinking Water Directive

- ▶ Includes a limit of 0.5 µg/l for all **PFAS**

Per- and polyfluoroalkyl substances (PFAS) – ECHA



# Beyond the Regulations...



# Supplier Pressure

Regulations don't matter  
if you can't get parts!

On December 20, 3M announced they will discontinue the manufacture of all PFAS chemicals by 2025 (impacting nearly 21,000 products), driving the risk of early obsolescence for materials downstream in the supply chain

[3M to Exit PFAS Manufacturing by the End of 2025 - Dec 20, 2022](#)



Last time buy of  
obsolete materials

**Excess inventory cost  
Warehouse real estate  
Increased scrap risk**

Last time build to support  
longer product availability  
and repair obligations





# Customer & NGO Pressure

## Consumers, Businesses, Government Customers Demand “PFAS-free”

Businesses that sell to the US government are increasingly required to declare that certain materials and products being sold are “PFAS-free”.

The U.S. federal government is the single largest purchaser in the world, spending more than \$630 billion on products and services each year.

Federal purchasers are directed, in the 2021 Executive Order 14057 on *Catalyzing American Clean Energy Industries and Jobs through Federal Sustainability and the Federal Sustainability Plan*, to procure products and services meeting the EPA’s [Recommendations of Specifications, Standards, and Ecolabels](#).

[How EPA’s Recommended Standards and Ecolabels Address Per- and Polyfluoroalkyl Substances \(PFAS\) | US EPA](#)



Some of the categories of products that must meet the federal requirements include:

- Cafeteria supplies
- Construction materials
- Custodial materials
- Electronics
- Office furniture



# Investor Pressure

NOVEMBER 29, 2022

PRESS RELEASE:

## Investors with \$8 trillion call for phase-out of dangerous “forever chemicals”

World’s biggest chemical companies turning blind eye to emerging global crisis

Investors with US\$8 trillion under management and advice are calling on the world’s biggest chemical producers to phase out persistent chemicals as the annual ChemScore ranking, released today, shows the industry is doing little to halt an emerging global crisis.

The 47 asset managers warn that growing awareness of the dangers posed by so-called “forever chemicals” — known as PFAS — that stay in the environment for generations, has triggered an increasing number of lawsuits against companies and sparked action to tighten legislation around the world.

In a letter to CEOs of the biggest chemical companies coordinated by Aviva Investors and Storebrand Asset Management, they wrote:

“We encourage you to lead, not be led, by phasing out and substituting these chemicals. In addition to the financial risks associated with litigation, producers of persistent chemicals face the risk of increased costs associated with reformulating products and modifying processes, which can have significant implications for company performance.”

The investors, which include **AXA IM, Credit Suisse Asset Management (Switzerland) AG, Resona Asset Management** and **Robeco**, called on companies to disclose the volume of all hazardous chemicals they produce and demonstrate action to improve their chemicals management by raising their ChemScore rankings.

“As investors, we believe that companies’ licence to operate is dependent on the public understanding of risks and impacts,” they wrote.

**“Most companies are taking little or no action to phase out hazardous chemicals despite the risks”**

Source: Chemsec. (2022, November 29). Investors with \$8 trillion call for phase-out of dangerous “forever chemicals.”

<https://chemsec.org/investors-with-8-trillion-call-for-phase-out-of-dangerous-forever-chemicals/>



“These impacts increase the risks facing chemical producers, and by extension, investors. For companies, risks range from litigation and regulatory to financial, operational and reputational. Our fiduciary duty as investors compels us to address these impacts and risks.”

— *BNP Paribas Asset Management’s head of stewardship Europe, Rachel Crossley*

Asset managers are increasingly concerned about the number of lawsuits and regulations related to PFAS and how that will impact the bottom line for companies that manufacture and use PFAS chemicals

- ▶ In 2022, a letter from 47 investment firms holding \$8 trillion in assets circulated a letter among 54 chemical companies demanding action from industry
- ▶ Support from the investment community doubled from the previous year when a similar letter was sent from 23 investors worth \$4.4 trillion

Source:

<https://www.theguardian.com/environment/2023/jan/06/pfas-toxic-forever-chemicals-manufacturers>

# Insur Pressure

## Litigation is on the Rise

Responding to rising litigation and anticipated remediation costs, **liability insurers are increasingly asking manufacturers about their use of PFAS chemicals in both processes and products**, impacting coverage if contamination is found or even underwriting of new policies

*“More and more carriers are not even willing to entertain coverage for PFAS,” said Jim Hamilton, vice president of insurance broker CRC Group. “It is becoming increasingly difficult to get coverage.”*

**Insurance professionals are concerned that PFAS is the “next asbestos”, resulting in countless legal bills and exposure for years to come**

### Considerations for Insurers

- Know your insureds:
  - 1) is there any PFAS-related history, either in a product line or raw/packaged products; and
  - 2) does the history include any PFAS chemical storage, waste disposal, fire suppression or manufacturing processes?
- Where site-specific coverage is implicated, retain environmental experts to conduct a forensic review of site use and history.
- Conduct a portfolio review of industries currently and potentially impacted: pulp/paper products, textile mills, sealants, food packaging, entities involved in manufacture and delivery of AFFF; airports, water districts.
- Develop coverage maps of potentially impacted coverage.
- On current coverages, insurers should consider utilizing PFAS exclusions wherever possible (several have begun to do so).
- Contribution/subrogation actions (by insurers and insureds) should be pursued where there are multiple contributors, causes or responsible parties.

**Guidance to insurers from Swiss Re  
Property & Casualty Trend Spotlight -  
PFAS: The Forever Chemical**

[PFAS Litigation Begins ‘Tip of the Iceberg’ Turn Toward Insurers - Bloomberg Law](#)





# Competitor Pressure

Many companies have made public announcements that they have already, or have action plans in place, to phase-out the use of PFAS, long before the EU REACH restriction would likely take effect.

Companies not yet sharing their plans may become under increasing pressure to make similar claims and promises.



*»It was a feat, but we are proud of the fact that we have already been successful in switching many of our materials to PFC-free DWR: From the Summer 2018 Season, we will use Eco Finish throughout the entire Apparel Collection. «*

Antje von Dewitz, CEO VAUDE

## PFC-free – The VAUDE Milestones



VAUDE apparel, shoes and backpacks PFC-free





# What Does This Mean for You?

Even if you're exempt from some regulations or if don't make PFAS chemicals yourself, the 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
- ▶ 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

Poor results



## Existing Data

### Useful, but has gaps against “all PFAS” requirements

- ▶ Customers who already use Assent modules can identify the presence of specific PFAS chemicals already included in specific regulations
  - ▶ e.g. 13 REACH SVHC’s
- ▶ Those modules will not provide data against other PFAS that haven’t yet been included
  - ▶ e.g. 10,000+ proposed Annex XVII additions

Some data



## 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

Some data



## Supply Chain Query

### Universally-accepted approach

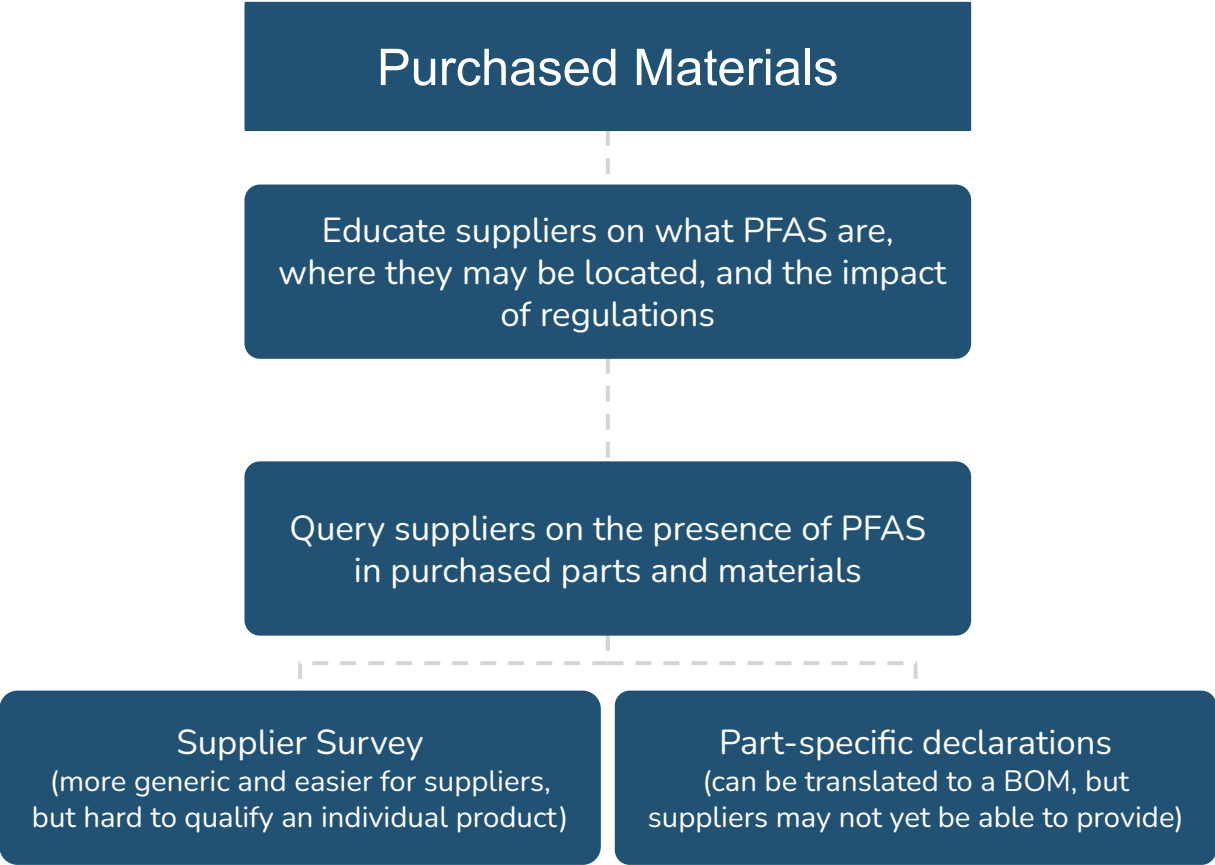
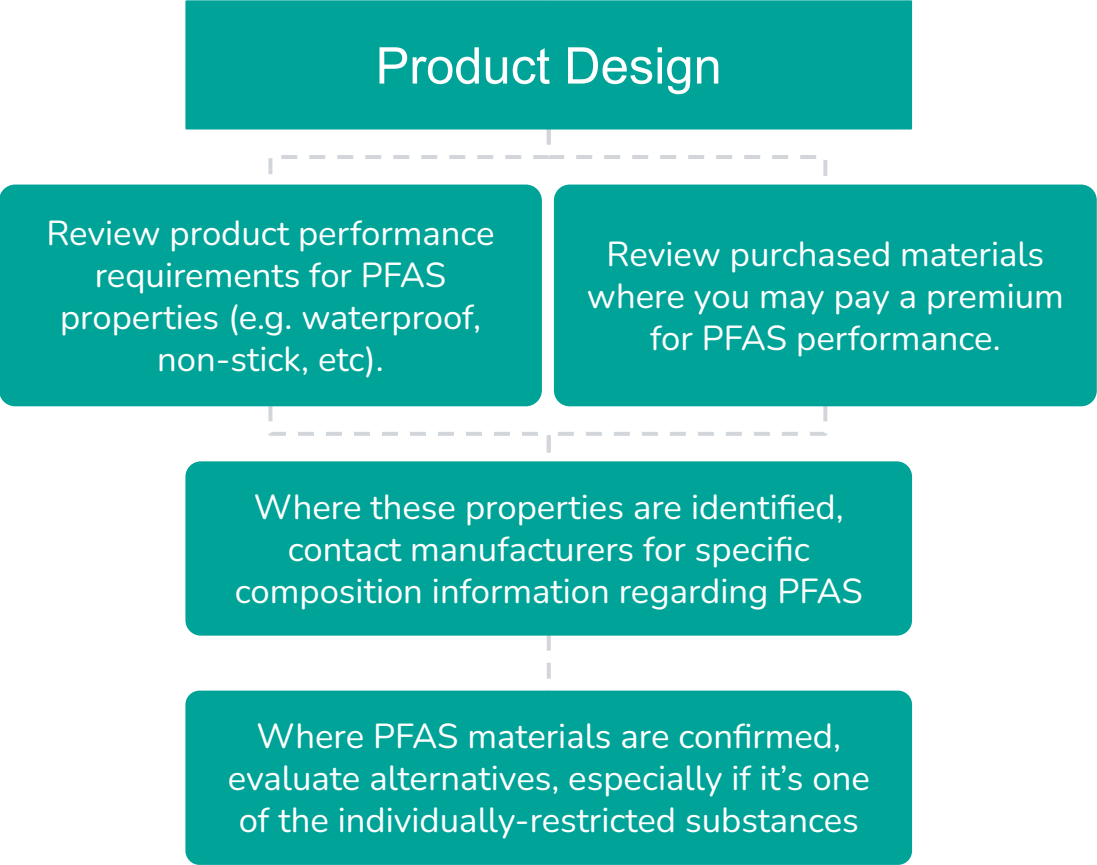
- ▶ The part-level approach is already internationally-recognized for materials compliance regulations (e.g. IEC 63000)
- ▶ US EPA recognizes in their section 8(a)(7) proposal that manufacturers’ attempts to gather reporting data may “include phone calls or email inquiries to upstream suppliers”

Best results



# Take Action!

Where do you need data?



**REMEMBER:** Purchased materials with PFAS may be at a higher risk for early obsolescence

# Best Practices

- ▶ Build up and maintain your technical files
- ▶ Initiate communication channels with your supply chain to establish expectations
- ▶ Monitor regulatory developments
- ▶ Leverage standards like IEC 63000 — this gives you a “presumption of conformity”
- ▶ Taking pre-emptive action can avoid significant problems down the line
- ▶ Work with specialist third parties to meet “due diligence”







 **Assent**<sup>®</sup>

Questions?