EU PFAS & REACH: Protecting Your Market Access in 2023

Thursday, 23 February 2023
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Our Regulatory Experience Is Your Advantage

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Housekeeping

Want to know more about today’s speaker(s)?

In the right side panel you will find:

- Chat – not in use!
- Polls – will be shared
- Docs (4 resources today)
- Q&A – submit your questions here
  👍 A thumbs up makes it a priority Q!

Interested in learning more about Assent’s product solutions, click Book a Demo button in the top navigation bar.
Today’s Presenters

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Feature Presentation: PFAS & REACH: Protecting Your Market Access in 2023

Note: Global regulations around this group of substances is rapidly evolving. The regulations listed in this presentation are a sample and do not represent the entirety of regulatory activity or requirements around PFAS substances.
Agenda

- PFAS Basics
- EU REACH Restriction Proposal
- Other EU Regulatory Activities
- Business Risk
- Call to Action
Per- and Polyfluoroalkyl Substances (PFAS)

PFAS is the family name of a group of durable, synthetic fluorocarbons that have been widely used since the 1940s

- Tight carbon-fluorine bonds provide certain properties to materials, including oil-, water-, temperature-, chemical-, and fire-resistance as well as providing electrical insulating properties.

The same tight chemical bonds that provide these properties also make it difficult for these substances to break down, giving them the nickname “forever chemicals”

- PFAS are present at low levels in humans and the environment around the world.

Image source: Western Virginia Water Authority
PFAS Health Impact

PFAS chemicals resist degradation in the environment and accumulate in the body. Those contaminants may be linked to serious adverse health effects in humans and animals.

Epidemiologic studies have shown that potential adverse human health effects from exposure to some PFAS include:

- Increased serum cholesterol
- Immune dysregulation
- Pregnancy-induced hypertension
- Kidney and testicular cancers
- Low birthweight in humans
- Suppressed immune system response
- Impaired kidney function
- Delayed onset of menstruation

Human studies suggest PFAS exposure may...

- Increase risk of thyroid disease
- Increase blood cholesterol levels
- Decrease the body’s response to vaccines
- Decrease fertility in women
- Increase risk of high blood pressure & preeclampsia
- Lower infant birth weight

Information sourced from Agency for Toxic Substances and Disease Registry. Additional health effects have been reported and those highlighted demonstrate a range of potential effects.
PFAS Families

PFAS Scoping

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 Scoping

Commonly Used PFAS

PTFE (polytetrafluoroethylene) such as Teflon®, Hyflon®, Fluon®, or Polyflon® resins

ePTFE (expanded PTFE) such as Gore-Tex®, VIRTEK®, or Durapore® membranes

PVDF and PVF (polyvinylidene or polyvinyl fluoride) such as Kynar®, Solef®, Hylar® or Tedlar® resins

PCTFE (polychlorotrifluoroethylene) such as Kel-F® or Voltalef® resins

PFA (perfluoroalkoxy) and FEP (fluorinated ethylene-propylene) such as Neoflon GP® or Everflon® FEP resins

Fluoroelastomers such as FKM, FPM, Viton®, Kalrez®, AFLAS®, or Fluonox® compounds
PFAS Product Environmental Impact

It’s not just about exposure to the user of the item — manufacturing and disposal have long-term environmental impacts. That’s also a driver for product regulations.

Source: Natural Resources Defense Council
Review of EU PFAS Restriction Process
The European Chemicals Agency (ECHA) has a detailed and complex strategy, leveraging multiple regulatory instruments, to address concerns around PFAS.
REACH Annex XVII

The “Restriction” List

- The “Restricted Substance List” is a list of hazardous substances that are currently restricted from being placed on the Common Market. Some exemptions may be allowed when documented in the restriction entry.

  Not all entries are outright bans — many are application specific. Just because a substance is listed in Annex XVII doesn’t mean you can’t use it for your products.

- The REACH Restricted List applies even to products subject to other EU hazardous substance regulations such as RoHS.

- There are currently 71 entries on the REACH Restricted List: Substances restricted under REACH - ECHA
PFAS Restriction Proposal Overview

High-Level Summary

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.
### Restriction Proposal Overview

**Two Options**

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Option 2</th>
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</table>
| ▶ FULL BAN  
▶ Limited number of derogations | ▶ Ban with use-specific time-limited derogation, based on:  
▶ Submitters analyses of PFASs uses and assumed alternatives.  
▶ Socio-economic considerations from submitters and feedback to consultations. |

Transition period of 18 months after the regulation enters into force.

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Option two is the submitter’s first choice
Restriction Proposal Overview

The Annex XV Restriction Report (which ultimately leads to Annex XVII restrictions) was published on 7 February.

- Submitted restrictions under consideration - ECHA

Restriction Report - Annex XV Report

- Annex A - Manufacture and uses
- Annex B - Information on hazard and risk
- Annex C - Justification for action on a Union-wide basis
- Annex D - Baseline
- Annex E - Impact assessment
- Annex F - Assumptions, uncertainties and sensitivities
- Annex G - Stakeholder information
- Appendix E4 - Compilation of analytical methods available for different matrices (by commodities; e.g. Food Contact Materials, Ski Wax, Medical, etc.)
- Appendix G1 - Call for evidence supporting an analysis of restriction options for PFAS
- Appendix G2 - 2nd Stakeholder Consultation on a Restriction for PFAS
EU PFAS Proposal – Key Timescales (ECHA)


1. 13 January 2023: Restriction Dossier Submitted

2. 7 February 2023: DRAFT Annex XV Report Published 
   ECHA Submitted Restrictions Under Consideration

3. 22 March 2023: Public Consultation on Annex XV Report Launched

4. April / May 2023: 1st Deadline in Annex XV Report Consultation

5. 22 September 2023: End of Public Consultation on Annex XV Report

6. 23 February 2023: 30-Day Period Proposal Conformity Checks

7. 5 Member States Update Intention to Restrict Notification

8. 22 March 2024: Completion of ECHA SEAC Activities
   ECHA SEAC Final Opinion

9. September / October: ECHA RAC + ECHA SEAC Evaluation


11. 22 March 2024: ECHA SEAC Draft Opinion Public Consultation End

12. February 2024: ECHA SEAC Draft Opinion Released

13. December 2023: ECHA RAC Final Opinion
   (Annex XV Publication Date + 9 Months)

Comment on SEAC Opinion

Wait

Here

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What Is the Process for a Derogation Request?

1. Monitor **Submitted restrictions under consideration page**
2. Identify ‘PFAS’ → Click Details
3. Click → Give Comments
4. Comments form will open up.
5. Section III - Select (i) Transitional period or (ii) Request for Exemption;
6. Follow the steps on slides 25-29 to generate justification
7. Complete remaining sections.
8. Submit initial derogation request and supporting evidence (1st deadline)
9. Completed version by end of consultation

For more detail on each step, download the slide deck and find more information in reference slides!

Keep an Eye Out for Annex XV Publication Date & Submit Comments

- Pre-publication of Annex XV report prior to consultation for and professional stakeholders (PFAS)
- Consultation on restriction report

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UK PFAS Restriction Proposal

Current Status

UK is a signatory to the Stockholm Convention which is committed to PFAS restriction:

- Following Brexit, in 2021 the UK first announced that it was introducing a UK PFAS restriction proposal, covering 9,000 PFASs.
- UK Environmental Agency study 2021, highlighted issues in identifying and analysing PFASs.
- Late 2021, UK HSE Launched a public consultation on UK PFAS Regulatory Management Options Assessment (RMOA);
- UK REACH Roadmap 2022-23 still shows PFAS restriction and a high-priority activity.

UK REACH processes are still in review, but the UK intention is to restrict — PFAS is NOT going away

UK RMOA due in 2023 followed by UK REACH restriction processing activities
Other EU Activities Around PFAS
### PFAS in Existing Regulations

Some specific PFAS substances (or families) have already been included in long-standing regulations.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Assent Solution</th>
<th>EU REACH SVHC</th>
<th>EU REACH Annex XVII</th>
<th>EU POPs</th>
<th>EU MDR EU IVDR</th>
<th>U.S. TSCA 8(a)(7)</th>
<th>CA Prop 65</th>
<th>CEPA</th>
<th>AD-DSL</th>
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<td>Perfluorooctanoic Acid</td>
<td>X</td>
<td>P?</td>
<td>P</td>
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<td>X</td>
<td>X</td>
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<td>Perfluorononan-1-oic acid</td>
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<td>P?</td>
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<td>X</td>
<td>P</td>
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<td>X</td>
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<td>Pentacosfluorotridecanoic acid</td>
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</table>

**X** = substance is already included in the regulation  
**P** = substance is proposed or being evaluated for future inclusion

This list is for example only and **not an exhaustive summary** of all PFAS substances covered by each regulation or industry DSL. Some specific PFAS substances (or families) have already been included in long-standing regulations.
Perfluoroheptanoic acid and its salts

- Common name: PFHpA
- A ‘C7’ PFAS fluorocarbon
- Primary uses: C6-C12 fluoro carboxylic acids are used as wetting, dispersing, emulsifying, and foaming agents
- Not registered under REACH - listed as an SVHC to avoid future regrettable substitution

References:
- ECHA
- PubChem

Reaction mass of

2,2,3,3,5,5,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and
2,2,3,3,5,5,6-octafluoro-4-(heptafluoropropyl)morpholine

- Common name: None
- Member of the PFAS fluorocarbon family
- Primary uses: May be found in fluoroelastomers and fluoropolymers
- RISK: Fluoroelastomer gaskets, seals, caulks; fluoropolymer materials

References:
- ECHA
EU Persistent Organic Pollutants (POPs)

PFAS Additions from Stockholm Convention

In June 2022, the Stockholm Convention added PFHxS to Annex A without specific exemptions

Chemical: Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds “Perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds” means the following:

▸ (i) Perfluorohexane sulfonic acid (CAS No. 355-46-4, PFHxS), including branched isomers;
▸ (ii) Its salts; (iii) Any substance that contains the chemical moiety C6F13SO2- as one of its structural elements and that potentially degrades to PFHxS.

Since EU POPs is the EU implementation of the Stockholm Convention, the POPs list will be updated with this same PFAS substance restriction.

▸ 24 November 2022 – Amendment proposal published
▸ 9 March 2023 – Deadline for comments
Other EU PFAS Activity

**REACH**
- C9-14 PFCA’s will be restricted from Feb 2023 under Annex XVII
- There are 13 entries for PFAS substances on the REACH SVHC List
- Restrictions have been proposed for PFHxS & PFHxA
- All PFAS used in firefighting foams have been proposed for restriction

**Persistent Organic Pollutants (POPs)**
- PFOS has been included in the Stockholm Convention since 2009 and is already restricted under POPs
- PFOA has been banned under POPs since 2020
- PFHxS and PFCAs are being considered for inclusion in the Stockholm Convention

**Classification, Labelling and Packaging (CLP)**
- A few PFAS are already in scope, including PFOA, APFO, PFNA, PFDA
- PFHpA is under evaluation

**Other Regulations**
- Drinking Water Directive includes a limit of 0.5 µg/l for all PFAS
- Cosmetic Products Regulation forbids the use of certain chemicals in covered products, including PFOS and PFOA

Per- and polyfluoroalkyl substances (PFAS) – ECHA
Member State Actions

**Denmark**
The Danish Ministry of Environment and Food banned PFAS chemicals in food contact paper, cardboard materials, and articles starting from May 2020 (Order No. 681). Denmark was the first country in the EU to ban PFAS in food contact materials.

Denmark has also recently approved a ban on PFAS in firefighting foams.

**Belgium**
Belgium plans to ban single-use plastics and increase recycled contents in plastic packaging, but Article 10 states “It is prohibited to place on the market for the first time packaging containing PFAS.”

**France**
On January 17, French authorities released the country’s first action plan specifically dedicated to PFAS. This plan is based on 6 areas of action, including:
- have standards to guide public action;
- a broad ban at European level;
- improve knowledge of discharges;
- significantly reduce industrial emissions;
- complete transparency of information;
- integrate actions on PFAS into the micropollutants plan.
Beyond the Regulations...

**SUPPLIERS**
Chemical manufacturers are discontinuing PFAS

**INSURERS**
Increasing litigation from both regulators and private citizens is driving insurers to push for discontinued use of PFAS

**CUSTOMERS and NGO's**
- Consumers want to buy PFAS-free products
- OEMs and B2B companies don't want the headache of regulations
- NGOs are pushing for less toxicity in the environment and harmful health effects for people

**COMPETITORS**
Many companies are publishing their intentions to eliminate PFAS from their products, raising expectations

**INVESTORS**
Investment firms are demanding that industry develop a plan to end their manufacture of PFAS
On December 20, 3M announced they will discontinue the manufacture of all PFAS chemicals by 2025, driving the risk of early obsolescence for materials downstream in the supply chain.

Why PFAS must be banned

Fact one: Widespread PFAS-use has created an irreversible toxic legacy of global contamination.

Fact two: PFAS pollution is already affecting communities across Europe and beyond.

Fact three: PFAS are accumulating in our bodies and those of our children.

Fact four: PFAS exposure poses an immediate threat to human health.

Fact five: PFAS pollution is fuelling the biodiversity crisis.

Fact six: PFAS pollution is a threat to our drinking water.

Fact seven: PFAS in products creates a barrier to the circular economy and a waste problem, yet to be solved.

Fact eight: PFAS-free solutions already exist, yet PFAS continue to be added unnecessarily to many consumer products.
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 danger 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, Resonant 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.

"Most companies are taking little or no action to phase out hazardous chemicals despite the risks."

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

"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
Insurer Pressure: Litigation Is on the Rise!

For several decades, 3M owned a PFOS manufacturing plant in Antwerp, Belgium.

- In 2021, citizens began testing soil and their blood for PFAS, which led to a discovery of elevated PFOS counts.

Belgium’s government ultimately forced 3M to discontinue manufacturing PFOS and reached an agreement with 3M to pay €571 million in environmental remediation costs.

- The agreement does not cover personal injury claims that citizens could bring. The Belgian government is still actively pursuing an environmental criminal investigation in the matter tied to illegal dumping of waste.

“The criminal case makes this more serious for 3M than what’s happened in the US. If convicted, 3M will not only have to face sky-high costs of compensating people and cleaning up the contamination, but prison sentences can be handed out.”

— Isabelle Larmuseau, environmental lawyer based in Ghent, Belgium

“In 2021, citizens began testing soil and their blood for PFAS, which led to a discovery of elevated PFOS counts. Belgium’s government ultimately forced 3M to discontinue manufacturing PFOS and reached an agreement with 3M to pay €571 million in environmental remediation costs. The agreement does not cover personal injury claims that citizens could bring. The Belgian government is still actively pursuing an environmental criminal investigation in the matter tied to illegal dumping of waste.”

— Isabelle Larmuseau, environmental lawyer based in Ghent, Belgium
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, even 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 had become common practice in the footwear industry to coat every little part of a shoe: the laces, the stitching, the heel counter, and on and on. We eliminated nearly 70 percent of our use of this class of chemistry without making any other changes. Just by stopping using it where we don’t need it."

— Chris Enlow, Senior Director of KEEN Effect
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!

▸ You can’t rely on Safety Data Sheets for this information
  ▸ Most PFAS are unlikely to be listed on most SDS
  ▸ Most purchased materials will not be provided with an SDS, nor is an SDS required by law for the majority of “articles”
  ▸ Even if the data were available on SDS, the manual work to collect, analyze and map data to regulations would be unsustainable
Take Action!

Where Do You Need More Data?

### Product Design
- Review product performance requirements for PFAS properties (e.g., waterproof, non-stick, etc).
- Review purchased materials where you may pay a premium for PFAS performance.

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
- 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 Survey (more generic and easier for suppliers, but hard to qualify an individual product)
- Part-specific declarations (can be translated to a BOM, but suppliers may not yet be able to provide)

**TIP:** Safety Data Sheets may not disclose the presence of PFAS, since they might not be classified as “hazardous” at this time.

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

What Are Your Obligations?

This is a rapidly-expanding area of legislation. It’s important to stay informed of new and developing legislation.

The Assent Regulatory and Sustainability Experts team is keeping track of all pending legislation on behalf of the Assent product as well as Assent customers and will ensure that they have the information they need.
Conclusion
Upcoming Events

Webinars

PFAS & REACH: Defending Your UK Market Access in 2023
March 2 @ 12 AM GMT

2023 UFLPA Update: Enforcement Is on the Rise
Can You Risk Product Seizures?
March 6 @ 11 AM EST

2023 PFAS Regulatory Update [January]
On-Demand

Conferences

Going Green - CARE INNOVATION 2023
8th - 11th May 2023
Vienna, Austria

European Procurement & Supply Chain Excellence Summit
17th – 18th April 2023
Frankfurt am Main, Germany

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Appendix

[Great Resources]
## Composition Obligations in EU REACH

<table>
<thead>
<tr>
<th>Purpose:</th>
<th>Identify Substances of Very High Concern (SVHC’s) – “dangerous” substances for possible inclusion on Annex XIV and a restriction or ban from the EU market.</th>
<th>Purpose:</th>
<th>Prohibit use and/or manufacture of “dangerous” substances on the EU market. Does NOT apply to “articles.”</th>
<th>Purpose:</th>
<th>Restricts particular use of substance or may ban substance completely. Details are listed in the entries for each substance or family.</th>
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</thead>
</table>

### Candidates for Authorisation

**Key Points:**
- Not a restriction, but other activities may result:
  - If present ≥0.1% at “article” level, manufacturer must notify customer (Article 33)
  - If the total amount of the substances placed on the market totals 1 tonne/year, the manufacturer must also notify ECHA (Article 7(2))
- 224 entries (substances and families) as of June 2022

### Annex XIV – Authorisation List

**Key Points:**
- Must not be used, manufactured or imported without the prior “authorization” of ECHA
- Ban is typically effective 3-4 years after being listed
- 59 entries (substances and families) as of April 2022

### Annex XVII - Restricted List

**Key Points:**
- Can be complete bans or limited constraints on specific applications of 71 entries (substances and families) (Article 67)
- Not all restrictions apply to all types of products
  - For example, Nickel restriction only applies to articles intended to come into direct and prolonged contact with skin
Derogation Requests
Step-by-Step Process
What Is A Derogation?

A “derogation” in the context of EU REACH is an exception or deviation from the rule.

Derogation enables either:

- (i) longer transitional period from when the PFAS restriction enters force, or;

- (ii) an exemption from PFAS restriction itself.
# How Should I Prepare A Derogation Request?

<table>
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<tr>
<th>#</th>
<th>Suggested Tasks</th>
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</table>
| 1  | **MUST Take Action NOW:** Soope → **PFASs are Everywhere, Pay Attention To:**  
     ▶ Mixtures and materials held in warehouse storage locations.  
     ▶ Mixtures and materials in use in ALL manufacturing facilities, consumed within products, used as process chemicals, and used as maintenance materials to support machinery.  

**Internally Defined Products:**  
▶ Obtain a product level Bill of Materials (BOM) extract all component part level information for an internally defined product;  
▶ Extract definition related data (Geometry drawings, material / process / industry standards)  
▶ Identify ALL chemical substances, mixtures, materials consumed to make products. |
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<tbody>
<tr>
<td>1</td>
<td><strong>External Supply Chain Engagement:</strong></td>
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<td></td>
<td>▶ Perform a supply chain communication, pertaining to the EU Restriction Proposal, flowing it down to all sub-tiers. Refer to (i) <a href="#">official press release</a>; (ii) <a href="#">Annex XV report</a> (table page 4~ list of PFASs); (iii) <a href="#">ECHA dedicated PFAS page</a>; (iv) <a href="#">YouTube video</a> on restriction proposal.</td>
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<td></td>
<td>▶ Ensure supplier(s) understand the PFAS restriction process, and tasks they may need to undertake.</td>
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<td></td>
<td>▶ Request suppliers to review the information.</td>
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<td></td>
<td>▶ Request suppliers provide you with data on the use and application of any PFASs, against the list of PFASs as shown above communication step (ii).</td>
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<td></td>
<td>▶ Collect, validate and record supplier responses</td>
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Compile:
List of Products containing PFASs and Usage information  

*Product number, internal / external, supplier name, PFAS substance name, identifiers CAS / EC, amount consumed, how it is being consumed*
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<tr>
<td>2</td>
<td><strong>DOWNLOAD Annex XV Report:</strong></td>
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<td></td>
<td>▶ Download the <a href="#">PFAS Annex XV report</a> [PFASs Restriction Proposal].</td>
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<td></td>
<td>▶ <strong>NOTE:</strong></td>
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<td></td>
<td>▶ <em>8th February 2023:</em> Watermarked as ‘Pre-Publication do not use’ this means it is a DRAFT version:</td>
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<td></td>
<td>▶ Assume in this state it is Worst Case Scenario restriction proposal.</td>
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<td></td>
<td>▶ Strongly recommend reviewing this version of the Annex XV report, following Steps 3-10</td>
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<td></td>
<td>▶ <em>22nd March 2023:</em> Published Annex XV report</td>
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<td>▶ Repeat steps 2 onwards, analyse any resulting changes and impacts</td>
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<td>3</td>
<td>REVIEW Annex XV Report:</td>
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<td>In conjunction with the list of your products with PFASs, as identified in Step (1) [Products]. Review Annex XV Report [Draft &amp; Published Versions] as follows:</td>
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<td></td>
<td>▶ Create a PFASs substances list based on the table presented in pages 4-8 [PFASs substance list].</td>
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<td>▶ Review Table 8 on pages 80-114, identify your sector, use of PFASs and record, the submitters identified alternatives [Assumed Alternatives].</td>
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<td>▶ Review Table 9 on pages 115-137. Identify your sector, use of PFASs, and record derogation status [Products, Risks]:</td>
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<td>▶ ‘derogation is proposed for’ → derogation has been allowed (5-12 years) → still provide feedback comments to either accept the time or justify extending timescales.</td>
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<td>▶ ‘no derogation proposed’ → provide detailed information in the derogation request with supporting evidence to justify derogation.</td>
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<td>▶ ‘for reconsideration’ → Further evidence needed. Update your derogation request to include supporting evidence.</td>
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<tr>
<td>4</td>
<td><strong>IDENTIFY Business Continuity Risks For Your Organisation:</strong></td>
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<td>Compile (from current draft) / Update (from published):</td>
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<tr>
<td></td>
<td>1. List of products containing PFASs from Step (1).</td>
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<tr>
<td></td>
<td>2. List of PFASs in scope created in Step (3)</td>
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<td>3. List of alternative PFASs extracted from Table 8 in Step (3)</td>
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<td></td>
<td>4. List of sectoral uses, application &amp; derogation status extracted from Table 9 in Step (3)</td>
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<td></td>
<td><strong>Risks:</strong></td>
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<td>(a) Compare your list of products containing PFASs List (1) Vs List (2) list of PFASs in scope, to identify products at risk.</td>
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<td>(b) Record any PFASs missing from List (2) that appear on List (1). Identify products needing derogation requests.</td>
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<td>(c) Do the PFASs in List (4) match your sector, use and application? Are there any derogations?</td>
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<td>(d) Investigate if the Alternative PFASs in List (3) are feasible for use, Record data.</td>
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## How Should I Prepare A Derogation Request?

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| 5  | **RAISE Industrial Sector Awareness:**  
Discuss the PFAS restriction proposal with any Applicable Industry Trade Association(s) *Collective Assertion of Impacts to Your Industry Sector*:  
▶ Understand the overall status and impacts posed by the EU PFAS restriction proposal to your industry sector,  
▶ Has the trade association defined its own position paper on the EU PFAS restriction proposal or is it working jointly with other trade associations? → Will a position paper be presented into the public consultations?  
▶ Is the trade association actively collecting data from members relating to the EU PFAS restriction proposal?  
  ▶ Yes → share your information on product types, PFASs identified, use and application generated in Step (4).  
▶ Are there any activities being undertaken investigating the use of alternatives?  
▶ Is the trade association going to participate in the PFAS restriction proposal public consultations? |
# How Should I Prepare A Derogation Request?

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| 6 | **PREPARE Initial Derogation Request:** [Initial Statement by 1st Deadline] From the products and risks identified in Step (4):  
**Review Official Guidance:**  
▸ **ECHA Guidance document on inputting to Annex XV report consultation.**  
▸ Pay attention to pages 1 to 3 for the overview of reportable section(s).  
▸ Use the addendum as an initial skeletal structure.  
▸ Populate with known data.  
▸ Supporting evidence is key! to justify any information being submitted. |

**For Every PFAS Identified Repeat These Steps to Identify:**  
▸ **Opening Statement:** Introduction to topic, based on review of Table 9 in Step (3) and risks identified in Step (4). What are you requesting (i) new derogation; (ii) registering a use on an existing derogation; (iii) providing supplementary information where derogation either transition periods are still under review or the derogation has a status as being under reconsideration.
### How Should I Prepare A Derogation Request?

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<td>6</td>
<td><strong>Impacted product or part numbers:</strong> (i) name; (ii) description; (iii) usage type: (a) current production part; (b) spare part; (iv) internally manufactured / assembled or sourced externally from supply chain;</td>
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<tr>
<td>6</td>
<td><strong>Identified PFASs:</strong> (i) PFAS substance name; (ii) PFAS identifiers such as CAS or EC no; (iii) amounts of PFAS being consumed; (iv) application of PFAS (as known);</td>
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<tr>
<td>6</td>
<td><strong>Performance Criteria Needed:</strong> Detail the specific product features that require the PFASs to be used [function of PFAS, internal / customer requirement, standards or other specifications]. Explain benefits of PFAS being used.</td>
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<td>6</td>
<td><strong>Detailed Life Cycle Analysis:</strong> Identify: (i) cradle to cradle information on PFAS and product LCA states; (ii) energy; (iii) waste, and (iv) emissions related data.</td>
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<tr>
<td>6</td>
<td><strong>Control Measures:</strong> Identify cradle to cradle measures to: (i) control storage and handling activities; (ii) define safe use control measures including Occupational Exposure Limits; (iii) control internal waste and recycling; (iv) control downstream user waste and recycling activities;</td>
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| 6  | ▶ **Assessment of Alternatives:** (i) review data extracted from Table 8, in Step (3); (ii) perform technical feasibility study on alternatives explored; (iii) identify activities to be, or already undertaken; (iv) outcomes.  
  ▶ **Socio-Economic Assessment:** Impacts: (i) loss of manufacturing capability; (ii) loss of market share, leading to loss of profitability resulting jobs loses, reduced R&D expenditure, downscaling other investments such as community investment projects; (iii) knock on effects to downstream users, consumers and society as a result of not being able to manufacture products. |

**Key:**
- What is the evidence that can be shown that technical and economically feasible alternatives are not available at the Entry Into Force (EIF) date of the EU PFAS restriction proposal? (2026)
- Provide Evidence and Justify
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<tr>
<td>7</td>
<td><strong>PREPARE UPDATED Derogation Request</strong></td>
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<td>- Repeat steps 1-6, making any updates to documentation.</td>
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<td>- Ensure all data is presented in a clear &amp; concise manner.</td>
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<td>- Data must be based on supporting evidence.</td>
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<td>- Detail assumptions made and calculations undertaken.</td>
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<td>- Re-submit data again by the end of the public consultation (22nd Sept 3023)</td>
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<td>8</td>
<td><strong>AWAIT Outcomes:</strong></td>
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<td>- <strong>ECHA RAC Decision (no public consultation):</strong></td>
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<td>- Feedback any concerns over decision to applicable Trade Association(s), they may be allowed to provide evidence outside of the public consultation window.</td>
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| 8  | **ECHA SEAC Opinions (Draft & Adopted) Feedback Comments:**  
  ▶ Only related to draft opinion only to the ECHA SEAC public consultation on Draft Consultation — Everything is ignored.  
  ▶ Any concerns related to the opinions to applicable Trade Association(s), they may be allowed to provide evidence outside of the public consultation window. |
| 9  | **Further Reading (approaches to alternative assessments):**  
  ▶ [EU Safe and Sustainable by Design Framework (2022)](#): Originally defined to be part of next revision of EU REACH. Now a standalone criteria, mandatory for any EU R&D funded projects. EU’s recommended methodology for assessing alternatives.  
  ▶ [EU SCHEER Guidance on Phthalates in Medical Devices (2019)](#): Defined in the context of EU Medical Devices Regulation, does provide an approach to examining alternative substances. |