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EU PFAS & REACH: Protecting Your Market Access in 2023

Thursday, 23 February 2023



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Managed Services

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Assent Sustainability Network

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Corporation



Our Regulatory Experience Is Your Advantage



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BUILD VS. BUY: MAKING THE RIGHT CHOICE FOR A PRODUCT COMPLIANCE PROGRAM

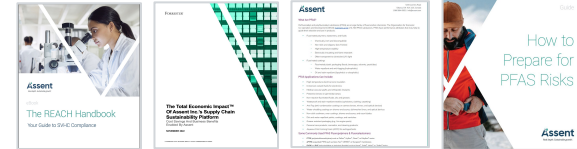
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Chat - Polls - Docs - Q&A

You will receive a follow-up email with a copy of the recording and resources. If you have any questions about this webinar, please contact us at corporate.events@assent.com

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



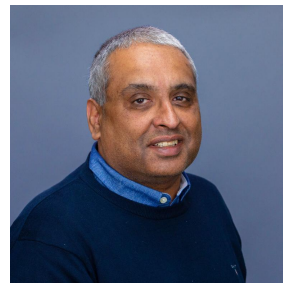
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Feature Presentation: PFAS & REACH: Protecting Your Market Access in 2023

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



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PFAS Basics

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

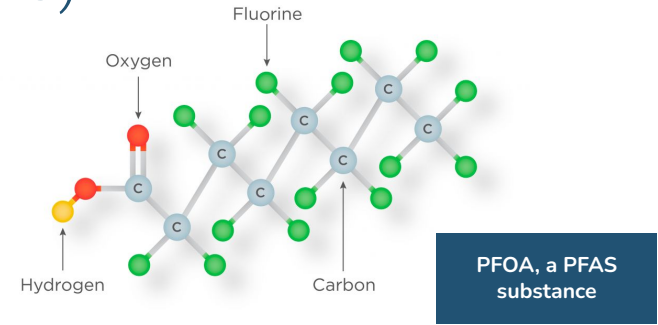


Image source: Western Virginia Water Authority



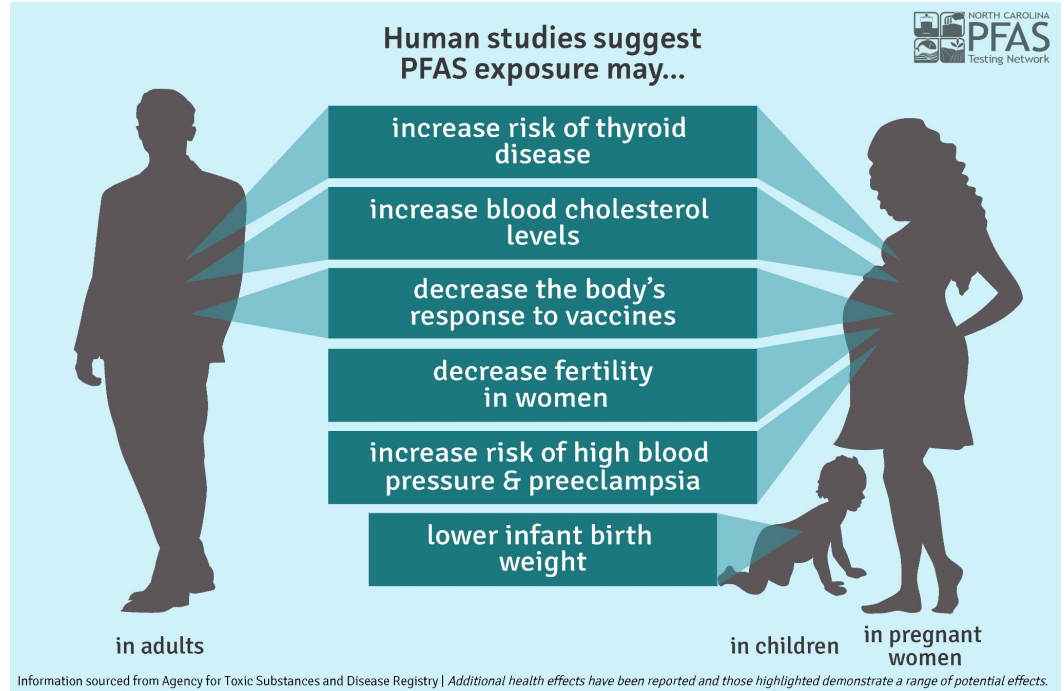
PFAS Health Impact

PFAS chemicals resist degradation in the environment and accumulate in the body.

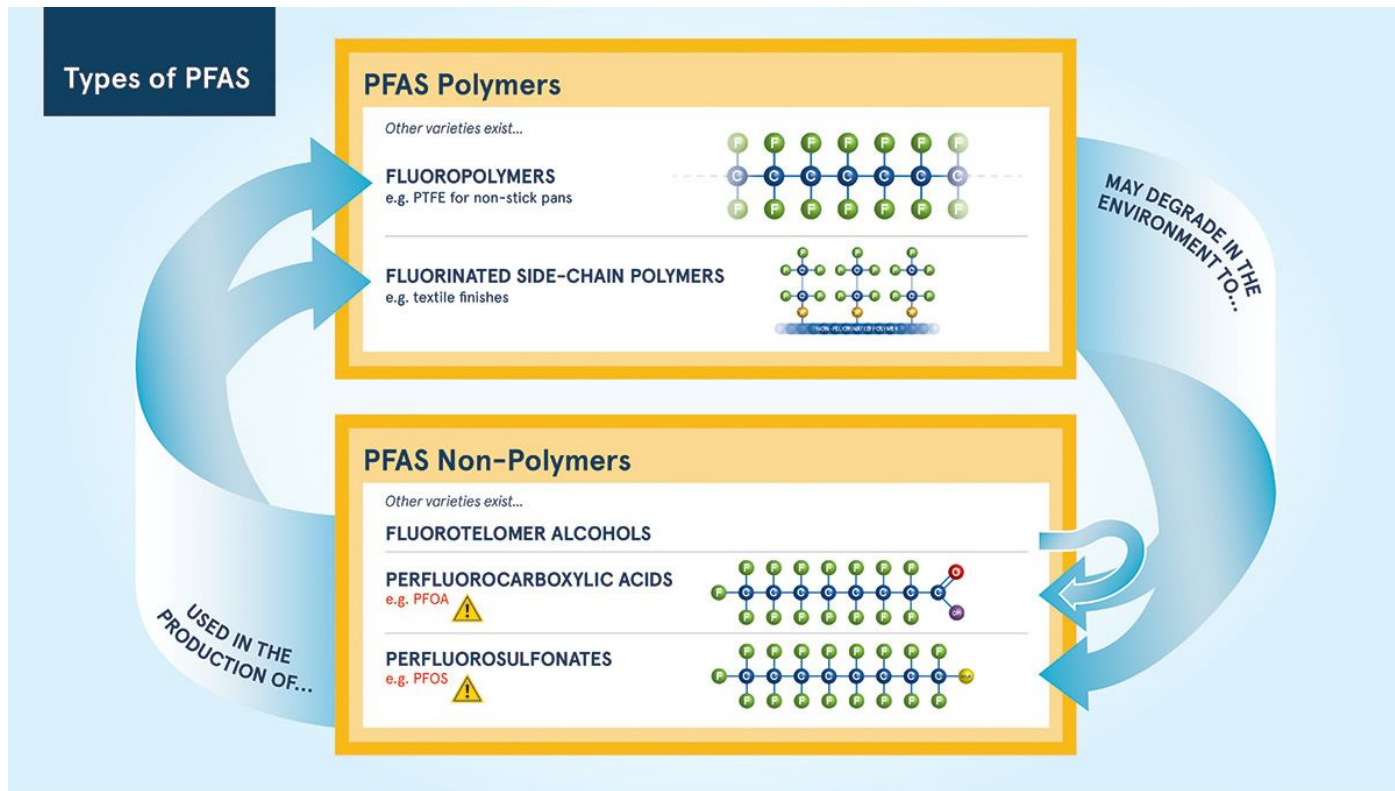
Those contaminants may be linked to serious adverse health effects in humans and animals.

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



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

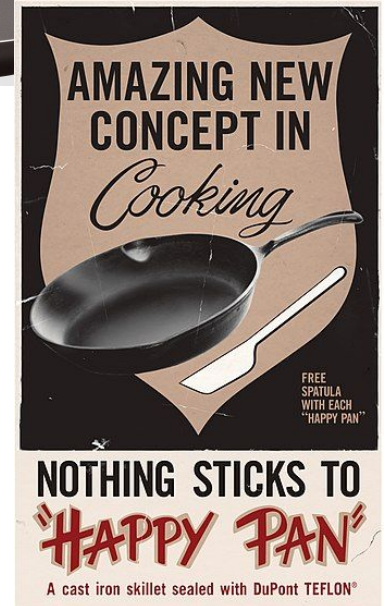
PFA (perfluoroalkoxy) and **FEP** (fluorinated ethylene-propylene) such as Neoflon GP[®] or Everflon[®] FEP resins

Fluoroelastomers such as FKM, FPM, Viton[®], Kalrez[®], AFLAS[®], or Fluonox[®] compounds

How Teflon Works

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

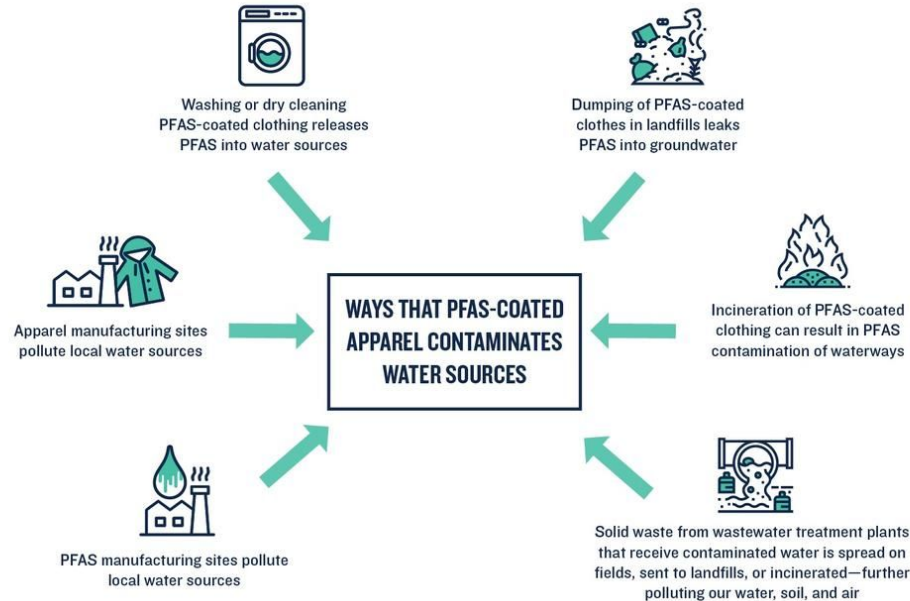
- The carbon and fluorine atoms stick to each other, but not to food or other substances.
- Roughing the pan surface helps Teflon stick to it.
- Sometimes chemical treatments on the pan change Teflon touching it, so it sticks.

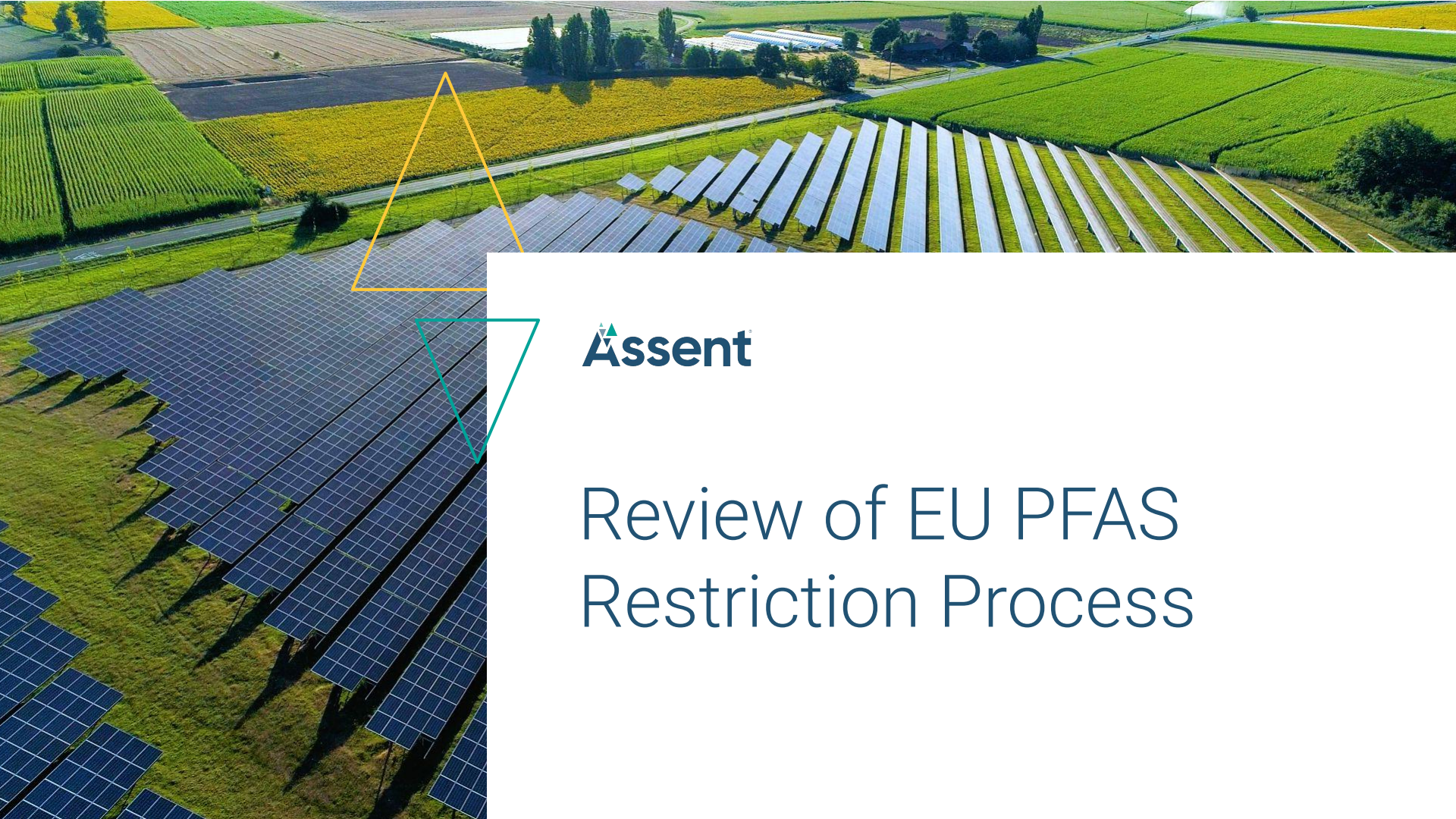


PFAS Product Environmental Impact

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.

WAYS THAT PFAS-COATED APPAREL CAN POLLUTE OUR WATER SUPPLIES





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Review of EU PFAS Restriction Process

EU PFAS Activities

The European Chemicals Agency (ECHA) has a detailed and complex strategy, leveraging multiple regulatory instruments, to address concerns around PFAS

What are ECHA and the EU doing on PFAS?

RESTRICTIONS



The production and use of some PFAS are already restricted as part of the EU's chemicals legislation.

STUDIES



ECHA and the European Commission are carrying out studies related to PFAS used in fire-fighting foams and textiles.

SAFER ALTERNATIVES



Placing them on the REACH Candidate List of substances of very high concern drives their substitution.

ASSESSMENT



Since 2014, ECHA has assessed PFAS in groups rather than one by one to speed up the process. ECHA's database contains more than 2 000 PFAS.

Check our database

<https://echa.europa.eu/information-on-chemicals/registered-substances>



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



Option 1	Option 2
<ul style="list-style-type: none">▶ FULL BAN▶ Limited number of derogations	<ul style="list-style-type: none">▶ Ban with use-specific time-limited derogation, based on:<ul style="list-style-type: none">▶ Submitters analyses of PFASs uses and assumed alternatives.▶ Socio-economic considerations from submitters and feedback to consultations.
<p>Transition period of 18 months after the regulation enters into force.</p>	

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

ECHA > Consultations > Submitted restrictions under consideration

Submitted restrictions under consideration

This table shows ongoing consultations on conforming restriction proposals and SEAC draft opinions; the links to the web forms for submitting comments to ECHA during the relevant consultations can be found by clicking on details. For consultations on conforming restriction proposals, two deadlines are given: comments submitted by the first deadline are often very influential as they will be considered in the first discussion on the proposed restriction and more substantial comments should be submitted at the latest 1 month before the final deadline.

Please note: the ECHA Committees will not take into account the comments received after the final deadline in their opinion making process.

Consultations close at 23:59 Helsinki time (EET).

Restriction

Adopted opinions on Registry of restriction intentions until outcome

Consultation guidance

< Substance Details

Name	Prepublica Per and pol
EC Number	
CAS Number	
Submitted by	Germany
Scope	Restriction o
Information note on restriction report	
Restriction report	Annex XV
Restriction report annexes	Annex A Annex B Annex C Annex D Annex E Annex F Annex G Appendix Appendix Appendix G2
Consultation on restriction report	

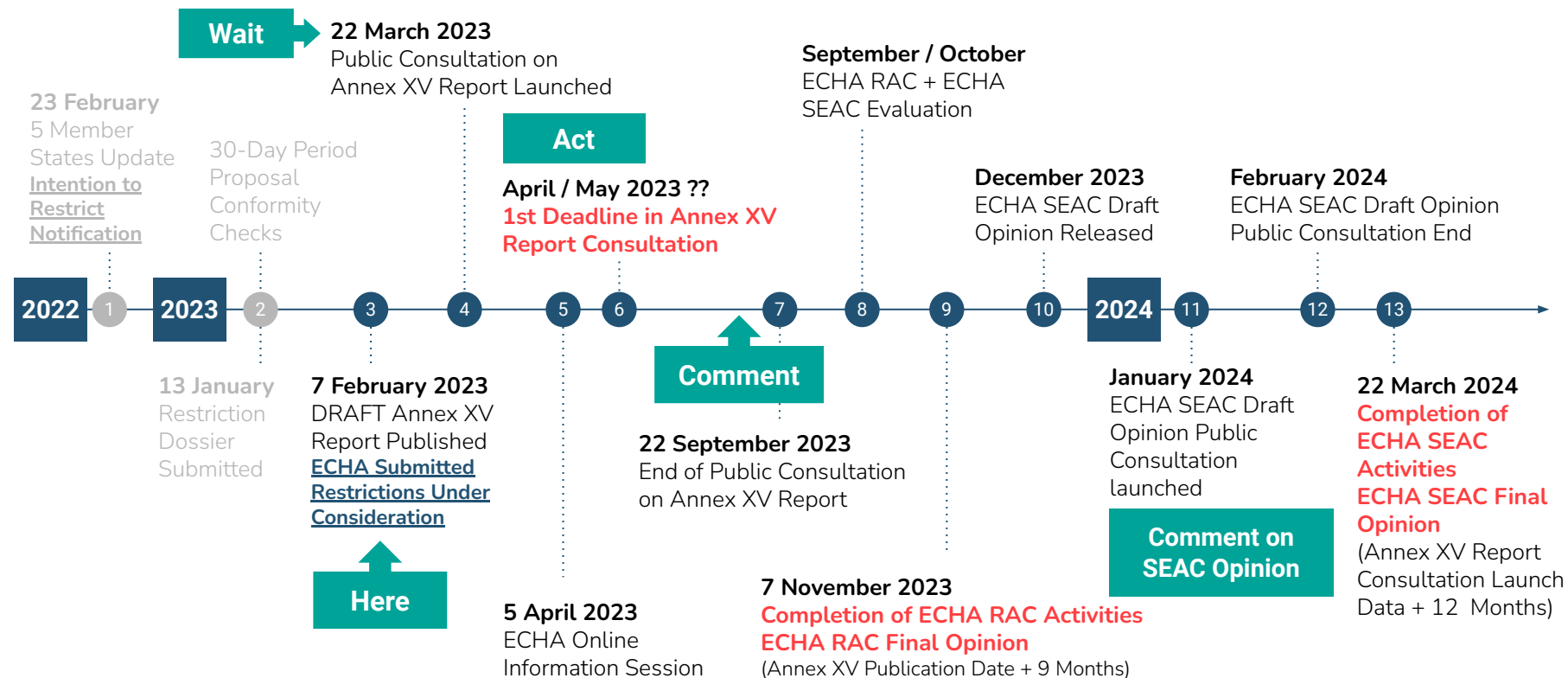
Annex XV report

- Annex A
- Annex B
- Annex C
- Annex D
- Annex E
- Annex F
- Annex G
- Appendix E4
- Appendix G1
- Appendix G2



EU PFAS Proposal – Key Timescales (ECHA)

EU Parliament, Council & Commission Review Processes



What Is the Process for a Derogation Request?

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

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!

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Restriction

Adopted opinions on Registry of restriction intentions until outcome

Consultation guidance

Name	EC Number	CAS Number	Start of consultation on Annex XV report	1st deadline for comments on Annex XV report	End of consultation on Annex XV report	Start of consultation on SEAC draft opinion	End of consultation on SEAC draft opinion	
4,4'-isopropylidenediphenol (Bisphenol A) as well as other bisphenols and bisphenol derivatives with endocrine disrupting properties for the environment	-	-	21/12/2022	25/01/2023	22/06/2023			Details
Pre-publication of Annex XV report prior to consultation Per- and polyfluoroalkyl substances (PFAS)	-	-						Details
Cresote and Cresote related	-	-	21/12/2022	25/01/2023	22/06/2023			Details

Consultation on restriction report [Give Comments](#)



UK PFAS Restriction Proposal

Current Status



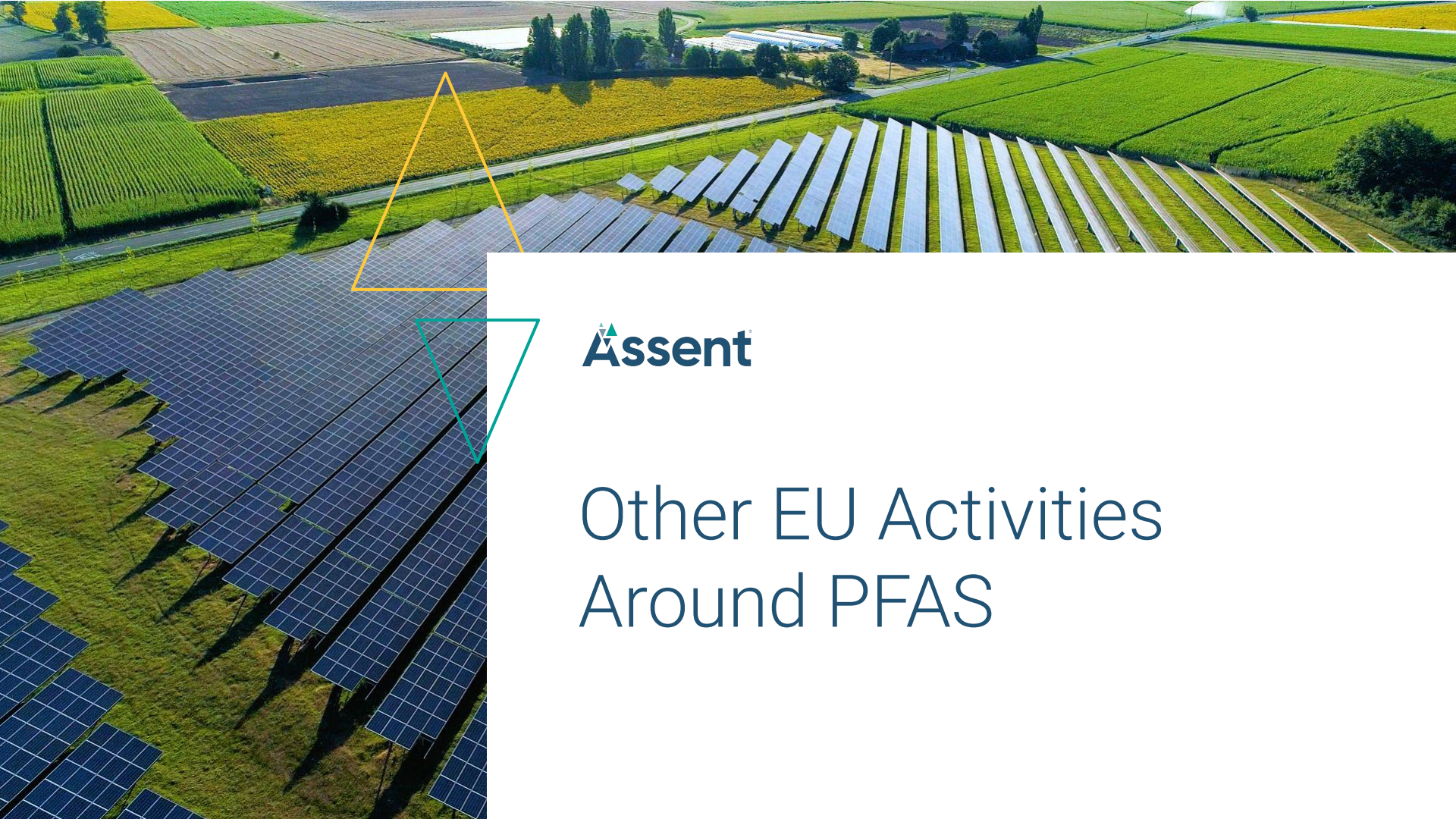
UK REACH processes are still in review, but the UK intention is to restrict – PFAS is NOT going away

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 RMOA due in 2023 followed by UK REACH restriction processing activities





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Other EU Activities Around PFAS

PFAS in Existing Regulations

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

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

Substance		Assent Solution								
		EU REACH SVHC	EU REACH Annex XVII	EU POPs	EU MDR EU IVDR	U.S. TSCA 8(a)(7)	CA Prop 65	CEPA	AD-DSL	ILFI Red List
PFOA	Perfluorooctanoic Acid	X	P?	X	X	P	X	X	X	X
PFOS	Perfluorooctane Sulfonate		P?	X	X	P	X	X	X	X
PFNA	Perfluorononan-1-oic acid	X	X		X	P	X	X	X	X
APFO	Ammonium pentadecafluorooctanoate	X	P?	X	X	P		X	X	X
PFUnDA	Henicosfluoroundecanoic acid	X	X			P	P	X	X	X
PFTTrDA	Pentacosfluorotridecanoic acid	X	X			P		X	X	X
PFTDA	Heptacosfluorotetradecanoic acid	X	X			P			X	X
PFDDoDA	Tricosfluorododecanoic acid	X	P			P		X	X	X
PFDA	Nonadecafluorodecanoic acid & salts	X	P		X	P	P		X	
GenX / HFPO	Hexafluoropropylene oxide dimer acid	X	P			P			X	X
PFBS	Perfluorobutane sulfonic acid and salts	X	P			P			X	
PFHxS	Perfluorohexane sulfonic acid and salts	X	P?	P		P	P		X	
C9-14 PFCAs	Perfluorinated carboxylic acids		X			P				
PFHpA	Perfluoroheptanoic acid and salts	X	P			P				
PFHxA	Undecafluorohexanoic acid		P			P				X
	Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine	X	P			P				



EU REACH – Candidate List (SVHCs)

Two PFAS Entries Added January 17, 2023

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

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

2,2,3,3,5,5,6,6-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



STOCKHOLM CONVENTION

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 **PFCA's** 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.**”

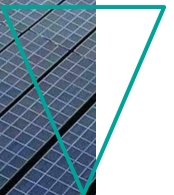


France

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.

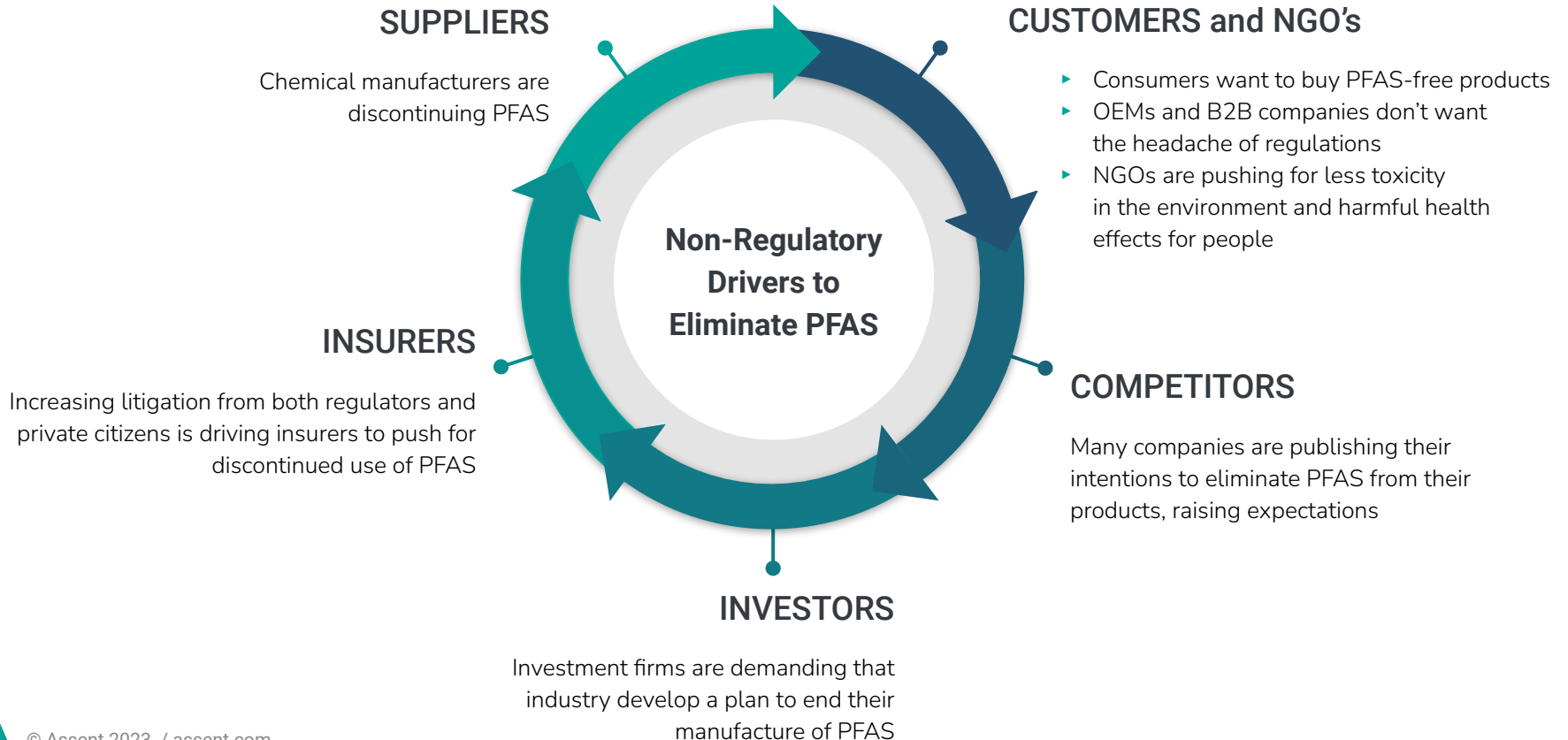




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Business Risk

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, driving the risk of early obsolescence for materials downstream in the supply chain

Source: 3M. (2022, December 20). *3M to Exit PFAS Manufacturing by the End of 2025*. <https://news.3m.com/2022-12-20-3M-to-Exit-PFAS-Manufacturing-by-the-End-of-2025>

The screenshot shows a 3M press release page. At the top left is the 3M logo and a hamburger menu icon. Below it is a breadcrumb trail: "3M United States > 3M News Center > Press Releases". On the right side, there is a "3M News Center" dropdown menu. Below the breadcrumb is a "Share:" section with icons for print, email, RSS, document, Facebook, Twitter, LinkedIn, and Pinterest. A link "Back To Press Releases" is on the left. The main headline is "3M to Exit PFAS Manufacturing by the End of 2025". The text of the release begins with "ST. PAUL, Minn., Dec. 20, 2022 /PRNewswire/ -- 3M (NYSE: MMM) today announced it will exit per- and polyfluoroalkyl substance (PFAS) manufacturing and work to discontinue the use of PFAS across its product portfolio by the end of 2025. 3M's decision is based on careful consideration and a thorough evaluation of the evolving external landscape, including multiple factors such as accelerating regulatory trends focused on reducing or eliminating the presence of PFAS in the environment and changing stakeholder expectations." A quote from 3M chairman and CEO Mike Roman follows: "This is a moment that demands the kind of innovation 3M is known for," said 3M chairman and chief executive officer Mike Roman. "While PFAS can be safely made and used, we also see an opportunity to lead in a rapidly evolving external regulatory and business landscape to make the greatest impact for those we serve. This action is another example of how we are positioning 3M for continued sustainable growth by optimizing our portfolio, innovating for our customers, and delivering long-term value for our shareholders."

Other Topics

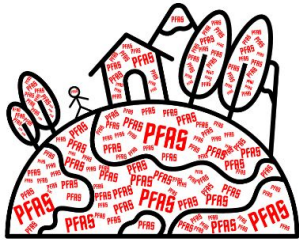
- 3M Company
- Industry
- Sustainability
- Social Justice
- Science Or STEM Advocacy
- Product Launch
- Science & Innovation
- Partnerships
- Environmental Stewardship
- Diversity, Equity & Inclusion
- Community
- Careers



Customer & NGO Pressure

Manifesto for an urgent ban of 'forever chemicals' PFAS

Can you spot the
PFAS pollution?
...it's not hard is it?



#BanPFAS

There is clear and unequivocal evidence that demonstrates global contamination of the environment, wildlife and human populations by PFAS - the most persistent human-made chemicals known to date. PFAS pose an unacceptable risk¹¹ for both current and future generations due to their extreme persistence, and the scientific evidence that links exposure to harmful impacts on wildlife and human health. There are 1000s of different PFAS. However, it is of great concern that only a handful are currently controlled by regulations at the global level even though many safer alternatives are readily available.

We, European civil society organisations, urge EU Member States and the Commission to ban all PFAS in consumer products by 2025 and to have a complete ban by 2030.

Source: <https://banpfasmanifesto.org/en/>

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 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>

Insurer Pressure: Litigation Is on the Rise!



“Polluter Pays”

3M's factory near Antwerp, Belgium

Photo: Bioplastics News

<https://www.bloomberg.com/graphics/2022-3m-pfas-toxic-forever-chemicals-europe/>

<https://www.natlawreview.com/article/european-pfas-litigation-wave-beginning>

“Zwijndrecht has become PFOS land, like it's Chernobyl”

— *Koen Doggen, Belgian organic farmer*

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*



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.

KEEN's Detox the Planet Initiative

Challenges Outdoor Footwear Industry to be PFC-Free by 2025

KEEN publishes the process it used to become PFC-Free in an open-source format so competitors in industry can follow and achieve the same goal in less time

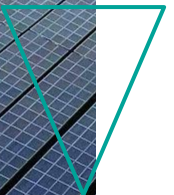
“It had become common practice in the footwear industry to coat every little part of a shoe: the laces, the stitching, the heel counter, and on and on. We eliminated nearly 70 percent of our use of this class of chemistry without making any other changes.

Just by stopping using it where we don't need it.”

— *Chris Enlow, Senior Director of KEEN Effect*

[PFAS Free: Getting 'Forever Chemicals' Out of Footwear](#)





Assent

Call to Action

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

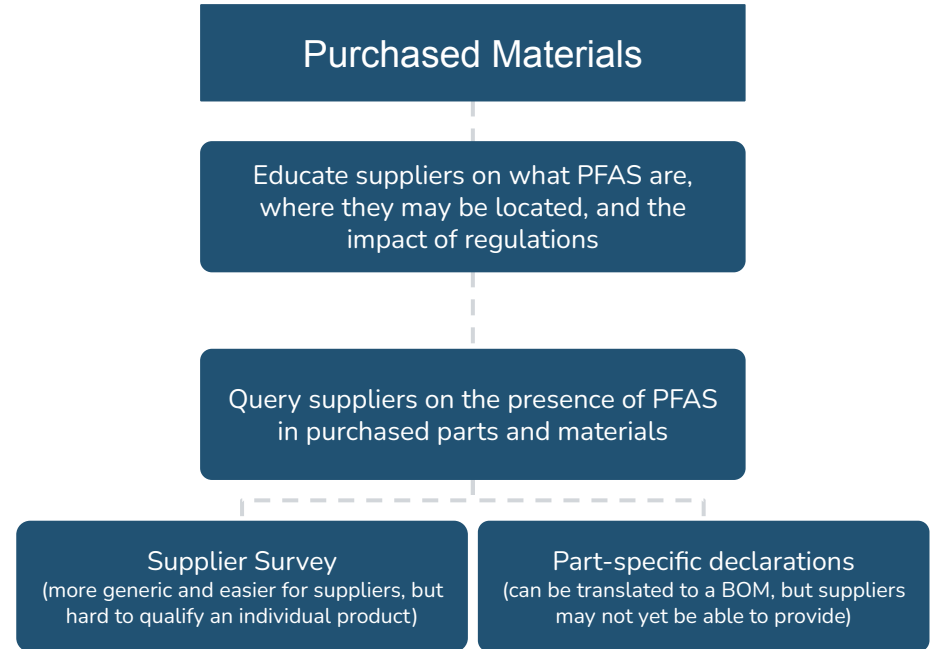


Take Action!

Where Do You Need More Data?



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.



Assent

Questions/Discussion

Conclusion

Upcoming Events

Webinars

PFAS & REACH:

Defending Your UK Market Access in 2023

March 2 @ 12 AM GMT

[Register Now](#)

2023 UFLPA Update: Enforcement Is on the Rise

Can You Risk Product Seizures?

March 6 @ 11 AM EST

[Register Now](#)

2023 PFAS Regulatory Update [January]

On-Demand

[Watch Now](#)

Conferences

Going Green - CARE INNOVATION 2023

8th - 11th May 2023

Vienna, Austria

[Register Now](#)

European Procurement & Supply Chain

Excellence Summit

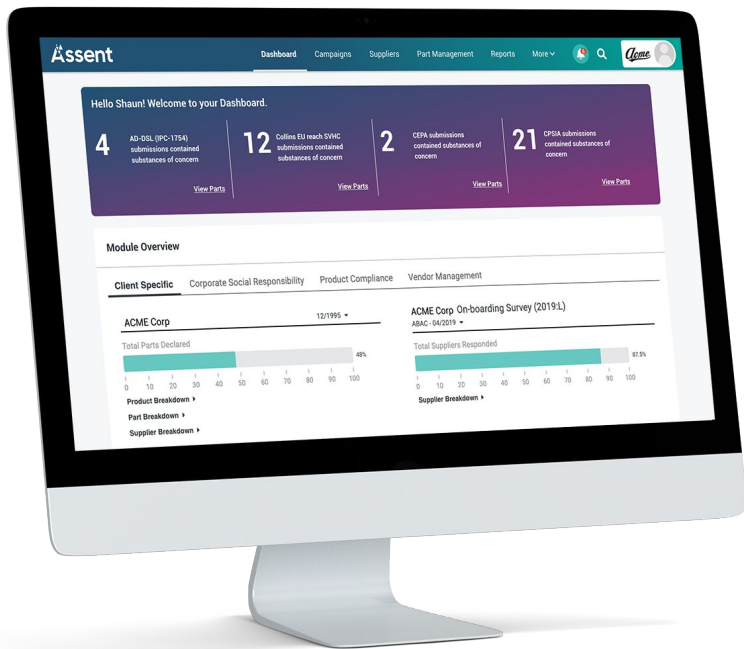
17th – 18th April 2023

Frankfurt am Main, Germany

[Register Now](#)

[Learn More - Assent Events](#)





Transform Your Supply Chain Sustainability Program

[Book Your Demo Now >](#)



Appendix

[Great Resources]



Composition Obligations in EU REACH

Candidates for Authorisation

Annex XIV – Authorisation List

Annex XVII - Restricted List

Purpose:

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.

<https://echa.europa.eu/candidate-list-table>

Purpose:

Prohibit use and/or manufacture of “dangerous” substances on the EU market.

Does NOT apply to “articles.”

<https://echa.europa.eu/authorisation-list>

Purpose:

Restricts particular use of substance or may ban substance completely. Details are listed in the entries for each substance or family.

<https://echa.europa.eu/substances-restricted-under-reach>

Key Points:

Not a *restriction*, but other activities may result:

- ▶ If present $\geq 0.1\%$ 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

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

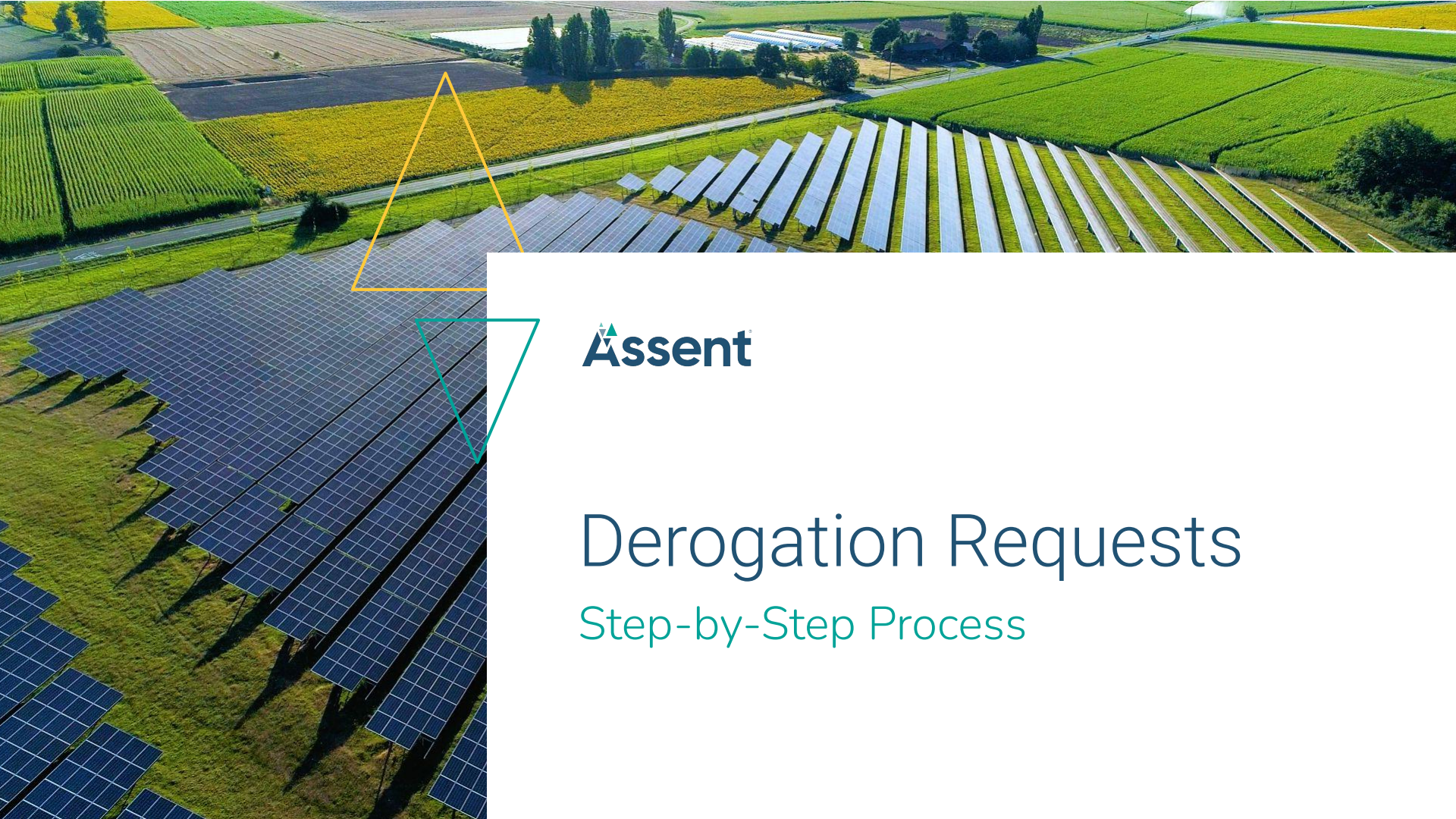
Key Points:

- ▶ 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

Least Restrictive

Most Restrictive





Assent

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?

#	Suggested Tasks
1	<p data-bbox="202 278 1651 322"><i>MUST Take Action NOW:</i> <i>Soope</i> → <i>PFASs are Everywhere, Pay Attention To:</i></p> <ul data-bbox="222 333 1767 529" style="list-style-type: none"><li data-bbox="222 333 1420 376">▶ Mixtures and materials held in warehouse storage locations.<li data-bbox="222 382 1767 529">▶ Mixtures and materials in use in ALL manufacturing facilities, consumed within products, used as process chemicals, and used as maintenance materials to support machinery. <p data-bbox="202 556 724 600"><i>Internally Defined Products:</i></p> <ul data-bbox="222 611 1787 911" style="list-style-type: none"><li data-bbox="222 611 1787 704">▶ Obtain a product level Bill of Materials (BOM) extract all component part level information for an internally defined product;<li data-bbox="222 715 1787 808">▶ Extract definition related data (Geometry drawings, material / process / industry standards)<li data-bbox="222 819 1661 911">▶ Identify ALL chemical substances, mixtures, materials consumed to make products.



How Should I Prepare A Derogation Request?

#	Suggested Tasks
1	<p><i>External Supply Chain Engagement:</i></p> <ul style="list-style-type: none">▶ Perform a supply chain communication, pertaining to the EU Restriction Proposal, flowing it down to all sub-tiers. Refer to (i) official press release; (ii) Annex XV report (table page 4~ list of PFASs); (iii) ECHA dedicated PFAS page; (iv) YouTube video on restriction proposal.▶ Ensure supplier(s) understand the PFAS restriction process, and tasks they may need to undertake.<ul style="list-style-type: none">▷ Request suppliers to review the information.▷ 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).▷ Collect, validate and record supplier responses <p>Compile: List of Products containing PFASs and Usage information [<i>Product number, internal / external, supplier name, PFAS substance name, identifiers CAS / EC, amount consumed, how it is being consumed</i>]</p>

How Should I Prepare A Derogation Request?

#	Suggested Tasks
2	<p>DOWNLOAD Annex XV Report:</p> <ul style="list-style-type: none">▶ Download the PFAS Annex XV report [<i>PFASs Restriction Proposal</i>].▶ NOTE:<ul style="list-style-type: none">▶ <i>8th February 2023</i>: Watermarked as 'Pre-Publication do not use' this means it is a DRAFT version:<ul style="list-style-type: none">» Assume in this state it is Worst Case Scenario restriction proposal.» Strongly recommend reviewing this version of the Annex XV report, following Steps 3-10▶ <i>22nd March 2023</i>: Published Annex XV report<ul style="list-style-type: none">» Repeat steps 2 onwards, analyse any resulting changes and impacts



How Should I Prepare A Derogation Request?

#	Suggested Tasks
3	<p data-bbox="202 278 685 322"><i>REVIEW Annex XV Report:</i></p> <p data-bbox="202 327 1777 420">In conjunction with the list of your products with PFASs, as identified in Step (1) [<i>Products</i>]. Review Annex XV Report [<i>Draft & Published Versions</i>] as follows:</p> <ul data-bbox="222 425 1845 1059" style="list-style-type: none"><li data-bbox="222 425 1738 518">▶ Create a PFASs substances list based on the table presented in pages 4-8 [<i>PFASs substance list</i>].<li data-bbox="222 524 1777 616">▶ Review Table 8 on pages 80-114, identify your sector, use of PFASs and record, the submitters identified alternatives [<i>Assumed Alternatives</i>].<li data-bbox="222 622 1845 1059">▶ Review Table 9 on pages 115-137. Identify your sector, use of PFASs, and record derogation status [<i>Products, Risks</i>]:<ul data-bbox="328 720 1845 1059" style="list-style-type: none"><li data-bbox="328 720 1845 868">▶ ‘<i>derogation is proposed for</i>’ → derogation has been allowed (5-12 years) → still provide feedback comments to either accept the time or justify extending timescales.<li data-bbox="328 873 1845 966">▶ ‘<i>no derogation proposed</i>’ → provide detailed information in the derogation request with supporting evidence to justify derogation.<li data-bbox="328 971 1845 1059">▶ ‘<i>for reconsideration</i>’ → Further evidence needed. Update your derogation request to include supporting evidence.

How Should I Prepare A Derogation Request?

#	Suggested Tasks
4	<p data-bbox="202 278 1304 322"><i>IDENTIFY Business Continuity Risks For Your Organisation:</i></p> <p data-bbox="202 333 1236 376"><i>Compile (from current draft) / Update (from published):</i></p> <ol data-bbox="222 387 1835 638" style="list-style-type: none">1. List of products containing PFASs from Step (1).2. List of PFASs in scope created in Step (3)3. List of alternative PFASs extracted from Table 8 in Step (3)4. List of sectoral uses, application & derogation status extracted from Table 9 in Step (3) <p data-bbox="202 649 318 693"><i>Risks:</i></p> <ol data-bbox="222 704 1806 1053" style="list-style-type: none">(a) Compare your list of products containing PFASs List (1) Vs List (2) list of PFASs in scope, to identify products at risk.(b) Record any PFASs missing from List (2) that appear on List (1). Identify products needing derogation requests.(c) Do the PFASs in List (4) match your sector, use and application? Are there any derogations?(d) Investigate if the Alternative PFASs in List (3) are feasible for use, Record data.

How Should I Prepare A Derogation Request?

#	Suggested Tasks
5	<p data-bbox="202 278 879 322"><i>RAISE Industrial Sector Awareness:</i></p> <p data-bbox="202 333 1584 431">Discuss the PFAS restriction proposal with any Applicable Industry Trade Association(s) [<i>Collective Assertion of Impacts to Your Industry Sector</i>]:</p> <ul data-bbox="222 436 1835 1042" style="list-style-type: none"><li data-bbox="222 436 1729 529">▶ Understand the overall status and impacts posed by the EU PFAS restriction proposal to your industry sector,<li data-bbox="222 540 1816 682">▶ 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?<li data-bbox="222 693 1796 889">▶ Is the trade association actively collecting data from members relating to the EU PFAS restriction proposal?<ul data-bbox="338 797 1767 889" style="list-style-type: none"><li data-bbox="338 797 1767 889">▷ Yes → share your information on product types, PFASs identified, use and application generated in Step (4).<li data-bbox="222 900 1767 944">▶ Are there any activities being undertaken investigating the use of alternatives?<li data-bbox="222 955 1835 1042">▶ Is the trade association going to participate in the PFAS restriction proposal public consultations?

How Should I Prepare A Derogation Request?

#	Suggested Tasks
6	<p data-bbox="202 281 1555 325"><i>PREPARE Initial Derogation Request:</i> [Initial Statement by 1st Deadline]</p> <p data-bbox="202 336 1130 380">From the products and risks identified in Step (4):</p> <p data-bbox="202 390 685 434"><i>Review Official Guidance:</i></p> <ul data-bbox="222 445 1709 687" style="list-style-type: none"><li data-bbox="222 445 1651 489">▶ <u>ECHA Guidance document on inputting to Annex XV report consultation.</u><ul data-bbox="338 500 1709 687" style="list-style-type: none"><li data-bbox="338 500 1709 543">▷ Pay attention to pages 1 to 3 for the overview of reportable section(s).<li data-bbox="338 554 1323 598">▷ Use the addendum as an initial skeletal structure.<li data-bbox="338 609 898 653">▷ Populate with known data.<li data-bbox="338 663 1709 687">▷ Supporting evidence is key! to justify any information being submitted. <p data-bbox="202 718 1284 762"><i>For Every PFAS Identified Repeat These Steps to Identify:</i></p> <ul data-bbox="222 773 1845 1015" style="list-style-type: none"><li data-bbox="222 773 1845 1015">▶ 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?

#	Suggested Tasks
6	<ul style="list-style-type: none"><li data-bbox="227 281 1831 426">▶ Impacted product or part numbers: (i) name; (ii) description; (iii) usage type: (a) current production part; (b) spare part; (iv) internally manufactured / assembled or sourced externally from supply chain;<li data-bbox="227 437 1831 532">▶ Identified PFASs: (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);<li data-bbox="227 543 1831 685">▶ Performance Criteria Needed: Detail the specific product features that require the PFASs to be used [<i>function of PFAS, internal / customer requirement, standards or other specifications</i>]. Explain benefits of PFAS being used.<li data-bbox="227 696 1831 791">▶ Detailed Life Cycle Analysis: Identify: (i) cradle to cradle information on PFAS and product LCA states; (ii) energy; (iii) waste, and (iv) emissions related data.<li data-bbox="227 802 1831 994">▶ Control Measures: 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;

How Should I Prepare A Derogation Request?

#	Suggested Tasks
6	<ul style="list-style-type: none">▶ 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. <p>Key:</p> <ul style="list-style-type: none">▶ 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



How Should I Prepare A Derogation Request?

#	Suggested Tasks
7	<p><i>PREPARE UPDATED Derogation Request</i></p> <ul style="list-style-type: none">▶ Repeat steps 1-6, making any updates to documentation.▶ Ensure all data is presented in a clear & concise manner.▶ Data must be based on supporting evidence.▶ Detail assumptions made and calculations undertaken.▶ Re-submit data again by the end of the public consultation (22nd Sept 3023)
8	<p><i>AWAIT Outcomes:</i></p> <ul style="list-style-type: none">▶ <i>ECHA RAC Decision (no public consultation):</i><ul style="list-style-type: none">▶ Feedback any concerns over decision to applicable Trade Association(s), they may be allowed to provide evidence outside of the public consultation window.



How Should I Prepare A Derogation Request?

#	Suggested Tasks
8	<p><i>ECHA SEAC Opinions (Draft & Adopted) Feedback Comments:</i></p> <ul style="list-style-type: none">▶ 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	<p><i>Further Reading (approaches to alternative assessments):</i></p> <ul style="list-style-type: none">▶ <u>EU Safe and Sustainable by Design Framework (2022)</u>: 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.▶ <u>EU SCHEER Guidance on Phthalates in Medical Devices (2019)</u>: Defined in the context of EU Medical Devices Regulation, does provide an approach to examining alternative substances.

