



# What is the ECHA PFAS Restriction proposal, what is the bioprocess industry doing about it ? How can we plan for the future ?



Sept 21, 2023 – Alflow SUT Conference  
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Applications & Quality

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# Who is the ECHA and what do they do ?



[ECHA Strategic Plan 2019-2023 final \(europa.eu\)](http://europa.eu)

## Mission

We, together with our partners, work for the safe use of chemicals.

## Vision

To be the centre of knowledge on the sustainable management of chemicals, serving a wide range of EU policies and global initiatives, for the benefit of citizens and the environment.



# Where do PFAS come from and what are the concerns ?

## PFAS Can Be Found in Many Places

PFAS can be present in our water, soil, air, and food as well as in materials found in our homes or workplaces, including:

- **Drinking water** – in public drinking water systems and private drinking water wells.
- **Soil and water at or near waste sites** - at landfills, disposal sites, and hazardous waste sites such as those that fall under the federal Superfund and Resource Conservation and Recovery Act programs.
- **Fire extinguishing foam** - in aqueous film-forming foams (or AFFFs) used to extinguish flammable liquid-based fires. Such foams are used in training and emergency response events at airports, shipyards, military bases, firefighting training facilities, chemical plants, and refineries.
- **Manufacturing or chemical production facilities that produce or use PFAS** – for example at chrome plating, electronics, and certain textile and paper manufacturers.
- **Food** – for example in fish caught from water contaminated by PFAS and dairy products from livestock exposed to PFAS.
- **Food packaging** – for example in grease-resistant paper, fast food containers/wrappers, microwave popcorn bags, pizza boxes, and candy wrappers.
- **Household products and dust** – for example in stain and water-repellent used on carpets, upholstery, clothing, and other fabrics; cleaning products; non-stick cookware; paints, varnishes, and sealants.
- **Personal care products** – for example in certain shampoo, dental floss, and cosmetics.
- **Biosolids** – for example fertilizer from wastewater treatment plants that is used on agricultural lands can affect ground and surface water and animals that graze on the land.

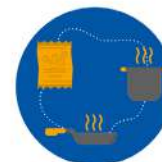


Poly- and perfluoroalkyl substances (PFAS) are manufactured chemicals that are widely used throughout society and found in the environment. PFAS resist degradation, persist in the environment and some stay in our bodies. For several of them, there are serious health concerns.

### Where can you find them?



Rain clothes, textiles and surface treatments



Non-stick coatings for frying pans and pots, and food packaging



Fire-fighting foams and fire protective clothing



Chrome plating, paints and construction materials

### How do some PFAS affect your health?

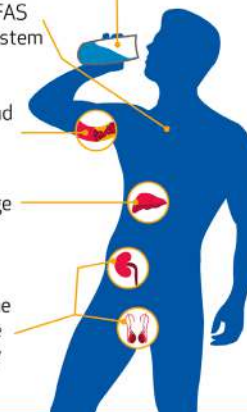
Studies have shown that PFAS have contaminated rainwater, drinking water and groundwater

Tests indicate some PFAS weaken the immune system

Can also be found in most people's blood and is linked to elevated cholesterol levels

Some PFAS can damage the liver

Studies show that some PFAS contribute to the development of kidney and testicular cancer



### What are ECHA and the EU doing?

#### RESTRICTIONS

The production and use of some PFAS are already restricted as part of the EU's chemicals legislation. A proposal to restrict all PFAS is expected in 2022.

#### 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:

[echa.europa.eu/information-on-chemicals/registered-substances](https://echa.europa.eu/information-on-chemicals/registered-substances)

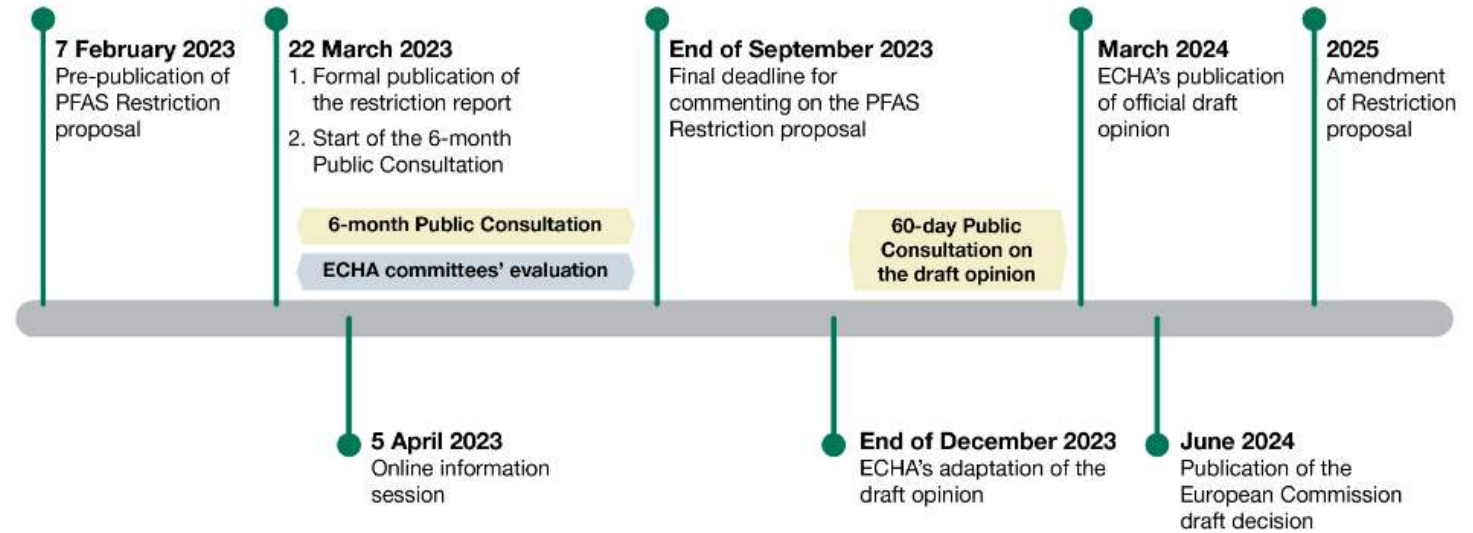




# What is ECHA proposing for PFAS restrictions

	No derogation (for certain identified sub-use(s))	Derogation proposed or for consideration (for certain identified sub-use(s))	Length of proposed / considered derogation	
			5-year	12-year
<b>TULAC</b> (textile, upholstery, leather, apparel and carpets)	✓	✓	✓	✓
<b>Food contact materials and packaging</b>	✓	✓	✓	
<b>Metal plating and manufacture of metal products</b>	✓	✓	✓	
<b>Consumer mixtures</b>	✓			
<b>Cosmetics</b>	✓			
<b>Ski wax</b>	✓			
<b>Applications of fluorinated gases</b>	✓	✓	✓	✓
<b>Medical devices</b>	✓	✓		✓
<b>Transport</b>		✓	✓	✓
<b>Electronics and semiconductors</b>	✓	✓		✓
<b>Energy sector</b>		✓	✓	
<b>Construction products</b>	✓			
<b>Lubricants</b>		✓		✓
<b>Petroleum and mining</b>	✓	✓		✓

## Responding to the PFAS Open Public Consultation



So, there is a chapter on ski wax, but not bioprocessing equipment and components.

Thus our main issue in thinking how to apply this proposal to bioprocess components and tools....."where do we fit in" ?

# BPOG is leading the way for our Industry Response



## About us

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A business-to-business membership organization, BioPhorum consists of ten phorums leading more than 110 industry-changing initiatives with the help of 7,500 active subject matter experts.

Established in 2008, we bring leaders and subject matter experts together to collaborate on challenges in existing and emerging topics that affect the whole industry including change notification, cybersecurity, extractables and leachables, forecast and demand planning, knowledge management, single-use systems, and sterile filtration. Many global companies collaborate with BioPhorum, such as license holders, manufacturers, and CDMOs. While academia and materials, equipment, IT, and engineering suppliers also send their best people to connect and collaborate.

**“Our mission is to create an environment where the global biopharmaceutical and device industry can collaborate and accelerate its rate of progress – for the benefit of all.”**

# Fluoropolymers have fundamental differences in properties versus the vast category of PFAS materials

Integrated Environmental Assessment and Management — Volume 00, Number 00—pp. 1–30

Received: 9 March 2022 | Revised: 7 June 2022 | Accepted: 7 June 2022

## Critical Review

### A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers

Stephen H. Korzeniowski,<sup>1</sup> Robert C. Buck,<sup>2</sup> Robin M. Newkold,<sup>2</sup> Ahmed El kassmi,<sup>3</sup> Evan Laganis,<sup>3</sup> Yasuhiko Matsuoka,<sup>4</sup> Bertrand Dinelli,<sup>5</sup> Severine Beauchet,<sup>5</sup> Frank Adamsky,<sup>6</sup> Karl Weilandt,<sup>7</sup> Vijay Kumar Soni,<sup>8</sup> Deepak Kapoor,<sup>9</sup> Priyanga Gunasekar,<sup>9</sup> Marco Malvasi,<sup>10</sup> Giulio Brinati,<sup>10</sup> and Stefana Musio<sup>10</sup>

This group fully support scientific and risk-based restriction of specific, hazardous PFAS that pose a danger due to bioavailability, bioaccumulative and toxic properties such as PFOA, PFOS, Gen-X and C-8- to C-14 PFCAs. However, fluoropolymers have very different properties to these PFAS of concern, are not classified as toxic and can be considered as polymers of low concern (PLC)2

Integrated Environmental Assessment and Management — Volume 14, Number 3—pp. 316–334

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Received: 26 September 2017 | Returned for Revision: 16 January 2018 | Accepted: 30 January 2018

## Critical Review

### A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers

Barbara J Henry,\*† Joseph P Carlin,† Jon A Hammerschmidt,† Robert C Buck,‡ L William Buxton,‡ Heidelore Fiedler,§ Jennifer Seed,|| and Oscar Hernandez#

†WL Gore & Associates, Elkton, Maryland, USA

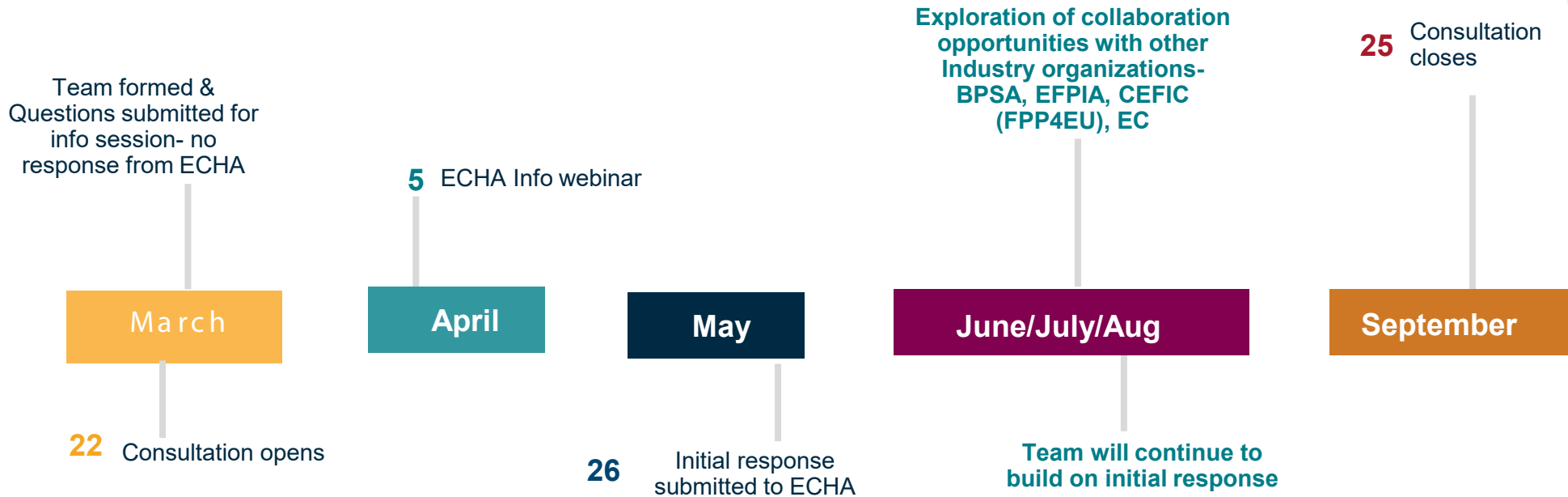
‡Chemours Company, Wilmington, Delaware, USA

§MTM Research Centre School of Science and Technology, Örebro University, Örebro, Sweden

||Risk Assessment Consultant, Alexandria, Virginia, USA

#Bergeson & Campbell, Washington, DC, USA

# PFAS Response Team Timeline



Response submitted to ECHA & published on BioPhorum.com [link](#)

Linked in campaign : [\(24\) Post](#) | [Feed](#) | [LinkedIn](#)





# The Basis of our Position on the Implications of this proposal on our industry

The extensive use of PFAS across the biopharma sector in medically critical applications:

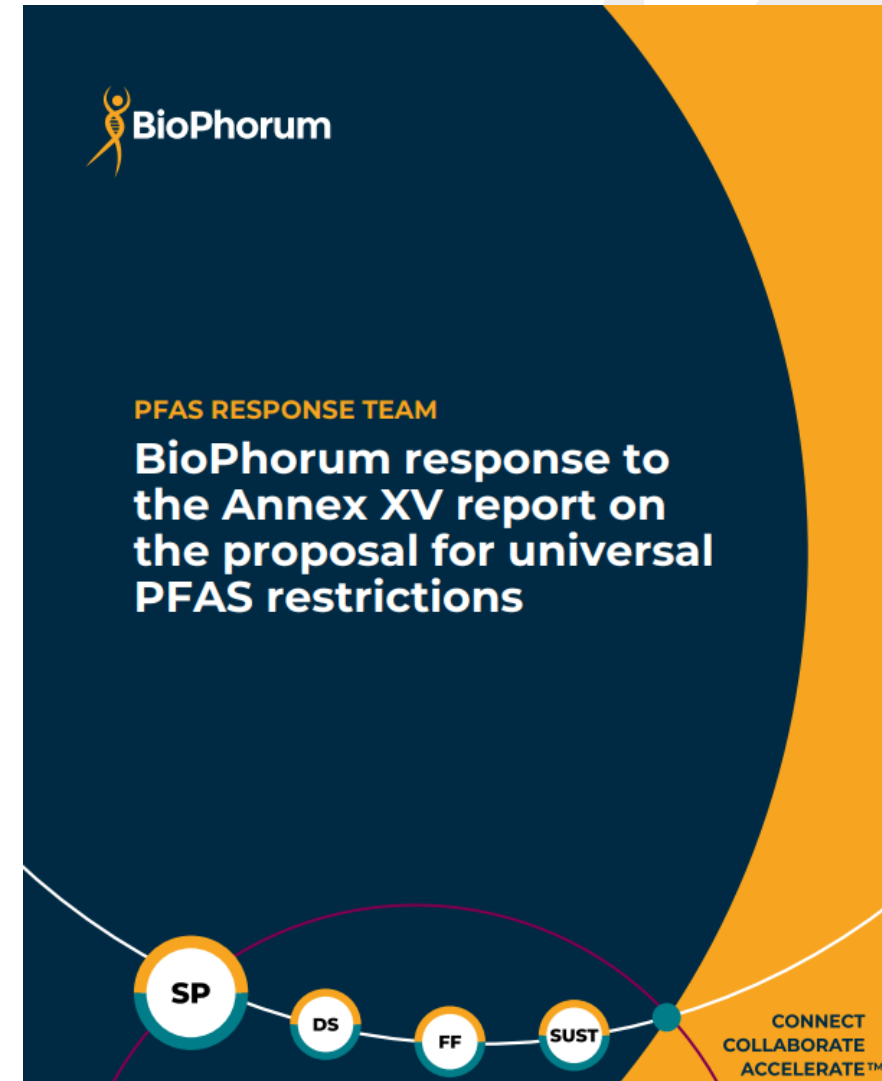
Biopharma sector as a missing use category

The impact on our industry of sourcing, testing, and validating PFAS alternatives

Impact on approvals by Regulatory Authorities—increased risk of supply disruptions

Categorization of Fluoropolymers vs PFAS

Improved environmental stewardship and waste management vs a wide-reaching ban



[The ECHA's proposed ban on PFAS and the impact on biopharma \(biophorum.com\)](https://www.biophorum.com)

# What are we asking for?

BioPharma industry should be considered a missing use category and be exempt from all proposed restrictions where alternatives are not available

**EXEMPTION** for any **direct** fluoropolymer materials used in BioPharma processing with critical quality attributes (direct impact on product quality).

**EXEMPTION (or at least maximum derogation -13.5yrs?)** for **other PFAS** materials used in BioPharma manufacturing processes (including manufacturing precursors and intermediates).



# Key steps for the team

Compile and submit initial response

Complete – submitted 26<sup>th</sup> May

[BioPhorum response to the Annex XV report on the proposal for universal PFAS restrictions - BioPhorum](#)

Continue to gather data to substantiate claims and submit further response

Team will meet fortnightly until consultation closes 25<sup>th</sup> Sep

Currently focusing on Q6 of ECHA request for additional information (see over)

Continue to work with other industry bodies to raise awareness and to align as an industry on our position

Alignment with CEFIC (FPP4EU), BPSA, EFPIA

Meeting held with European Commission 19<sup>th</sup> July – report attached





# Our Response May Be Having an Impact

## EU to drop ban of hazardous chemicals after industry pressure

**Exclusive: Leaked documents show that as little as 1% of products containing hazardous substances could be prohibited**



CHEMICAL REGULATION

## The battle over PFAS in Europe

Industry pushes back on government proposal to ban fluoropolymers

by *Alex Scott*

September 18, 2023 | A version of this story appeared in **Volume 101, Issue 31**



[The battle over PFAS in Europe \(acs.org\)](https://acs.org)

[EU to drop ban of hazardous chemicals after industry pressure | PFAS | The Guardian](#)

# BPOG Mapping of PFAS application

The team have started mapping usage of PFAS across the industry and identifying if alternatives are available.

Application	PFAS Type	Possible Alternatives
Liquid filtration- filter membranes	PVDF	alternatives for PVDF (PES/nylon/cellulose)- may not have same performance, will require extensive testing and revalidation
Films/plastics (1° contact material) in Containment of drug intermediates and final product (containers/films/bottles/vials/syringe stoppers/ Single use processing bags/SU bioreactors plus probes/inserts)	PVDF, PTFE bottles, FEP bags/bottles, PFA glass vial lining	
Tubing & tube fittings (manufacturing engineering systems,) incl gaskets & O-rings	PVDF FKM (tubing/O-rings/gaskets) FEP PFA	<ul style="list-style-type: none"> <li>•tube fitting alternative = polysulfone, polycarbonate (will require revalidation)</li> <li>•no suitable alternatives for tubing capable of matching PFAS properties</li> </ul>
Vent Filtration	PVDF and PTFE	no alternative for PTFE used in Steam In Place (stainless steel) vent filters. some membranes have PFAS coatings)
Support filters (e.g. HEPA)	PTFE other materials with hydrophobic or non hydrophobic coating	
Hardware systems (lined pipes, TFF cassette seals/components/solvent exchange systems/lined valves/gaskets). Pumps & components (diaphragm)	PVDF PTFE FKM	
Electrical components, heat and/or chemical resistant, non reactive coatings/insulation/lubricants/Refrigerants, electrical wiring	PTFE on its own or as an additive in ABS and polycarbonate	
PTFE thread sealing tape	PTFE	



# BPOG View Impact of Material Changes on Biopharmaceutical



Depending on Product Lifecycle Stage and Criticality of Disposable, multi-year Change Process to be expected

Step	Activity	Estimated Timeline
Development of a new suitable disposable	Selection of small scale disposables, ordering, testing in small scale studies	at least 6 months
Establishment of the new disposable in GMP environment	Change Request, inventory system update, review of certificates and documents, ordering, initial E&L assessment	1-2 months
	development of release testing method (e.g. primary packaging)	2-6 months
Ordering of GMP / full scale disposable	Procurement, Supplier Lead Time	3-12 months
Release of Disposable	Check of batch certificates + documents / Release testing	0.5 months 2 months (if QC testing required, e.g. prim. packaging)
Supplier / Manufacturer Qualification	staged concept, Questionnaire up to Auditing	6 months
Validation (late phase / commercial)	Component validation in several batches (compatibility, functionality,...), process validation (if needed), comparability exercise for resulting DS/DP (release testing, stability studies,...), Leachable studies	6-12 months + stability (years)
Regulatory Filing of Changes / Amendments	Update of TRDs, Submission to relevant Health Authorities	years, depending on number of countries



Most recent submission to specifically answer question proposed in open consultation period

Hot off press just completed 19 – Sept - 2023

**BioPhorum Response to the Annex XV report on the proposal for universal restrictions (Part II)**

Contact: [louisa.mitchell@biophorum.com](mailto:louisa.mitchell@biophorum.com)

**Connect  
Collaborate  
Accelerate™**

- Our More detailed response to improve and include more evidence to back our arguments on the impacts of proposal and desire to seek lifetime derogation for our industry
- Will be socialized on linked in and through networks
- Will be posted on BPOG website

# How we as Industry can continue to improve sustainability and practice environmental stewardship if exemption is received

Research News

## 'Forever chemicals' destroyed by simple method

New process causes PFAS to degrade into benign end products

September 12, 2022

['Forever chemicals' destroyed by simple method | NSF - National Science Foundation](#)

[PFAS chemicals do not last forever | News \(ucr.edu\)](#)

<https://www.nytimes.com/2022/08/18/science/pfas-forever-chemicals.html>

- Entegris has capable recycler for fluoropolymers including Aramus
- Feasibility studies on post gamma irradiated material are being completed
- We are interested to pilot take back / recycle program with Aramus customers

[Recycling and the end of life assessment of fluoropolymers: recent developments, challenges and future trends - Chemical Society Reviews \(RSC Publishing\)](#)

A background image showing silhouettes of five business professionals in a meeting, overlaid with a city skyline and a network of glowing blue lines. The scene is set against a light blue sky and water.

# Questions and Discussion