Simplifying Progress

Understanding PFAS in Biopharma Manufacturing

How current and emerging regulations are shaping the industry

May 2026 | Markus Junior Maring, Dr. Lukas Raddatz

Keywords or phrases:
PFAS, PFAS restriction, PES membranes, Sartopore Evo® filters, sterile filtration, adsorption, strategic quality, fill and finish, regulatory compliance, REACH, PFAS alternatives

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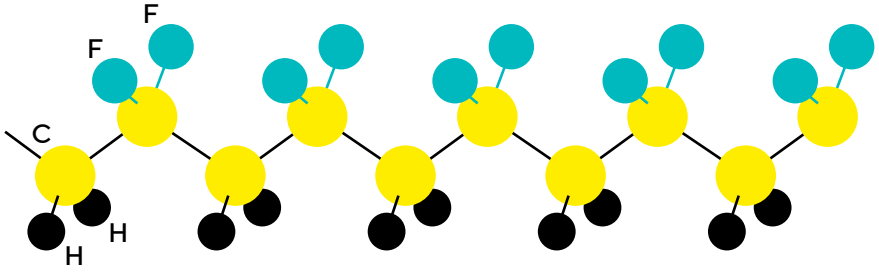
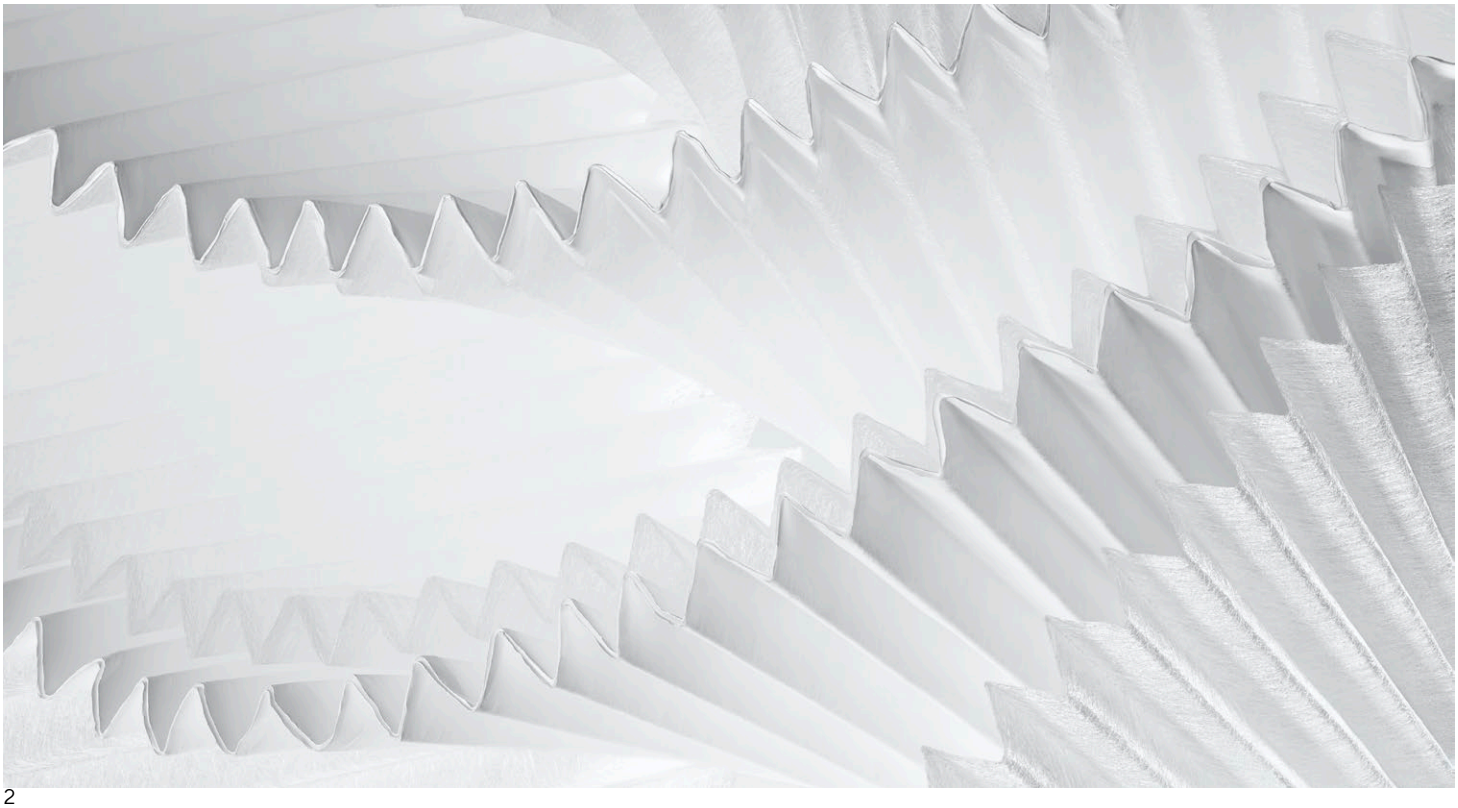
Introduction

Per- and polyfluoroalkyl substances (PFAS; Figure 1) are a large class of synthetic chemicals that have been widely used in industrial and consumer products since the mid-20th century, owing to their remarkable durability and physical properties, which offer oil | water repellence, chemical stability, and heat resistance.[1]
These unique characteristics are due to the highly stable polar carbon-fluorine bonds, which are among the strongest in organic chemistry. This structural stability is a key reason many PFAS resist degradation in the environment and can persist for long periods.[2,3]

However, this persistence has led to PFAS being given the label of "forever chemicals" and becoming a major focus of environmental monitoring and management worldwide. The U.S. Environmental Protection Agency (EPA)[4] and the European Chemicals Agency (ECHA)[3] highlight that some PFAS substances accumulate over time in soil, water, and living organisms. This accumulation raises significant concerns, with links to pathological inflammation and cancers.[5]

Figure 1: Molecular structure of PVDF, a PFAS polymer





PFAS polymers vs. PFAS surfactants

Importantly, PFAS are not a single substance: thousands of different chemicals fall under the PFAS umbrella, and the available hazard evidence varies significantly across individual PFAS.[6] When discussing PFAS in industry, it is critical to distinguish longer-chained polymeric PFAS, including fluoropolymers (Figure 1), from non-polymeric PFAS, including perfluorinated and partly fluorinated (telomeric) alkanes, cycloalkanes, alcohols, acids, esters, ethers, reactive molecules (acrylates, methacrylates, etc.), and PFAS gases.

PFAS polymers are generally more inert than short-chained PFAS, do not naturally deteriorate, and do not pose an immediate health risk. In contrast, PFAS surfactants—e.g., C8 (PFOA)—exhibit ecotoxicity, and are the main contributors to PFAS-associated pathologies.[7] These short-chained, water-soluble substances are already subject to regulation and restriction.[8] Health evidence is strongest for a subset of well-studied PFAS surfactants (such as PFOA and PFOS). For example, the International Agency for Research on Cancer (IARC) has classified PFOA as carcinogenic to humans (Group 1) and PFOS as possibly carcinogenic to humans (Group 2B), reflecting the evolving evidence base and ongoing scientific scrutiny.[9]

It is PFAS polymers—not surfactants or other short-chained PFAS—that are used in biomanufacturing equipment, including some products in the Sartorius portfolio. These polymeric materials are generally considered to present low exposure risk during use. In 2025, the U.S. Food and Drug Administration (FDA) issued an official statement affirming the essential role of fluoropolymers in life-saving medical devices and noting their safe use in such applications for decades.[10] However, scientific and policy discussions increasingly focus on life-cycle considerations, particularly upstream and monomer manufacturing as well as end-of-life management.

As materials containing PFAS have been widely adopted by multiple industries due to their performance-enhancing capabilities, the risk of a potential ban | restriction has spurred heated debates, turning them into a focal point of global environmental policy and industry discussions.

In this white paper, we provide an overview of the current status of evolving PFAS regulations, their potential impact on biopharmaceutical production, and introduce alternative solutions to help the industry respond to these changes.

The Importance of PFAS in Biopharma

PFAS are seldom added to pharmaceutical formulations; however, some active substances and excipients contain perfluorinated groups. Instead, PFAS polymers are most commonly found within the materials of construction of biopharma manufacturing equipment including coatings, seals and gaskets, filter membranes, connectors, and certain types of tubing (where chemical resistance, thermal stability, and low interaction with process fluids are required).[11] These applications fall within the scope of the regulatory framework currently under development in the EU.

In the highly regulated manufacturing of pharmaceuticals, patient safety is protected through tight process validations, in-process controls, and rigorous product quality controls. As such, validated PFAS materials do not pose a process or patient risk. To ensure compliance, only process materials that have been demonstrated not to release substances from their materials of construction into the process stream—and therefore not to introduce such substances into the final drug product—are selected. From a product quality perspective, many fluoropolymer materials are valued because they are generally inert and have a low propensity to interact with process fluids during use.

Despite this, attention to PFAS is increasing in the public eye as a health risk and sustainability concern, with fast-moving consumer goods already using "PFAS-free" claims in their branding.

As a result of increased public scrutiny, the regulatory environment is evolving. In the EU, several PFAS are already regulated, and a broader PFAS restriction proposal under REACH is being evaluated, with outcomes and transition provisions still under development.[12, 13] Selecting materials for future aseptic processes will require a combined view of performance, supply security, environmental impact, and regulatory readiness.

Regulatory landscape and industry progress

Governments and industry groups are actively tightening oversight of PFAS, driven by concerns about persistence, emissions, and exposure, and by significant societal pressure for reduction of emissions and PFAS substitution. Global initiatives such as the Stockholm Convention[14] and related UN frameworks[15] contribute to regulatory convergence, particularly for PFOS, PFOA, and PFHxS. While the Stockholm Convention is an international agreement, it becomes legally binding only through implementation in national legislation, which in the EU is achieved via POPs regulations.

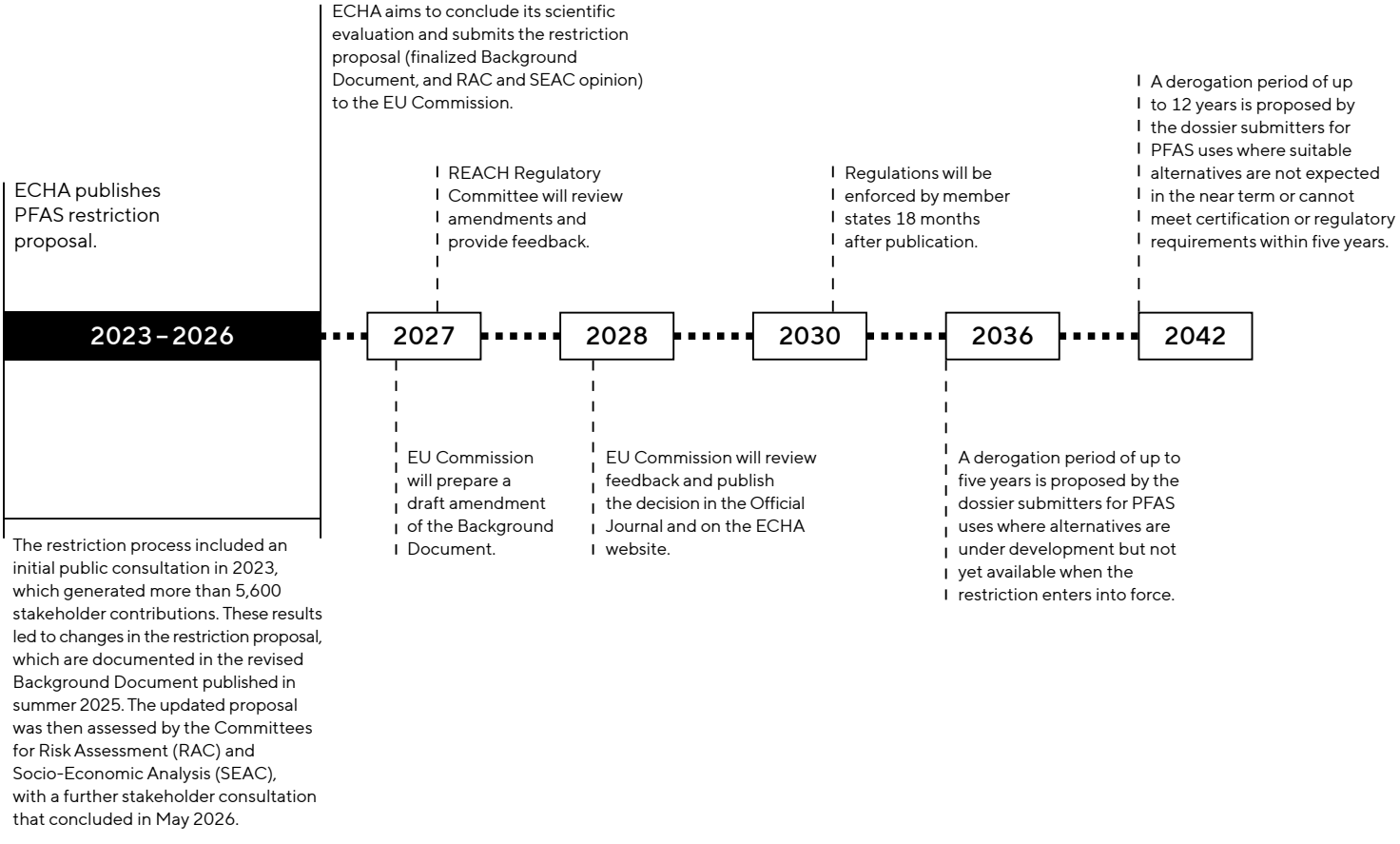
European Union

In the EU, authorities from Denmark, Germany, the Netherlands, Norway, and Sweden submitted a broad PFAS restriction proposal to the ECHA on 13 January 2023 under the REACH restriction process.[16] ECHA's public consultation ran from 22 March to 25 September 2023 and received over 5,600 stakeholder comments.[13]

Rather than an outright ban, the proposal is a comprehensive restriction package that groups all PFAS together under a single regulatory framework, with controls applied differently across use cases. The Annex XV work has historically described restriction options that range from a broad restriction after a transition period to derogations | exemptions for certain uses, with proposed timelines that can extend to 13.5 years (transition period plus longer derogation periods), subject to the ongoing socio-economic evaluation (Figure 2).[17]

ECHA published an updated restriction proposal in August 2025 and invited stakeholders to provide information on the Committee for Socio-Economic Analysis (SEAC) draft opinion in spring 2026,[18] with the committees aiming to conclude their scientific evaluation by the end of 2026.[12] Subsequent EU decision-making will follow.

Figure 2: Estimated timeline for PFAS regulations in the EU



If broad EU PFAS restrictions are adopted—with exemptions for certain sectors such as military applications, medical implants, or areas lacking viable alternatives—the practical implications will depend on which restriction approach is ultimately adopted. In the updated PFAS restriction documentation,[12] the dossier submitters assess three main restriction options (ROs):

- **RO1:** a broad restriction (full ban) after an 18-month transition period
- **RO2:** a restriction with time-limited derogations (typically 6.5 or 13.5 years depending on substitution feasibility and implementation timelines)
- **RO3:** continued use in limited cases under strict emission limits and | or additional emission controls.

For the biopharmaceutical industry, the EU Commission's decision on the PFAS restriction proposal carries significant uncertainty. Regardless of which restriction option ultimately applies to process materials, process owners will face substantial effort to evaluate existing materials, assess sourcing and supply risks, and implement amendments to approved product and process dossiers. In some cases, this may require lengthy revalidation activities and resubmission to regulatory authorities. Industry groups have highlighted these challenges in their responses to the restriction proposal.

United States

In the U.S., the EPA finalized national drinking water standards for several PFAS in April 2024, implemented under 40 CFR Part 141 (Subpart Z) (with associated implementation under Part 142).[19]

In parallel, EPA has expanded PFAS oversight through other federal authorities, including:

- Toxic Substances Control Act (TSCA) PFAS reporting requirements under 40 CFR Part 705 (TSCA section 8(a)(7)).[20, 21]
- Designation of PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), enabling release reporting and supporting cleanup accountability.[22]

Individual U.S. states have their own laws. At this level, PFAS restrictions increasingly focus on specific CERCLA product categories (e.g., food packaging, textiles, and cosmetics), and the legal requirements vary materially by state and application. In Minnesota, "Amara's Law" introduces phased prohibitions beginning January 1, 2025, and expands toward a broader prohibition by January 1, 2032, subject to "currently unavoidable use" determinations.[23]

In summary, the use of PFAS is not prohibited but is subject to regulatory restrictions.

Canada, Australia, and Asia-Pacific

Canada is advancing a PFAS risk management approach (notably with a defined scope that excludes fluoropolymers in the referenced federal approach) and is consulting on reporting and release-reduction mechanisms.[24, 25]

Australia has updated national drinking water guidance on PFAS (June 2025) and is also implementing controls consistent with Stockholm Convention listings (e.g., measures addressing PFOS, PFOA, and PFHxS).[26, 27]

Across parts of Asia-Pacific, multiple jurisdictions are strengthening PFAS management—often focusing first on Stockholm-listed PFAS. For example, the Organisation for Economic Co-operation and Development (OECD) country summary notes that Japan's framework includes drinking water targets and planned tightening of standards, alongside measures addressing production and use.[28]

Responses from industry consortia

Industry groups are also responding to proposed legislation. A joint statement from the European Federation of Pharmaceutical Industries and Associations (EFPIA), Life Science Manufacturers Association (LSMA), and other healthcare associations raised concerns about ECHA's decision not to conduct an individual evaluation on the impacts of PFAS restrictions on the healthcare sector.[29] They urged for a proportional, targeted approach and industry collaboration to define a clear process for applications where alternatives are unavailable.

BioPhorum has advocated for a pragmatic approach to PFAS restriction in the biopharmaceutical industry.[30] They emphasize the importance of considering both environmental concerns and the socio-economic impact of potential drug shortages, noting that 100% of biopharmaceuticals currently being developed or already licensed for sale in the U.S. use PFAS somewhere in the drug manufacturing process. Active collaboration between industry groups is ongoing to navigate these changes.

Practical Implications for Biopharma

For the biopharma industry, any regulatory outcome that drives material changes (e.g., filters, tubing, seals, packaging components) is likely to increase the cost and workload associated with quality risk management, supplier qualification, extractables and leachables assessment, and process validation activities.
The scope of the impact will be use-case specific and driven by the extent of required substitutions and the criticality of the component to product quality.
The risks are summarized in Figure 3. Additional operational implications are listed below.

Expanding documentation expectations
A higher standard for supplier documentation will be expected as regulations tighten. Many companies are already requesting increased transparency through, for example, PFAS content disclosures and substantiated "PFAS-free" claims with clearly stated scope and test basis.

Rising substitution pressure
Components containing PFAS polymers (e.g., PVDF-based elements, fluoropolymer liners, certain elastomers | coatings) are likely to face heightened scrutiny. Authorities may question whether alternatives such as PES or other non-PFAS materials could also meet process performance. Manufacturers may be expected to justify material selection and demonstrate that any substitutions meet performance and quality requirements.

Regulatory compliance while meeting performance requirements
When replacing PFAS-containing components, alternative materials must withstand regulatory scrutiny without introducing new patient, product, or process risk.
EU GMP Annex 1 emphasizes a risk-based approach to material selection and process design, including demonstration that (i) the chosen material does not adversely affect the product (e.g., via extractables and leachables or adsorption), and (ii) the process fluid does not adversely affect the material (e.g., via chemical compatibility, swelling, embrittlement, or performance drift).[31]

Accordingly, non-intentionally-added PFAS alternatives should demonstrate comparably low-risk extractables and leachables profiles, chemical compatibility under relevant operating ranges (including pH, temperature, and exposure time), mechanical and functional stability, and integrity assurance across the full use scenario (including sterilization and in-process hold times). In parallel, the alternative must meet process performance requirements, such as throughput | capacity, flow | flux, pressure-drop behavior, and retention, while maintaining acceptable adsorption characteristics (e.g., minimal binding of product, proteins, or key excipients such as polysorbates) to avoid yield loss or unintended shifts in product quality.
As such, a strategic view of quality is advisable.

Figure 3: Risks of PFAS restrictions in the biopharma industry

Material supply

Many raw material suppliers and chemical manufacturers are moving away from PFAS, affecting vendor supply and disrupting the availability of bioprocessing equipment and consumables for drug manufacturers.

Limited alternatives

For many biopharmaceutical applications, alternatives to PFAS that provide the required chemical resistance and physical properties for reliable performance are limited or not readily available.

Change control

Where alternatives are available, characterizing and validating their suitability within individual processes will be hugely time-consuming and costly. Capacity limitations at third-party validation services and regulatory authorities may create additional bottlenecks.

Drug supply

The development of new therapies may be hindered, and the supply of existing medicines could be disrupted.

Proactive planning

The current regulatory uncertainty is already impacting material supply. Key manufacturers are starting to limit their use of PFAS; at the end of 2025, 3M ceased all PFAS manufacturing, including fluoropolymers and PFAS-based additive products,[32] and BASF has stated it will phase out chemical products formulated with PFAS.[33]

These measures are motivating many biopharma manufacturers to evaluate alternative materials and suppliers for critical components to reduce business continuity risk. Depending on how restrictions and derogations are implemented, upstream supply and capacity decisions could affect availability, lead times, and pricing for certain PFAS-containing materials.

Regardless of the outcome, users of PFAS-containing materials would be wise to evaluate current and future alternatives to avoid any surprises and ensure their supply is future-ready. Companies that consider these implications now—by auditing suppliers and integrating PFAS-free alternatives—will avoid costly remediation and stay ahead of changing regulations.

The search for alternatives

For many use cases, there is currently no suitable alternative to PFAS-containing materials. A recent meta-study underscores the challenges of finding alternatives to PFAS across multiple industries.[34] Using AI-assisted screening of more than 35,000 scientific publications, the study identified 420 candidate materials, which were evaluated against critical PFAS functionalities. They found that only a very small number of candidates could partially replicate required performance, and in many applications no viable substitutes were identified. The experts emphasize that large-scale substitution is currently limited by technical constraints, long development timelines, and a high probability of regrettable substitution.

However, in response to evolving regulatory requirements affecting biopharmaceutical manufacturers, suppliers are increasingly motivated to support the industry by developing and bringing PFAS-alternative process materials to market. Sartorius believes that such targeted regulatory constraints can act as a catalyst for technological advancement, driving increased research activity and the development of novel material solutions that may not have been prioritized in the absence of these requirements.

Implications for Sterile Filtration

One of the most significant impacts of PFAS restrictions in biopharmaceutical manufacturing will be on fill and finish operations: many processes rely on sterilizing-grade filters, and PVDF membranes are widely used for their robust performance and low binding characteristics. PVDF is a fluoropolymer and may fall within PFAS definitions used in some regulatory and policy contexts.

Historically, membrane selection for final sterile filtration has been formulation-dependent. Polyethersulfone (PES), while used in many buffer filtrations and some final filling applications, has typically been associated with high adsorption of excipients and, therefore, not seen as a viable substitute for sensitive applications. In response to increasing PFAS scrutiny and customer demand for alternative options for sterile filtration, Sartorius has introduced a new generation of PES sterilizing-grade filter: Sartopore Evo®. Sartopore Evo® filters are engineered with a unique modified PES membrane, designed to minimize adsorption of proteins and excipients to support formulation stability in fill and finish operations.[35, 36]

Sartopore Evo® filters deliver the well-known high performance (higher flowrates and throughput) associated with PES membranes when compared to traditional PVDF membranes, but with equal to or lower adsorption of polysorbates and proteins, for which PVDF membranes were traditionally selected.[37] As such, it offers the strong performance associated with PES and low adsorption of PVDF, being manufactured without PFAS materials.

For further information on Sartopore Evo® filters, visit
sartorius.com/sartopore-evo

PFAS FREE

Use caution with "PFAS-free" claims

There is currently no universally accepted definition of "PFAS-free," and the absence of clear test standards can make such claims difficult to substantiate.

Where PFAS-related claims are made, they should be explicitly scoped (e.g., materials of construction; no fluoropolymers; no intentionally added PFAS in defined manufacturing steps) and supported by supplier declarations and | or analytical screening with stated methods and limits of detection.

Sartorius Commitment to Sustainability, Quality, and Performance

Owing to their higher throughput and more efficient flow profile compared to PVDF membranes, Sartopore Evo® filters can reduce the number or size of filter elements required per batch. This minimizes disposable waste and also lowers the total cost of ownership, supporting both sustainability goals and lean manufacturing initiatives (note that the impact is process-specific and should be assessed through sizing and validation testing). By providing a non-fluoropolymer sterilizing-grade option for sensitive final filtration, the platform can also support evolving customer expectations for material transparency.

Beyond individual products, addressing PFAS-related expectations also requires a coordinated, global approach. Sartorius has established a cross-functional PFAS program to evaluate our use of PFAS, implement strategies for impacted products, and develop a product lifecycle management roadmap. We are also participating in international initiatives to provide feedback and help shape future PFAS legislation.

For further information on sustainability, visit
sartorius.com/en/company/sustainability

Conclusion

PFAS regulation is redefining how the biopharma industry approaches materials, supply chains, and sustainability. As global trends change and as regulators increase their focus on PFAS, biopharma companies must also adapt to ensure product integrity while ensuring compliance.

At Sartorius, we are committed to providing transparent, reliable information on evolving regulatory changes and supporting our partners in maintaining resilient supply chains to help ensure the continued availability of life-saving drug products, while actively developing new products without the intentional use of PFAS.

Contact us to find out more about PFAS regulations.

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For more information about fill and finish, visit
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Markus Junior Maring is Product Manager for Sterile Filtration at Sartorius, where he leads the rollout of Sartopore Evo®, a new generation PES filter designed to meet evolving regulatory and sustainability requirements. With a background in microbiology and medical engineering, he spent 14 years in pharmaceutical quality roles, working closely with manufacturing operations before moving into product development.

Markus joined Sartorius in 2022, working in Confidence® Validation Services, where he supported biopharma customers in complex validation projects. He is currently pursuing an MBA at Edinburgh Business School.

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Dr Lukas Raddatz is PFAS Program Manager at Sartorius, coordinating and overseeing the company's cross-functional activities around PFAS to advance compliant, sustainable product strategies. In parallel, he serves as Manager of Manufacturing Technology R&D, leading a team that scouts and evaluates technologies to accelerate product development and enable custom solutions.

Before joining Sartorius in 2019, he completed his studies in Germany and the United States and earned his PhD in Biotechnology and Chemistry from the University of Hannover (Germany).

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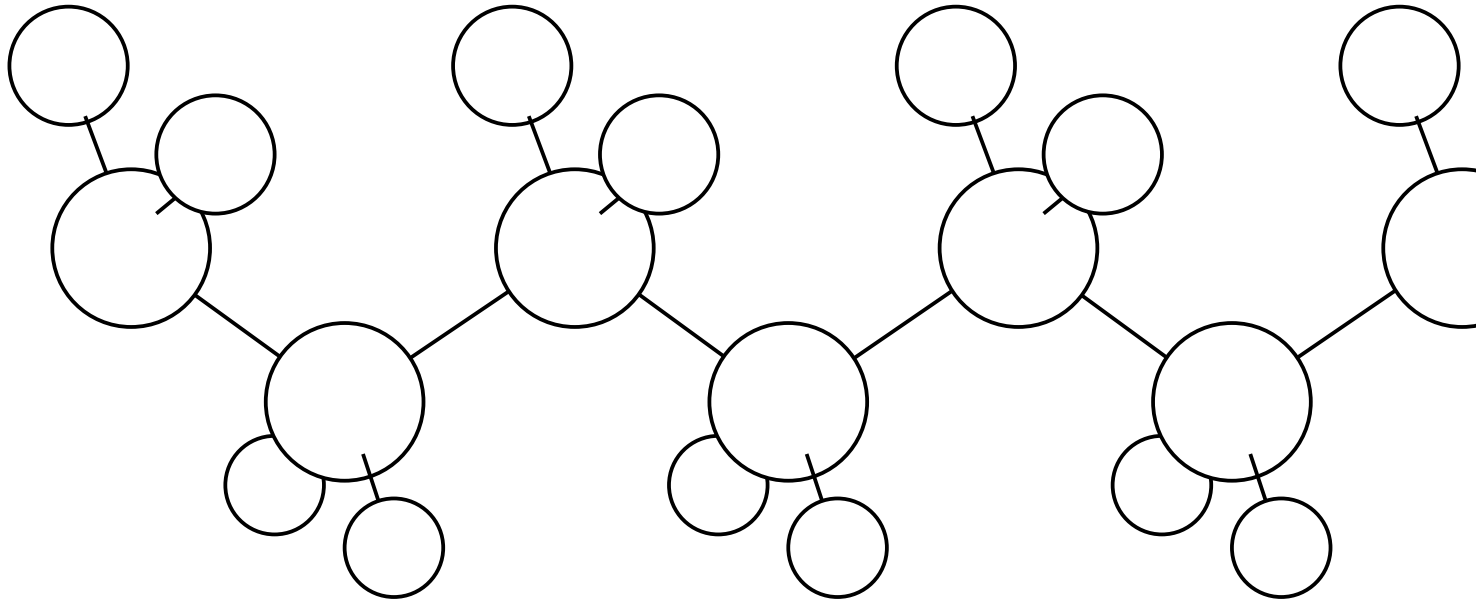

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Last modified: 06 | 2026