



SPECTARIS on the ongoing PFAS restriction process in the EU **“PFAS ban must not become a high-tech ban”**

Since the draft regulation on the restriction of PFAS (per- and polyfluoroalkyl substances) was submitted by the competent REACH authorities in Germany, the Netherlands, Denmark, Sweden, and Norway in February 2023, the European Union has been engaged in the most comprehensive regulatory process in its history. It is unprecedented in its scope, its systematic approach, and the large number of substances addressed, each with different intrinsic properties.

The evaluation process at the level of the ECHA's scientific committees – the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) – is in its final phase, with considerable delays. The updated background documentⁱ was made available to the general public on August 20, 2025. It comprises around 3,500 pages, including appendices, and contains proposals for mostly temporary exemptions from the comprehensive ban, both for manufacturing itself and for 14 sectors. Eight additional sectors were identified during the evaluation of the public consultation by the dossier submitters. However, due to time constraints, these will not be evaluated in depth by ECHA before the dossier will be submitted to the EU Commission.

A far-reaching PFAS ban with temporary derogations based on a complex assessment system is planned. Despite considerable data uncertainty and questionable consistency of these criteria, the originally proposed transition periods are going to be implemented: a basic period of 18 months plus additional derogations of 5 or 12 years, resulting in total periods of 1.5, 6.5, and 13.5 years. These are each linked to extensive requirements for the entire value chain. This restriction logic marks a paradigm shift in European chemicals policy. This is problematic in that the ban also covers the subgroup of fluoropolymers, which have a very low risk profile and are indispensable and largely irreplaceable for high-tech industries.

The consultation process on the SEAC's preliminary opinion, which is anchored in the process and is expected to begin in March 2026, is set to last 60 days. In contrast to the previous open consultation format, it is to take place in a standardized questionnaire format with predefined questions and without the possibility of submitting technical documents. This type of consultation actively opposes the request for new findings, new studies, and well-founded feedback from stakeholders since the last consultation in 2023, in favor of an untransparent and hasty approach.

Fluoropolymers in particular are characterized by a unique combination of technical properties: they are temperature, pressure, and corrosion resistant, chemically inert, and mechanically flexible. It is precisely this combination of necessary technical properties that is the basis for regulatory criticism: environmental persistence is the only justification for

Contact: Jörg Mayer, Managing Director

SPECTARIS • German Industry Association for Optics,

Photonics, Analysis and Medical Technology e. V.

Robert-Koch-Platz 4 (postal address) | Hannoversche Str. 19 (visiting address) | D-10115 Berlin

www.spectaris.de | Email: mayer@spectaris.de



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German Industry Association for Optics,
Photonics, Analytical and Medical Technologies

restricting the entire group. No scientific evidence of specific risks to humans and the environment has been presented. Persistence has the physical dimension of time and, by itself, does not constitute a risk.

The proposed restrictions affect a large number of key areas of application in analytical, bio, and laboratory technology, optics, photonics, and medical technology, not only in terms of end products, but also in terms of their manufacturing processes, in which PFAS play a key role. SPECTARIS, as the industry association for these German high-tech industries, remains extremely concerned about the PFAS restriction process. Ultimately, the background document leads to micromanagement that cannot be controlled by either the regulatory authorities or the finely interlocking parts of the highly complex supply chains.

SPECTARIS criticizes crucial points, both with regard to the chosen regulatory logic and the procedure itself. With regard to the SEAC assessment, there are considerable concerns that meaningful conclusions will be drawn on the basis of limited, insufficient information requests. This is underscored by the fact that the eight newly identified sectors will neither be dealt with separately in the ECHA's scientific committees nor be part of the upcoming consultation in any depth, meaning that only a selective excerpt will be available as a basis for decision-making. If a sectoral approach is unavoidable, it must be comprehensive in terms of applications, their ecosystems, and their supply chains. We fundamentally criticize the scientific standard, which does not correspond to a normal peer review process and can be considered biased in certain parts. It is incomprehensible that opinions based on outdated and incomplete discussions are to be presented to the Commission.

We consider the path proposed so far to be an accelerator of further deindustrialization in Europe, with irresponsible collateral damage for Europe as a center of technology, research, and health, which will ultimately drive these unique structures and our innovative key industries out of Europe.

Our key recommendations are:

- **Return to a risk-based approach**
- **Remove fluoropolymers from the scope of application, regulate emissions**
- **Ensure practical manageability**
- **Stop the regulatory spiral**
- **Realistic transition periods**
- **No double regulation, no forgotten applications**

The PFAS group restriction must not set a precedent for future group regulations. Regulation based primarily on structural similarity rather than substance-specific risk assessment runs the risk of being extended to other groups of substances. This leads to disproportionate restrictions, considerable legal uncertainty, and far-reaching consequences for innovation, security of supply, and European value chains, without any discernible benefit to the environment or health. The basic principles of the REACH Regulation – risk-based, substance-specific, and proportionate – must therefore be upheld.

SPECTARIS urgently calls for political decisions at the highest level to fundamentally correct the course that has been set. Although the comitology procedure will not officially start until the end of 2026, we need reliable political signals very soon. In particular, we expect clarification of what the legislator understands by a risk-based approach under REACH and what considerations need to be made in order to determine an unacceptable risk. There are conflicting views on this issue on the part of both the Commission and the German government, which is why the German government's position in the REACH Committee can only be determined after thorough interministerial consultation, taking economic policy considerations into account. Industry needs certainty immediately, as this is a key prerequisite for investment, technological development, and competitiveness. The REACH Regulation – also with a view to the upcoming revision – must be implemented in line with the strategic objectives of the EU Competitiveness Compass 2025.

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SPECTARIS • German Industry Association for Optics,

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Robert-Koch-Platz 4 (postal address) | Hannoversche Str. 19 (visiting address) | D-10115 Berlin

www.spectaris.de | Email: mayer@spectaris.de

The updated dossier (background document)

The background document (BD) published in August 2025 has fundamental methodological and procedural weaknesses that make it considerably more difficult to reliably assess the PFAS restriction. It is based neither on a classic REACH risk assessment nor on a consistent hazard analysis, but follows a mixture of the precautionary principle, a zero-emission approach, and a structure-based substance group principle. As a result, fluoropolymers remain within the scope of the regulation despite their very low risk profile, emissions are assessed independently of actual exposure, and substitution options are either assumed across the board or even used as justification for a blanket ban.

In addition, the document has an incomplete data basis, unrealistic transition periods, and incorrect assumptions about substitutability. These are factors that significantly limit practicable and proportionate regulation. Despite the submission of extensive information by stakeholders from all industrial sectors, it remains unclear why some contributions were not taken into account or were rejected. In particular, there is a lack of comprehensible justification for technically demanding applications and the PFAS derogation criteria. Inconsistencies and technical uncertainties, for example in the classification of optical applications such as eyeglass lenses or analytical equipment used beyond research and development, illustrate that the background document does not adequately and, above all, incompletely reflect key industrial realities.

SPECTARIS' key recommendations:

1. Return to the risk-based approach in accordance with REACH Article 68

SPECTARIS advocates a consistent return to the risk-based approach of the REACH Regulation, which requires a demonstrably unacceptable risk to health or the environment. An unfounded blanket assumption of risk throughout the life cycle is not sufficient for this. The argumentation of persistence as a significant cause for concern, as provided for in the restriction proposal, represents a departure from this proven risk-based principle: persistence alone as a dimension of time does not constitute an immediate risk; only in combination with exposure and hazard potential does it provide a sound basis for assessment. The PFAS group comprises over 10,000 substances with significant differences in physicochemical properties, exposure pathways, and resulting risk profiles. This heterogeneity requires differentiated, risk-based regulation at the substance or subgroup level, rather than bans with countless confusing exceptions and staggered time limits. Even the OECD points out that the term "PFAS" in itself does not provide any information as to whether a compound is harmful or not.ⁱⁱ

The focus of the restriction must be on PFAS with proven unacceptable risks and their applications, while substances or substance subgroups that do not pose an unacceptable risk must be removed from the scope.

A positive example is the risk-based restriction of **undecafluorohexanoic acid** (PFHxA) under Regulation (EU) 2019/1021 (Regulation on Persistent Organic Pollutants, POP Regulation)ⁱⁱⁱ. Here, a substance with a proven risk, including its derivatives and precursors, is regulated to a degree that minimizes the risk to the public by prohibiting (consumer) applications where emissions to the environment cannot be avoided, while at the same time respecting closed industrial applications or essential and highly innovative applications.

2. Removing fluoropolymers from the scope of the restriction

Although fluoropolymers such as PTFE/Teflon™ are highly persistent substances, they have a proven non-critical risk profile. They are neither water-soluble, bioaccumulative, toxic nor mobile and are considered non-bioavailable. Their clinical safety has been proven in medical technology for over 45 years. Studies on permanently implanted PTFE cardiovascular systems show no evidence of chronic toxicity, carcinogenicity, or endocrine-disrupting effects. Since

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German Industry Association for Optics,
Photonics, Analytical and Medical Technologies

emissions from manufacturing, industrial and commercial processing, and use can be effectively controlled by established technical control measures, there is no unacceptable risk within the meaning of REACH Art. 68. Fluoropolymers should therefore be completely excluded from the scope of the PFAS restriction.

Life cycle assessment confirms low risk

Fluoropolymers are manufactured in closed, strictly monitored systems. The Fluoropolymer Group (FPG) Manufacturing Programme^{iv} sets itself binding emission limits, which have been recognized by the dossier compilers and included in the restriction dossier as a prerequisite for effective risk management. In fact, the manufacture of all PFAS substances is to remain permitted in the EU for an indefinite period if the relevant emission values are complied with.

Industrial and professional processing, for example of granulates, semi-finished products such as pipes, films, fibers, or coated products, also takes place under controlled conditions. During the use phase of products containing fluoropolymers, the exposure potential is minimal due to the inherently stress-resistant properties of fluoropolymers and certainly not, as is generally and unfoundedly assumed, at levels anywhere close to 50 %. The main disposal method, thermal waste treatment, can be considered equally safe. Studies such as a study by the Karlsruhe Institute of Technology (2024)^v prove almost complete destruction (>99.99%) through high-temperature incineration. Extensive follow-up studies on an industrial scale, such as at the Schweinfurt joint power plant^{vi}, will show that these highly efficient mineralization rates can also be achieved in conventional waste incineration plants. It can thus be demonstrably shown that the risks of fluoropolymers across all life cycle phases are sufficiently manageable in industrial and professional environments.

Sector-specific exemptions lead to considerable economic damage

Sector-specific exemptions for fluoropolymer applications, as provided for in the restriction proposal, are insufficient. Fluoropolymers are produced by a small number of specialized manufacturers whose production lines cannot be technically separated by end-using industry. The same precursors are supplied simultaneously to, for example, medical technology, the automotive industry, electronics, chemicals, analytics, photonics, and consumer products. Since suppliers are often unaware of the end-use sector, sector-specific and order-specific legal safeguards would be neither economically nor organizationally feasible. The ongoing restriction procedure, with its regulatory complexity, is already leading to the discontinuation of entire product lines. Even if temporary derogations are planned for individual applications in the future, fluoropolymer manufacturers are faced with the decision of whether it is still worthwhile to continue supplying in individual cases. In addition to economic considerations, legal uncertainties about the validity of application-specific exemptions are increasing the pressure. The already small and fragmented European fluoropolymer market could shrink further, supply chains would be disrupted, and process-oriented operations along the value chain would be significantly impaired. The impact is particularly critical for modern high-tech industries, which often require fluoropolymers in very small quantities or for highly specialized niche applications.

Only a consistently risk-based, substance-based approach, with restrictions where risks cannot be controlled, will ensure stable supply chains, technological performance, and planning security for research- and innovation-intensive industries.

Blanket substitution requirement not appropriate

Technically equivalent alternatives do not exist for most high-tech applications without significant losses in functionality and safety. A potential substitute would have to have the same functional properties – including the high persistence that is criticized by regulators. In medical technology, additional requirements for biocompatibility, sterilizability, low friction, and long-term stability are indispensable. Thousands of medical devices would be discontinued from the market because they could no longer be produced and would no longer be approved by notified bodies without the properties of fluoropolymers. A blanket substitution requirement would mean that fluoropolymers would have to be replaced by inherently inferior materials. Furthermore, such a requirement contradicts the fundamental REACH concept of a risk-based approach.

Contact: Jörg Mayer, Managing Director

SPECTARIS • German Industry Association for Optics,
Photonics, Analysis and Medical Technology e. V.
Robert-Koch-Platz 4 (postal address) | Hannoversche Str. 19 (visiting address) | D-10115 Berlin
www.spectaris.de | Email: mayer@spectaris.de

The particular importance of fluoropolymers is most evident in medical technology: they are indispensable for invasive, implanted, and non-invasive medical devices, as well as sterile packaging and production processes. In minimally invasive and endoscopic surgery, they enable friction-free instruments. Their elimination would mean that procedures on the gallbladder, appendix, hernia, uterus, or prostate, for example, would have to be performed openly again, with all the associated increased risks, longer hospital stays, higher costs, and poorer healing processes, especially for older and multiply ill patients. Even open surgery depends on medical devices that cannot function without the use of fluoropolymers. The development and approval of potential alternatives for complex medical devices would take 15 to 20 years and could still fail.

Overall, it is clear that fluoropolymers are technically and medically indispensable, can be handled safely throughout their entire life cycle, and do not pose an unacceptable risk. A blanket restriction on the entire PFAS group would significantly impair supply security, innovation, and patient welfare without achieving any discernible benefit for the environment or health. Risk-based regulation at the substance level, which takes into account the actual properties and controllability of emissions, therefore remains the most sensible regulatory approach.

Should the scientific consensus change in the future, with fluoropolymers being clearly proven to pose an unacceptable risk, an alternative approach in the form of risk-based regulation for this subgroup of substances would be conceivable. Such an alternative approach would have to take into account that there are no foreseeable substitutes for a large number of applications. At present, this is not yet in sight.

3. Ensuring practical manageability

The current restriction proposal is not enforceable in its present form, as key questions regarding practical implementation remain unanswered.

The broad, purely structure-based definition of the PFAS substance group makes it difficult to identify the specific PFAS used in products, especially in multi-stage and international supply chains. There is no functioning mechanism for passing on information on substance identity, and it would not be possible to implement one across the board without excessive additional reporting requirements. The resulting lack of transparency along the value chain is a key cause of the current uncertainty surrounding PFAS with unacceptable risks. An information obligation, starting with the distributors of such PFAS, would therefore be essential to enable traceability in the first place. Only on this basis can relevant applications, exposure pathways, and potential risks be identified and assessed in complex, multi-stage structures.

Market surveillance and customs authorities will also be overwhelmed from a technical and organizational perspective: they are unable to comprehensively check small-scale product exemptions or reliably verify the absence of PFAS in very low concentrations, as there is no detection method that can be applied to all PFAS. In addition, there is a lack of reliable control mechanisms and harmonized analysis methods for imported products, which are a basic prerequisite for legally compliant proof of compliance.

Under these conditions, effective enforcement cannot be guaranteed either technically or organizationally. A regulation that is unenforceable in practice is legally highly questionable and causes disproportionate economic damage. Unilateral EU regulations lead to considerable competitive disadvantages at the expense of European industry.

4. Stop the regulatory spiral

In its current form, the proposed restriction will lead to a massive bureaucratic burden, which most companies will avoid by discontinuing products. The dossier includes 74 different exemptions with individual transition periods, annual reporting requirements for thousands of companies, site-specific management plans, multi-layered documentation along the supply chain, and third-party certifications for which sufficient laboratory capacity is not yet available.

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SPECTARIS • German Industry Association for Optics,

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Robert-Koch-Platz 4 (postal address) | Hannoversche Str. 19 (visiting address) | D-10115 Berlin

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In addition, companies that use mixtures or components containing PFAS under a temporary exemption – such as SPECTARIS high-tech companies that purchase fluoropolymers – would have to fulfill a multitude of obligations, some of which are unclear and fragmented. These obligations are vaguely distributed between formal reporting requirements, implicit documentation requirements, ongoing proof of substitution efforts, and additional burdens from inspections.

This effort is disproportionate, especially for fluoropolymers. The only remedy is a consistently risk-based approach: regulation should focus on verifiable, uncontrollable risks.

5. Realistic transition periods based on the actual availability and market readiness of potential substitutes

Transition periods only make sense if the substances in question pose unacceptable risks, realistic substitution paths exist, or technically and regulatory suitable alternatives are already available. In many industrial sectors, but especially in highly regulated applications such as medical technology and other high-tech sectors, this is currently not the case. For fluoropolymers in medical technology applications, there is a proven lack of functional substitutes that also meet all regulatory requirements. A blanket deadline of 13.5 years falsely suggests that alternatives will be widely available by then. We need flexible transition periods with the option of timely extension if no functionally equivalent and safe substitute is foreseeably available.

We note that options (RO3) for a PFAS restriction without a general time limit are currently being discussed at ECHA level – provided that emissions can be controlled and the risk is manageable throughout the entire life cycle. In our view, it is crucial that the planned emission controls are proportionate and can be implemented in practice in an industrial environment. There must be no control system that leads to a disproportionately high level of bureaucracy in practice or is intended to measure emissions that cannot occur in the first place. However, RO3 is not a good solution, as it also disregards the benchmark of unacceptable risk and, to date, has only been considered for selected sectors.

6. No double regulation, no forgotten applications

The scope of the PFAS restriction also covers a subgroup of fluorinated greenhouse gases (F-gases), which are used in medical devices, among other sectors, but also in laboratory equipment such as centrifuges and refrigerators. The F-Gas Regulation is intended in particular to create an incentive to use alternatives. The regulation is regularly updated – most recently with the entry into force of the new EU F-Gas Regulation^{vii} in March 2024. The proposed PFAS restriction must not create any contradictory regulations to existing transitional provisions for F-gases.

In addition to double regulation, the incompleteness of the proposed sectoral restriction would have a massive impact on the availability of important products. The dossier submitters' definition of sectors deviates from market reality or ignores existing regulatory classifications. It would therefore be necessary to comprehensively map all socially important sectors, including their complex supply chains and ecosystems:

In their current form, analytical and laboratory equipment are not clearly covered by the proposed restrictions across the whole range of their applications. The authorities submitting the dossier and the ECHA provide contradictory classifications for this product field, which in the worst case could result in a total ban on use categories not covered by derogations, as the equipment itself is not covered by research-related exemptions, only the preparations being examined. The result would be massive supply gaps in food, drug, and drinking water analysis, not to mention vital medical analytics. This inadequacy of the dossier underscores our criticism that, despite the confusing complexity of the procedure applied, there are obvious gaps and we must expect “regrettable legislation.”

A similar problem arises in the field of visual aids / eye glasses: not only are these incorrectly classified as non-medical devices, but dirt- and damage-resistant coatings for eyeglass lenses, which greatly increase both wearing comfort and product life, have also been removed from the dossier. This means that they would have to be withdrawn from the market

Contact: Jörg Mayer, Managing Director

SPECTARIS • German Industry Association for Optics,

Photonics, Analysis and Medical Technology e. V.

Robert-Koch-Platz 4 (postal address) | Hannoversche Str. 19 (visiting address) | D-10115 Berlin

www.spectaris.de | Email: mayer@spectaris.de



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without replacement no later than 18 months after the regulation comes into force. The result would be a switch to inferior products, along with a sharp increase in waste, unreasonably higher costs, and dangers for eyeglass wearers, such as impaired vision due to a lack of anti-fog protection, which increases the risk of accidents in nighttime traffic.

Examples of areas affected: semiconductor technology and high-performance microscopy

A blanket ban on PFAS would have an immediate and profound impact on the European semiconductor industry, as PFAS materials are indispensable for highly complex lithography systems. These systems operate under extreme requirements for precision, UV resistance, and purity; even minimal outgassing or material changes would destroy their optical performance. Without PFAS, neither the pioneering EUV systems nor the established 193 or 248 nanometer systems could be manufactured or reliably operated in Europe. This would slow down chip production worldwide, exacerbate the already tense supply situation, and jeopardize key European value chains – including planned major investments under the European Chips Act. The result would be a massive exodus of chip manufacturing and production technology to regions without comparable restrictions.

The consequences for high-performance microscopy, which is essential for research, medicine, pharmaceuticals, materials testing, and semiconductor inspection, would be similarly serious. Here, too, PFAS are necessary in seals, lubricants, optical coatings, bearings, and cable insulation to keep systems stable against UV light, aggressive cleaning agents, and vacuum conditions. Without these materials, European top-of-the-line microscopes could no longer be manufactured, their precision would no longer be achievable, and they would lose their global competitiveness. Research institutions and industrial companies would be dependent on less powerful technologies or those imported from third countries, which would slow down innovation processes and weaken European sovereignty in key technologies. Overall, a blanket ban on PFAS would not lead to the intended risk minimization, but would instead pose a lasting threat to key future industries in Europe.

Conclusion

SPECTARIS calls on political decision-makers at national and EU level to fundamentally revise the ongoing PFAS restriction procedure. A blanket ban on a group of substances without a substance-specific risk assessment contradicts the basic principles of REACH and jeopardizes not only Europe's technological sovereignty, but also fundamentally our industrial location and, ultimately, social peace. The industry now needs clear political signals, even before the official start of the comitology procedure at the end of 2026. Fluoropolymers must be removed from the scope of the restriction. Only a risk-based approach with practicable enforcement regulations, realistic transition periods, and mandatory review mechanisms can equally guarantee innovation, security of supply, and environmental protection. A sectoral approach could quickly fail due to the complexity of supply chains and forms of use. If this path were nevertheless pursued, it would have to meet the requirement of fully covering all socially important sectors.

Contact: Jörg Mayer, Managing Director

SPECTARIS • German Industry Association for Optics,
Photonics, Analysis and Medical Technology e. V.
Robert-Koch-Platz 4 (postal address) | Hannoversche Str. 19 (visiting address) | D-10115 Berlin
www.spectaris.de | Email: mayer@spectaris.de

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- ii Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances, OECD, published on July 9, 2021, page 8:
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