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

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in advance to: executive-director@echa.europa.eu

SPECTARIS' Critical Evaluation of the PFAS restriction process at ECHA

Dear Mrs. McGuinness,

we are addressing this letter to you because of our far-reaching concerns regarding the current restriction procedure for per- and polyfluoroalkyl substances (PFAS) and, at the same time, to submit constructive and practical suggestions for improvement.

The German Industry Association is representing the interests of 400 member companies from the high-tech sectors of optics, photonics, analysis, bio and laboratory technology, and medical technology in Germany. Most of them are small and medium-sized companies. Here you can find more information about our membership base, our objectives and our major topics: www.spectaris.de. (EU transparency register #: 55587639351-53)
In December 2025 we have published a new position paper on the PFAS restriction procedure:
https://www.spectaris.de/fileadmin/Content/Verband/Positionen/SPECTARIS_Position-on-PFAS_Dec2025.pdf

Since the PFAS restriction procedure began in February 2023, we have received numerous responses from our member companies. In these responses, they express considerable concerns both about the chosen approach and the procedure itself, as well as about the background document on which the scientific assessment is based and the planned format of the consultation on the draft SEAC opinion.

Therefor, the have collected the feedback, divided into three main areas:

I. The restriction approach and the restriction process
II. The background document
III. The public consultation on the draft SEAC opinion

We hope that our remarks on the following pages will be heard and that the restriction process can still be revised to make it more transparent and fully in line with the requirements of the REACH Regulation.

Yours sincerely,

Jörg Mayer
Managing Director SPECTARIS

I. The restriction approach and the restriction process

The key point of criticism raised unanimously by SPECTARIS, our members, and other stakeholders relates to the chosen restriction approach itself. In our view, a restriction based on an so called “Annex XV dossier” of Regulation (EU) 1907/2006 (REACH) is not suitable for regulating such a heterogeneous and extensive group of substances as PFAS, which comprises more than 10,000 individual substances.

Incompatibility of the blanket group approach with the basic principles of REACH

Although the aim of avoiding the risk of “unfortunate substitutions” through a broad-based approach is fundamentally understandable, this aim is being pursued without consistently and substance-specifically applying the central REACH principle of demonstrating an unacceptable risk to humans and the environment in accordance with Article 68(1). In essence, it remains a broad ban with permission reserved for defined exceptions, regardless of the risks. In our view, a general ban based solely on persistence contradicts this principle. The blanket group approach means that even industrially indispensable substances with no proven hazard potential and very low risks are covered, such as fluoropolymers like polytetrafluoroethylene (PTFE)/Teflon™.

Capacity limits of RAC and SEAC

Due to the diversity of substances, breadth of application, and complexity, the chosen regulatory approach clearly exceeds the capacities of the scientific committees RAC and SEAC. It was clear early on that the associated workload would be unmanageable, which has led to considerable delays in the process. Even at the end of 2025, the final opinions are still not available – almost three years after the start of the procedure – although they are usually prepared within nine to twelve months.

The attempt to assess all PFAS uses in a single process not only creates planning and investment uncertainty, but paradoxically even delays the more urgent restrictions on high-risk PFAS. In order to speed up the process, the eight new sectors identified during the revision of the background document were no longer assessed by ECHA. Consequently, there is neither a sound risk assessment nor a socioeconomic assessment for these areas. The omission of this scientific assessment represents a methodological break, resulting in the absence of a key prerequisite for a proportionate and robust restriction decision. In our view, this circumstance may have significant technical, legal, and procedural consequences.

Lack of transparency and uncertainty for affected value chains

A process of this magnitude should have been designed to be more transparent and dialogue-oriented from the outset. In particular, it would have been necessary to publish the interim results of the RAC and SEAC at an early stage and to provide revised versions of the background document on an ongoing basis in order to enable technical feedback in a timely manner. There is still no transparent presentation of how the dossier submitters dealt with the comments and data submissions from industry.

Instead, the final background document was not published until the end of August 2025, at a time when identified errors or methodological weaknesses could no longer be effectively incorporated into the scientific process. This means that the data basis for further opinion-forming is virtually set in stone. This makes it all the more important to ensure maximum transparency in the remaining procedural steps — in particular, the drafting of the SEAC opinion and the preparation of the decision at Commission level — and to deal openly with existing uncertainties and assumptions.

Conclusion

The overload at ECHA, significant delays, and the decision not to conduct scientific assessments of entire cross-sectional applications show that the chosen restriction procedure is not appropriate for the task at hand. The assessment of so-called “Annex XV dossiers” under REACH requires that regulatory conclusions be based on reliable, relevant, and transparent scientific data.

From SPECTARIS's point of view, it is not too late to critically question the underlying regulatory logic and return to targeted, risk-based regulation of PFA-Substances with proven, unacceptable risks.

But if the chosen procedure remains unchanged, an effective corrective mechanism should now be put in place to systematically review and correct technical errors, blanket assumptions, and methodological weaknesses before a final recommendation is submitted by ECHA to the European Commission.

The European Commission and ECHA should ensure that the eight identified applications are either fully scientifically evaluated or explicitly excluded from the scope of the restriction before a final decision is taken. The Commission's decision must be based on complete, up-to-date, and scientifically sound data in order to make the procedure practicable and proportionate. This is the only way to avoid significant economic and legal consequences without compromising environmental and health protection.

II. The dossier/background document

The 2nd key point of criticism relates to the restriction dossier (Annex XV) and the revised and final version 14.

From SPECTARIS's point of view, the PFAS background document published in August 2025 continues to have significant structural and methodological shortcomings despite multiple revisions. There is no sign of a fundamental change in the chosen regulatory approach; in particular, fluoropolymers remain fully within the scope of the proposed restriction.

The background document is characterized by a very high degree of complexity, and a consistent and clearly comprehensible system is not apparent. Sectoral boundaries remain unclear in many cases, and the classification of individual uses is not always comprehensible. This makes both scientific evaluation and practical classification by affected companies considerably more difficult.

In terms of content, the background document relies on blanket assumptions in key areas, which are justified by the lack of reliable, sector-specific data. As a result, actual conditions of use, real emission pathways, and technical specifics are often not sufficiently taken into account. This can lead to a distorted and, in some cases, unrealistic risk assessment. In particular, it does not adequately reflect the fact that there are currently no technically equivalent substitutes available for numerous highly specialized PFAS applications – and this is likely to remain the case well beyond the 13.5-year period.

The restriction proposal imposes new documentation, certification, and labeling requirements on users, including annually updated site-specific management plans with information on substance identification, intended use, and disposal details. Given the diversity of uses, a considerable increase in bureaucracy is to be expected, which contradicts the EU's goals of reducing bureaucracy. These burdens disproportionately affect SMEs in particular. The socioeconomic impact of a near-total ban on PFAS is underestimated. The potential consequences for innovation, industrial value creation, security of supply, and the competitiveness of European high-tech industries have not been analyzed sufficiently or reliably.

Lack of clear classification of the entire spectrum of applications in the field of analytical, biological, and laboratory technology (Art. 67 REACH)

The analytical, bio-, and laboratory technology industry, which SPECTARIS also represents, is subject to considerable uncertainty in this regard. Above all, the background document does not adequately cover the commercial applications that fall within this sector. Upon inquiry with the German Federal Institute for Occupational Safety and Health (BAuA), one of the dossier submitting institutions, we were repeatedly assured that, in the opinion of the BAuA, these applications will not be affected by the restriction under REACH Article 67 as part of scientific research and development (SR&D).

Even if this assessment seems reassuring at first glance, it raises serious problems:

- In supporting documents from the ECHA, the exemption for R&D is also extended to test laboratories and quality management, but this only refers to the use of restricted substances as consumables, not as part of the analytical equipment.
- Upon direct inquiry with ECHA, we were also informed that devices must be evaluated on a component-specific basis. Depending on its use in the device, the same component may fall under different restriction sectors, which is an insurmountable task for devices with several thousand components.

These contradictory interpretations are not resolved in the dossier and therefore do not provide a reliable basis for companies to plan ahead. This issue must be addressed and clarified by the scientific committees of the ECHA.

Incorrect emission assumptions for fluoropolymers in medical technology

The background document makes a blanket assumption that 50% of the fluoropolymers used in medical technology are released into the environment as PFAS emissions during the manufacture of medical devices. This assumption does not take into account the fact that the relevant production processes take place under strictly controlled industrial conditions. Against this background, the assumption is technically untenable and requires urgent correction, as it systematically distorts the risk and socioeconomic assessment based on it.

Optometry

A similar problem arises in the field of optometry. Not only has the former dedicated exemption “6k) Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF” been deleted, but according to the dossier submitters, it is now to be covered by the exemption “5jj) Excipients in medicinal products for ophthalmic and dermatological therapies”, an exemption that applies to medicinal products (pharma!). The classification of ophthalmic lenses as medicinal products is fundamentally incorrect. The explanatory paragraph on exemption 5jj) in the background document is also incorrect and, in its current version, has no reference to the exemption.

In addition, coatings on eyeglass lenses are not realistically assessed in the dossier. They are a fundamentally important application in vision aids, which, as things stand, will no longer be allowed to be used with the usual safety and quality standards 18 months after the entry into force. The consequences are far-reaching restrictions for millions of people with vision impairments in terms of product durability and comfort, but above all in terms of their safety. Inferior coatings pose an increased risk due to poor protection against dirt and fogging and reduced damage resistance, especially in nighttime traffic, for example.

Conclusion

Even if the background document itself is no longer amended, ECHA should subject the document to a much more critical technical analysis as part of the preparation of the final draft opinion. Existing data gaps, methodological weaknesses, and uncertainties must be disclosed transparently and clearly identified. The proposed documentation and reporting requirements must be reviewed for proportionality, feasibility, and enforceability in order to avoid excessive bureaucracy. The aim is to ensure that the European Commission is aware of the potential economic and social impacts in the comitology process and can make its policy decisions on this balanced basis.

III. Consultation on the SEAC draft opinion – structural inadequacy of participation

The consultation planned for March 2026 is the last opportunity for companies and stakeholders to formally and effectively participate in the restriction process. However, the information currently available on the content, structure, and procedure of the consultation is worrying in several respects and requires structural adjustments.

The greatest concerns arise from the announced move away from the established open consultation format to a rigid questionnaire with free text fields and a fixed character limit. The planned restriction of free text entries to 5,000 characters is an absolutely insufficient limit for the transmission of new or supplementary data on sometimes highly complex applications and prevents the proper presentation of technical, economic, and social aspects.

In addition, it is planned that neither files nor links can be submitted directly as part of the consultation. Instead, submitters are only to refer to existing sources. This approach is not practical, as additional information would only have to be submitted at the request of the ECHA, which would still delay the process. In order to enable efficient and transparent evaluation, it must be possible to submit studies, evidence, and technical documentation directly.

In conjunction with the already criticized lack of transparency in the evaluation of studies in the restriction dossier, this approach undermines confidence in the consultation process. This is particularly true given that the eight new sectors are not to be given dedicated sections in the consultation questionnaire, but can only be addressed in the general part of the consultation. This solution is completely inadequate, as it effectively prevents a structured, sector-specific, and evidence-based presentation. From SPECTARIS's point of view, it is therefore necessary to first deal with these sectors in a well-founded manner in the scientific committees; based on this, the public consultation must address these sectors clearly and specifically, in the same way as the other 14 sectors.

Against this background, the fundamental question arises as to how sectors could be classified as relevant enough to be re-identified by both the proposers of the restriction and the ECHA, but on the other hand are not given an adequate opportunity for in-depth discussion and evaluation in the final consultation. This inconsistency must be resolved in the further procedure.

Conclusion

The ECHA should open up the consultation format and avoid rigid character limits, which would enable the comprehensive presentation of technical, economic, and social aspects; in addition, the direct submission of studies, evidence, and technical documentation, including file attachments and links, must be permitted; Finally, separate, clearly defined consultation sections should be set up for the eight newly identified sectors to ensure equal, sector-specific, and evidence-based participation analogous to the sectors already addressed.