POSITION PAPER

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# PFAS Restriction Process: why a targeted, proportionate and evidence-based approach is fundamental


## Executive Summary

Given the relevance of PFAS for Europe's technology industries' production and following the assessment of the Risk Assessment Committee (RAC) opinion and the Socio-Economic Analysis Committee (SEAC) draft opinion from European Chemicals Agency (ECHA) scientific committees, Orgalim remains concerned about persistent information gaps regarding technical feasibility, the availability of alternatives, socio-economic impacts and several PFAS uses that are not yet adequately captured by the PFAS REACH restriction proposal. In light of the upcoming Commission proposal, Orgalim calls on the legislator to act on the following ten key asks to achieve a workable PFAS restriction and preserve Europe's industrial backbone:

1. Apply a targeted, differentiated and risk-based regulatory approach instead of a universal ban to ensure proportionality.
2. Avoid restricting uses where no technically and economically feasible alternatives exist and ensure that the assessment of alternatives reflects real-world conditions.
3. Ensure the meaningful involvement of impacted stakeholders, in particular downstream users of PFAS, in the evaluation and restriction process.
4. Ensure alignment and coherence with other PFAS-related legislation.
5. Strengthen the evidence based on PFAS emissions, differentiating between real-life data and modelling assumptions.
6. Exclude fluoropolymers from the restriction scope where suitable alternatives do not exist.
7. Extend the baseline transition period to four – eight years to enable realistic adaptation processes.
8. Exclude spare parts, repair, refurbished products and products already placed on the market from future restrictions.
9. Apply a threshold of 0.1% w/w for PFAS in complex objects to enable proper market surveillance and enforcement.
10. Derogations: implement an open and review-based system that avoids complex requirements for derogated products and uses.

# Introduction

Orgalim, representing Europe's technology industries, supports the objective of reducing emissions of hazardous substances and ensuring a high level of protection for human health and the environment, including from Per- and polyfluoroalkyl substances (PFAS) where and whenever they have demonstrated real-life risks. Today, PFAS are widely and safely used in Europe's technology industries due to their unique technical properties, enabling the performance, durability and safety of products that are crucial for the green and digital transitions as well as Europe's industrial competitiveness. They are used in products important for daily life such as mobile phones, computers, cars, batteries, aeroplanes, energy generation and distribution and the whole medical sector, and are also relevant for direct or indirect employment during the manufacturing or use of these products.

Following our assessment of the opinion of the Risk Assessment Committee (RAC) and the draft opinion of the Socio-Economic Analysis Committee (SEAC), **Orgalim is greatly concerned about persistent information gaps regarding technical feasibility, the availability of alternatives, socio-economic impacts and several PFAS uses that are not yet adequately captured by the restriction proposal**. This is particularly evident for the eight additional sectors, such as sealing and machinery applications, which did not undergo sufficient assessment. **In the absence of such an assessment, it would not be acceptable if these sectors were to become subject to restriction**. As a minimum, they require open-ended derogations subject to review until a complete assessment of technical feasibility, alternatives, emissions and socio-economic impacts has been carried out.

Under REACH, a restriction must be based on a demonstrated unacceptable risk and a robust assessment of proportionality. Where uses, alternatives, emissions and socio-economic impacts have not been sufficiently assessed, a restriction cannot be justified merely by reference to the broad PFAS group definition or to general uncertainty. In other words, without robust, use-specific evidence, the restriction would be **disproportionate, legally uncertain and difficult to implement**, while leading to unintended consequences for industrial production, investment decisions and the achievement of broader EU policy objectives. The impact on society and the end-user caused by the use of discontinued or less robust products will be significant, but this has not yet been taken into account by SEAC.

The assessment should therefore be much broader in scope and consider not only substance-level substitution effects but also system-level effects on, for example, the certification cycle, supply chain readiness, imported articles, spare parts, repair, refurbishment and the circular economy. In light of these concerns Orgalim calls on the European Commission to act on the ten recommendations below and follow a targeted, proportionate and evidence-based approach to the PFAS restriction.

# Key asks from Europe's technology industries for the PFAS REACH Restriction Proposal

## 1. Apply a targeted, differentiated and risk-based regulatory approach instead of a universal ban to ensure proportionality

Future PFAS restrictions should focus on specific uses where risks are evidenced and not adequately controlled. A horizontal ban covering thousands of substances used in highly diverse applications would be disproportionate and, overall, unjustified.

- **PFAS-containing products and applications should be assessed according to their actual exposure and emission potential, as risks differ significantly between sectors and uses**. Even within the broad category of consumer products, exposure scenarios vary considerably, ranging from consumable goods like cosmetics and chemical mixtures to textiles and durable goods such as home appliances, laptops, washing machines, or machinery where PFAS-containing components are often embedded within the product materials and not normally in direct contact with consumers during use.
- **Treating all PFAS under a single assessment framework overlooks significant differences in risk, emissions and technical functions, and risks capturing critical uses that are currently irreplaceable or effectively managed in practice**. Such an approach does not meet the proportionality principle embedded in REACH. Targeted measures addressing clearly identified risks would be more effective, legally robust and enforceable than a broad restriction followed by multiple corrective derogations.

## 2. Avoid restricting uses where no technically and economically feasible alternatives exist and ensure that the assessment of alternatives reflects real-world conditions

Should a PFAS use be restricted without a viable, market-ready alternative, the consequences for European industry, and even more for society and the end-user, could be severe. Production may become impossible or unattractive in the EU, forcing relocation outside Europe or the withdrawal of essential products from the market. This would directly undermine Europe's industrial competitiveness, strategic autonomy and ability to deliver key technologies for the green and digital transitions.

- **The mere theoretical existence of an alternative cannot automatically justify a restriction**. In technical applications a unique combination of requirements must be fulfilled, resulting in a case-by-case investigation if a possible alternative is, in fact, working in practice. Alternatives must be available at scale, technically validated, economically feasible, and capable of meeting the required performance, safety and certification requirements, while also functioning reliably as part of complex systems and integrated products.
- **In practice, substitution requires extensive redesign, testing, certification and validation under real-life operating conditions, often across complex supply chains**. These processes take many years and involve significant technical and financial risk. Ignoring these realities creates a high risk of

unsuitable substitutions and reduced product performance, durability or safety. Alternatives must provide the same performance as current products, otherwise this will lead to a shorter useful life of parts and increased waste generation, and a loss of competitiveness for industry.

## 3. Ensure the meaningful involvement of impacted stakeholders, in particular downstream users of PFAS, in the evaluation and restriction process

The current process raises several fundamental procedural concerns, reflected in a legal opinion[1] commissioned by several industry associations[2]. The legal opinion substantiates concerns regarding the evidence base, effective stakeholder participation and proportionality of the procedure:

- The PFAS evaluation and restriction process has so far proved extremely difficult for stakeholders to engage with in a meaningful way. **Stakeholders were given only two months to respond to an exceptionally complex consultation**, while ECHA's committees have taken several years to develop their opinions, far exceeding the timelines foreseen in the REACH Regulation. This imbalance hampers effective stakeholder participation and risks not including important evidence.
- The process places a disproportionate burden on affected companies, including SMEs, to identify and justify uses in highly complex supply chains, while several sectors and uses have not yet been fully assessed by the authorities. This raises concerns regarding effective consultation, the evidence base of the restriction and the proportionality of the procedure as a whole.
- **Sector boundaries are often intertwined**, making it unclear at which level specific uses were assessed and complicating the allocation of comments to the appropriate sectoral analysis.
- **Harmonised guidance, clear documentation requirements and an explicit mechanism for additional or extended derogations are needed for uses that were not identified or could not be fully assessed.**
- **Effective stakeholder participation requires the timely inclusion of relevant substances on the REACH Candidate List, as this is necessary to trigger the transparency and information flow needed for complex articles**. Even after Candidate List inclusion, information typically requires one to two years to propagate through multi-tier supply chains and be validated. Without this upstream step and a sufficient preparatory period, reliable data on uses, alternatives and impacts of complex articles cannot be collected in time. Targeted and proportionate restrictions can only be developed based on transparency regarding actual uses. Without such transparency, both the evidence base of the restriction assessment and the ability of stakeholders to contribute meaningfully to the consultation process are undermined.

[1] On the UPFAS-Restriction Proposal, Brief opinion on procedural aspects, May 2026, Commissioned by BDI, VDMA and ZVEI among others.
[2] The associations include BDI, and Orgalim member associations VDMA and ZVEI, and submitted to the SEAC consultation

## 4. Ensure alignment and coherence with other PFAS-related legislation

Where Union legislation already regulates specific applications of PFAS, such as fluorinated gases or substance related requirements in the context of drinking water and food contact materials, this legislation should remain the primary regulatory mechanism.

## 5. Strengthen the evidence based on PFAS emissions, differentiating between real-life data and modelling assumptions

Orgalim notes that important elements related to PFAS emissions, waste treatment and end-of-life management are still under investigation, including ongoing investigation on incineration[3]. Regulatory conclusions should not be finalised before these studies are duly completed and assessed. Furthermore, existing and currently evolving legislation should be included in this assessment. Unrealistic, non-confirmed projections of growth rates for the next 30 to 50 years create unrealistically high figures for PFAS uses and their resulting emissions.

- **The initial restriction assumption "PFAS are always an issue either in production, in use or in waste stage" has been proved not to be true anymore**. Properly managed, PFAS have no risk in many cases and restrictions in REACH should only be implemented where relevant emissions happen in scope of REACH. PFAS assessment in waste state should take place under the Waste Framework Directive.
- **If financial instruments are to be considered to prevent waste PFAS pollution, they should target cases where PFAS are actually released into the environment**, particularly into water, rather than the mere presence of PFAS in final products.

## 6. Exclude fluoropolymers from the restriction scope where suitable alternatives do not exist

When used as intended and foreseen, fluoropolymers do not typically lead to emissions during the use phase. Today, they are widely used in a number of critically important industrial applications, often as part of materials, components and products that require high levels of performance, durability and safety. Their inclusion in a blanket restriction would therefore seem unjustified and disproportionate. Where potential risks are present during the manufacturing process or at the end of life they can, and should, continue to be addressed effectively through existing or targeted occupational safety, emissions and waste legislation (rather than through a general ban under REACH on placing on the market).

[3] SPECTARIS Scientific Report on Fluoropolymers End-of-Life , 2026, Barbara J. Henry, Ph.D., June 2026, End of Life Report for Spectaris June 17 2026 MT JM FG really final PDF and PFAS/Fluorpolymere | SPECTARIS: Spectaris

## 7. Extend the baseline transition period to four – eight years to enable realistic adaptation processes

The transition periods currently foreseen (18 months) fall short of what is realistically needed for complex industrial processes to adapt and phase in potential alternatives. Given long product development cycles, qualification requirements and certification obligations, significantly longer transition periods are necessary to avoid product discontinuation, regrettable substitutions, or uses of less robust products with negative impacts on society and end-users. In practice, the following timelines typically apply for less complex articles (for complex objects and installations the qualification period may be significantly longer):

| | | **Typical timeframe:** |
|---|---|---|
| 1 | Qualifying substitutes, performance and reliability testing | 1-2 Years |
| 2 | Production part development | 1-2 years |
| 3 | Conformity assessment, regulatory certification and production ramp-up | 2-4 years |
| | **ESTIMATED TOTAL TIMEFRAME** | **4-8 years** |

## 8. Exclude spare parts, repair, refurbished products and articles already placed on the market from future restrictions

Future restrictions should not prevent the repair, maintenance, resale, refurbishment or further distribution of products or components that have already been placed on the EU market. For long-life equipment, spare parts and consumables are essential to maintain industrial competitiveness, safety, functionality, circularity and resource efficiency. A repair-as-produced principle should apply, and derogations for spare parts should not be limited by unrealistic deadlines that are shorter than the typical lifetime of the products involved.

- **Future restrictions text should clearly define "spare parts" and "consumables", cover wear and used parts** used for routine service and maintenance, and avoid proof-of-origin, traceability or labelling obligations that would discourage the use of recovered materials or secondary raw materials.

## 9. Apply a threshold of 0.1% w/w for PFAS in complex objects to enable proper market surveillance and enforcement

The future restriction could give rise to serious enforcement challenges due to the lack of reliable analytical methods, the complexity of certain products and time constraints in global supply chains. In addition, the currently proposed thresholds of 25 ppb are set too low to be practically enforceable, especially for complex articles. Such a threshold would focus enforcement on deliberate PFAS use rather than unavoidable trace contamination. Without enforceable thresholds, authorities will not be able to effectively check compliance – particularly for imported products.

- **Under REACH, only restrictions that can be enforced in practice should be adopted.** A 100% incoming goods chemical analysis is impractical and extremely expensive. Self-certification in the

supply chain stating 0,1% w/w ensures adequate safety levels and is the only practically feasible approach to maintain short delivery times and avoid waste generation because of negative analysis results.

## 10. Derogations: implement an open and review-based system that avoids complex requirements for derogated products and uses

In the case that a non-targeted approach is pursued, derogations must be granted when no suitable alternatives are available. Setting fixed deadlines without a structured review mechanism risks restricting uses even where alternatives have still not materialised in practice as well as creating situations where previously unidentified uses would be restricted without information on whether additional exemptions can be sought.

- **A derogation should not expire where no technically and economically suitable PFAS-free alternative is available** at the required scale and quality, or where expiry would lead to the withdrawal of essential products without viable replacements.
- **Derogations must also cover the necessary upstream supply chain,** including substances, mixtures, intermediates, components and process steps required to supply the derogated use. Otherwise, derogations for final products or specific applications may become ineffective in practice.

We advise against introducing overly burdensome requirements for products that are ultimately covered by derogations.

- For example, imposing extensive labelling or information obligations for uses granted time-limited derogations of five or ten years would create unnecessary administrative complexity without delivering proportional environmental benefits.
    - **Labelling obligations for complex products or waste electric and electronic equipment should only be considered where they demonstrably add environmental value** because they would otherwise create a substantial administrative burden without improving waste treatment or enforcement. A realistic view on end-of-life treatment for complex articles should be considered to avoid adding unnecessary information that will never be used.