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Orgalim position and recommendations on the proposed PFAS restriction

Executive summary

Europe's technology industries are fully committed to reducing the content of hazardous substances in their products to support a more circular economy and a healthier environment. However, the proposed general ban on the production, use, and market availability of per- and polyfluorinated alkyl substances (PFAS) would significantly impact on our industries' ability to produce robust and reliable products. Here are our key messages on the proposed PFAS restriction:

1. **Implementing a blanket PFAS ban will jeopardise the fulfillment of the Green Deal** (climate goals and circular economy): The technology industry offers a wide array of solutions for current challenges, such as semiconductors, lithium batteries, heat pumps, high-temperature seals, specialised refrigeration equipment, technologies for energy transmission and distribution, energy-efficient industrial equipment, and sustainable professional goods. **These products can only be produced today with the use of PFAS** and would not work at all or work significantly less efficiently without it. The current proposal would result in reduced product durability and a substantial increase in waste generation. **Therefore, restricting substances should not be implemented without a differentiated consideration of their uses and the consequences.**
2. A **risk-based and substance-based approach** should be used for PFAS. We consider the proposed blanket restriction of all PFAS, regardless of their toxicity and risk profile disproportionate.
3. Use of **PFAS must remain possible as long as there is no full-scale availability of suitable and technically developed substitutes.**
4. The introduction of an **information obligation for "intentionally added" PFAS** prior to the introduction of targeted restrictions will allow all relevant uses to be included in the assessment in due time and any necessary exemptions to be applied for.
5. A **long-term general derogation with review before expiration** of fluoropolymers without relevant risk is **necessary.**
6. A clearly **defined procedure for the application, review and extension of derogations is crucial**, especially in the case of a broad restriction on previously non-declarable substances. The **derogations currently envisaged are insufficient and do not take into account the relevance of PFAS for a wide range of uses and ongoing innovations in the technology industry.**
7. The **repair-as-produced principle shall be applied.** Indefinite derogations for spare parts, refurbished parts, and equipment as well as products already having been placed on the market for the first time shall be granted.
8. Ensuring effective **enforcement through the market surveillance system** will foster a level playing field.

Introduction

Earlier this year, the competent authorities of five European countries proposed a wide-ranging restriction on per- and polyfluorinated alkyl substances (PFAS) under the European chemicals regulation (REACH). This is the EU's biggest substance restriction to date, and it is a key component of the EU Green Deal's Chemicals Strategy for Sustainability (CSS).

Orgalim represents Europe's technology industries, providing innovative technology solutions which are underpinning the twin green and digital transitions and can unlock a greener, healthier, and more prosperous future for the European Union and its citizens. Our industries are fully committed to reducing the content of hazardous substances in their products to support a more circular economy. Our position and recommendations on the circular economy can be found [here](#), and our comments on the REACH revision roadmap can be found [here](#).

Moreover, we fully support the Commission's Chemicals Strategy for Sustainability, and we believe that individual substances that pose an unacceptable risk due to their properties and use profile should be restricted or regulated based on scientific evaluation. Our technology industries, major downstream users of chemicals and article manufacturers are committed to continuously improving the environmental performance and safety of the products they place on the market.

However, the proposed general ban on the manufacture, use and placing on the market of any kind of PFAS (in substances, mixtures, and articles) would have a massive impact on nearly all our member companies, whose technologies are essential for the energy transition, digitisation, European infrastructure, transport and logistic chains, healthcare, process automation/measurement technology, being the sustainability of these products intricately linked to the use of PFAS.¹

We see the production, research, and development locations of the European technology industries as well as their global competitiveness, at serious risk in the event of a blanket ban and therefore call for a fundamental revision of the restriction proposal in key areas.

Our recommendations

On the PFAS restriction approach/procedure

Our industries support the **objective of avoiding emissions of hazardous substances into the environment** and an appropriate regulation of uncontrollable risks posed by individual substances. Our industries are committed to continuously improving the environmental compatibility and safety of the products they place on the market.

Our society is facing major challenges in the energy transition. Mobility and energy supply should become climate-neutral within a few decades and the European economy should do the same by 2050. Europe's technology industries offer a wide range of the solutions required for this transition, such as semiconductors, lithium batteries, heat pumps, high-temperature seals, specialised refrigeration, technologies for energy transmission and distribution, energy-efficient industrial equipment, and sustainable professional goods. All of these **can only be produced today with the use of PFAS** and would not work at all or work significantly less efficiently without it. Additional time is needed to develop durable and safe alternatives, and to secure enough time for verification and certification etc. of such alternatives to fulfil all other applicable legislations. Therefore, restricting substances should not be implemented without a differentiated consideration of their uses and the consequences.

¹ BDI position on the restriction of PFAS, 2021, [publication \(bdi.eu\)](https://www.bdi.eu/publication)

What is needed is a **more differentiated regulatory approach** that is **risk-based** according to Article 68(1) REACH and **substance-based** according to Article 69 REACH, as proposed by other governments². The proposed blanket restriction of all PFAS, regardless of their individual toxicity and risk profile, does not meet this requirement. Given their enormous importance in the industry, **uses of PFAS must remain possible as long as their risks can be sufficiently managed by appropriate containment measures or in case no suitable substitutes are available.**

It is important to **distinguish between the different PFAS (groups) and the risks from each use.** It is also important to consider whether identified risks can be minimised through targeted measures, e.g. in occupational health and safety/emission control or waste legislation, rather than through a general ban under REACH.³

We call authorities to stick to the risk-based approach, meaning that only applications associated with an identified risk and those for which a technically suitable, economically proportionate, and less environmentally and health-damaging alternative exists should be restricted. The alternative would be a long, unmanageable list of very specific derogations or the unnecessary exclusion of products and processes from the European market despite their importance to our competitiveness and climate goals.

Only the **introduction of an information obligation for "intentionally added" PFAS** (e.g. through inclusion in the REACH candidate list) prior to the introduction of targeted restrictions will allow all relevant uses to be included in the assessment in due time, alternatives to be developed and any necessary derogations to be applied for. There is currently no legal basis for the dissemination and communication of information on PFAS in products along the supply chains. Most PFAS are neither classified in a harmonised way according to Classification, Labelling and Packaging (CLP) Regulation nor included in the REACH candidate list. As information on PFAS in products is only fragmentarily available in the complex international supply chains, exhaustive identification, and assessment of PFAS uses, potential alternatives and socio-economic impacts are virtually impossible for downstream users. It will take years to fill these information gaps.

Adequate transition periods of four to eight years after entry into force (depending on use, product life and development times) **for full conversion are needed,** as provided for in other legislation, e.g. RoHS⁴. An 18-month transition period for the full conversion of products and processes, as provided for in the proposal, is insufficient and will disrupt and damage supply chains with long lasting effects on the prosperity of the EU market. Unsatisfactory substitutions must be avoided and too short transition periods will increase the risk of less durable and, in worst case, less safe products being placed on the market. The supply of less durable products is not in line with the EU Green Deal and circularity ambitions and will increase the waste in the EU.

Ensuring effective **enforcement through the market surveillance system** will be of the utmost importance for the success of the PFAS proposed restriction, generating good and fair opportunities for manufacturers, and constituting the most effective regime to reach sustainability objectives in addition to levelling the playing field. However, requesting product information will not help if an adequate working capacity is not allocated by Member States. Increased focus on enforcement with more uniform requirements for the Member States will also foster a level playing field.

We observe that the definition of PFAS encompasses Hydrofluoroolefins (HFOs) for refrigerants. **HFOs are already alternative substances for refrigerants following the bans imposed by the F-Gas Regulation and the Montreal Protocol,** making them an environmentally-friendly option with a small global warming potential (GWP) compared to certain more harmful fluorinated gases. However, the proposed restriction of PFAS also includes the removal of HFOs, and since they are already covered by both regulations, it is crucial to **avoid double regulation to ensure that there will**

² <https://www.gov.uk/government/publications/environmental-risk-evaluation-reports-per-and-polyfluoroalkyl-substances-pfas/environmental-risk-evaluation-reports-per-and-polyfluoroalkyl-substances-pfas-summary>

³ [Report: Government Risk Management Approaches Used for Chemicals Management](#)

⁴ cf. amending Directive 2015/863/EU to RoHS Directive 2011/65/EU, inclusion of four phthalates in Annex II with a transition period of 4 or 6 years, depending on the category.

be alternatives left for refrigerants. Therefore, the interface with other regulations related to substances meeting the proposed PFAS definition (e.g., upcoming revised F-Gas Regulation) must be clarified.

Overall, the current restriction process of PFAS appears premature, as the present REACH lacks essential provisions necessary to effectively address such a wide range of substance groups. To ensure a comprehensive framework and avoid legal uncertainties, we support the **postponement of the PFAS restriction until the adoption of the REACH revision**, allowing our industries to adapt to potential changes in the REACH requirements.

Derogations

A clearly **defined procedure for the application, review and extension of derogations** is necessary, especially in the case of a broad restriction of previously non-declarable substances. The **derogations currently envisaged are insufficient** and do not take into account the relevance of PFAS for a wide range of uses and innovations needed in the technology industry to fulfil other environmental targets and strategic objectives set out by the EU.

For example, the **semiconductor industry is very reliant upon many applications of materials falling under the definition of PFAS.** Those materials are used in manufacturing process chemistries, in specific functional layers and packages, manufacturing equipment, manufacturing infrastructure, and support equipment in addition to the semiconductor device. Therefore, a blanket ban of PFAS will also mean an important hit to achieve other strategic EU policy objectives, such as the Chips Act to boost R&D and production of semiconductors.

To help prevent such unintended consequences of the proposed PFAS restriction, we want to highlight the following necessary derogations:

- **Spare parts and refurbished products should be excluded from the restriction.** The **repair-as-produced principle** should be applied to the placing of spare parts on the market and wear and used parts for the purposes of sustainability and economic efficiency. Premature replacement due to the non-availability of spare parts or repair services would contradict the sustainability goal of resource efficiency.

This restriction proposal would also be **contradictory** to various elements of the European Green Deal, notably the **Ecodesign and Right to Repair initiatives**, which emphasize the importance of the circular economy, including the use of these spare parts and the right to repair. Indeed, **PFAS are present in all products currently on the market**, making it seemingly impossible to reuse, refurbish, and repair products with PFAS-free components. **Compatibility between products and spare parts, as well as certain conformity tests, would be compromised without an exclusion from the restriction.**

- **A general derogation is also needed for products that have already been placed on the market for the first time.** Otherwise, they cannot be resold, repaired, maintained, or further processed and placed on the market again as a component of more complex products/articles. The only option would be disposal, which does not bring about any benefit from an environmental perspective. This general derogation should not mean additional burdens for industry (e.g., management plan).
- **A derogation is needed on the presence of PFAS in recycled materials**, in particular for products that do not present a risk of PFAS emissions into the environment during the use phase.
- **Fluoropolymers** meeting the criteria for "polymers of low concern"^{5,6} **and safe uses of PFAS in industrial applications, equipment, and components** generally do not cause relevant emissions to the environment when

⁵ Henry, B. J.; Carlin, J. P.; Hammerschmidt, J. A.; Buck, R. C.; Buxton, L. W.; Fiedler, H.; Seed, J.; Hernandez, O. A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers. *Integr. Environ. Assess. Manage.* 2018, 14 (3), 316-334.)

⁶ Korzeniowski SH, Buck RC, Newkold RM, Kassmi AE, Laganis E, Matsuoka Y, Dinelli B, Beauchet S, Adamsky F, Weilandt K, Soni VK, Kapoor D, Gunasekar P, Malvasi M, Brinati G, Musio S. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. *Integr Environ Assess Manag.* 2023 Mar;19(2):326-354. doi: 10.1002/ieam.4646. epub 2022 Aug 9. PMID: 35678199.

used as intended. Due to the high industrial importance, **A long-term general derogation with review before expiration of fluoropolymers is necessary**, especially if not technically suitable and environmentally safer alternatives are known to allow companies to fulfil the identification, development, and mass production of alternatives. Risks in the manufacturing and waste phase are better addressed in the relevant legislation (emissions/occupational health and safety, waste legislation)

Monitoring/Conformity

Existing **laboratory capacity, availability/usability of analytical methods and the burden on businesses** (staff, time, equipment) must be taken into account when setting transition periods of the PFAS restriction proposal as verification of compliance for incoming products and materials, as well as finished manufactured goods, is a time-consuming process. Furthermore, testing is occasionally necessary after specific manufacturing steps and these procedures escalate production costs, necessitating expenditure on testing equipment or external testing services. Orgalim calls for **longer transition periods**.

Compliance with the proposed restriction cannot be verified for all uses with currently available analytical methods and in the absence of a complete substance list. We emphasise the necessity of having **practical and standardised analytical and extraction methods for all the restricted substances and their various applications prior to the imposition of any legal restrictions on PFAS**. A potential solution suggested by Orgalim involves **restricting only well-defined substances that can be precisely analysed and identified within complex articles**, even under streamlined customs control conditions.

Recognising the potential distortions of competition within the Single Market that may occur in practice, **market surveillance needs to be strengthened**, especially at external borders, but also within the EU to identify PFAS 'free riders'. We question the ability of inspection bodies to assess the presence of numerous PFAS in imported product, especially in complex products. The European Chemicals Agency (ECHA) should carry out an **impact assessment to examine the capacity of ECHA and national enforcement authorities to inspect the conformity** of products entering the European market and being manufactured within the EU, quantifying the supplementary resources required to effectively enforce the proposed PFAS restriction as it stands. **Only enforceable restrictions should be established**.

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of over €2,906 billion, manufacturing one-third of all European exports and providing 11.19 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.