Compliance & Risks

EU Takes Action Against Harmful PFAS Chemicals: Analyzing the Draft Restriction Proposal

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1. Introduction

The European Union's recent publication of the draft restriction proposal for per- and polyfluoroalkyl substances (PFAS) marks a significant milestone in the global effort to reduce the environmental and health impacts of these persistent chemicals. PFAS are widely used in a range of industrial and consumer applications, from food packaging to firefighting foams, due to their unique properties such as water and stain resistance. However, their pervasive nature and potential harm to human health have raised concerns among policymakers, scientists, and the public, leading to increasing regulatory actions and industry scrutiny. The EU's proposed restriction is one of the most far-reaching measures to date, covering a broad range of products and applications and setting strict limits on the use and release of PFAS.

This whitepaper aims to provide a comprehensive analysis of the EU's draft restriction proposal for PFAS, including its scope, key provisions, and implications for business owners. We will examine the scientific and policy context of the proposed restriction, highlighting the current state of knowledge on the environmental and health effects of PFAS. We will also explore the challenges and opportunities of implementing the proposed restriction and implications for companies operating in the EU and beyond. Our goal is to provide a balanced and informed assessment of the EU's proposed restriction, as well as a roadmap for businesses and policymakers to navigate this rapidly evolving regulatory landscape.

The proposed EU restriction of around 10 000 per- and polyfluoroalkyl substances (PFASs) is now available to see as a pre publication version on ECHA’s website, pending formal release following the ECHA Risk Assessment Committee and SocioEconomic Assessment Committee (RAC/SEAC) meeting next month. It aims to reduce PFAS emissions to the environment and make products and processes safer for people.

2. PFAS Restriction

Scope

The restriction will cover all PFAS in all uses above extremely low concentrations. It affects PFAS used on their own including intermediate use, PFAS in mixtures, and PFAS in articles including imports. The PFAS restriction uses the same definition as the OECD: “Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).”

All substances and families of substances listed in the OECD list of PFAS can be considered included in the proposal, however this only lists 4730 substances, and the proposal covers far more.

Concentration Limits

The concentration limits above which the restriction applies, are onerous.

They are:

- 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)
- 250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification)
- 50 ppm for PFASs (polymeric PFASs included). If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.

3. PFAS Products

Sources and Common Uses

PFAS are present in mixtures as surfactants, flow-aids and wetting agents, anti-foaming, and film-formers, PFAS are also used in working fluids, lubricants and greases as additives to reduce friction, minimise wear and increase part life. They are used in firefighting fluids like advanced firefighting foams (AFFF) and in Film Forming Fluoro-Protein (FFFP). They are used in various sprays such as release aids, stain resistant treatments and anti-seize. Many PFAS used in mixtures have no hazardous classification in the globally harmonised system for classification and labelling (CLP), and are not substances of very high concern (SVHC) on the candidate list, and therefore many PFAS are not shown on safety data sheets even though the substance is present.

In articles, PFAS are used as flame retardants and manufacturing aids in plastics, and are used for surface coatings on all kinds of materials, including metals, textiles, leather and plastic and rubbers.

Restricted Uses

Based on the current proposal, all the following uses will be restricted:

- Fluoroelastomers FKM (Viton®) and FKKM (Kalrez®) are used for gaskets, seals, high temperature hoses and cables,
- Homopolymers such as Polytetrafluoroethylene (PTFE), and Polyvinylidene fluoride (PVDF, Kynar®) are used in many plumbing and pipework applications, both for water systems and in systems where pipe / valve corrosion and fluid contamination are risks,
- PFAS in electrical and electronic equipment (EEE), which is a very wide range. PFAS for example are in batteries, fibre optics, lasers, smart phones and tablets, computers, servers and electronic component test fluids and test equipment. They can be found all the way down to small parts like semiconductor packages, PCB components (diodes, capacitors etc) and PCBs themselves, wire, cable, glands, seals and housings, and even in the packaging.

4. Impact To Businesses

After the Restriction enters into force, all PFAS will no longer be legal to use in their current applications in the EU, or imported into the EU after the 18 month transition period. Although the timeline is not fully known, this could mean that the restriction could be implemented as soon as mid 2026.

The exception to this is if there is a derogation listed in the regulation, for 5 years with a 18 month transition period, or 12 years with a 18 month transition period. These derogations have to be agreed prior to the publication of the restriction, and there is currently no process for asking for derogation time periods to be extended. If your use is able to continue under one of the proposed derogations, any manufactures or importers of PFAS will have annual reporting obligations to the regulator. In addition to this, any importers or downstream users of fluoropolymers and perfluoropolyethers will need a management plan (available for enforcement inspection on request) for each site where they are used covering:

- The identify of the PFAS and the products that they are used in
- The justification of each use of the PFAS
- Details on the conditions of use and safe disposal.

The loss of the majority of PFAS applications from the market will have a significant impact on PFAS availability as the market adjusts. There are already signs of this triggering obsolescence prior to the regulatory changes, as 3M have announced that they will cease manufacture of PFAS by the end of 2025.

RINA Recommendations:

- Identifying all uses of PFAS within your product portfolio, in your manufacturing facilities, and start qualifying PFAS free alternatives wherever possible.
- Wherever PFAS is required beyond mid-2026, your business and any sector trade association should engage with the regulator and provide detailed socio economic reasons for any derogation you request into the consultation before the end of the consultation period (22 September 2023) at the absolute latest. Otherwise the use of the substance may likely no longer be permitted.
- Not assuming that proposed derogations are automatically granted: the regulator needs to know if the time frame is realistic, and in the proposal many derogations require more detail to support their case before they are accepted and finalised. If you have relevant information, provide it.

5. Restriction Process

Next Steps

ECHA's scientific committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) meet in March 2023 to check that the proposal meets the legal requirements of REACH and if satisfied, they will upgrade the pre-publication version currently online to the formal published version for comment. Presuming they agree to the proposal, a six-month consultation will start on 22 March 2023. RAC and SEAC will then begin their scientific evaluation of the proposal.

The RAC will review early responses to the consultation and will develop their opinion in parallel to the public consultation. They will publish their opinion 6 weeks after the end of the consultation.

The SEAC will review all socioeconomic arguments that respondents choose to submit in the consultation period, and are likely to publish their responses between 22 March 24 and 22 June 2024, depending on the number of responses received.

There will then be an opportunity to comment on the SEAC and RAC opinions before they are issued to the European Commission and the restriction is likely to be finally agreed and published in late 2024 or during 2025. There will then be the 18 month transition period.

Rina Manufacturer Recommendations

- Review their PFAS uses as a matter of urgency, identifying all PFAS upon which their product range relies,
- Respond to the consultation if affected by the PFAS restriction, which opens on 22 March 2023,
- Respond to the RAC and SEAC opinions when that consultation opens in approximately 12 – 15 months.

6. Conclusion

In conclusion, the EU's draft restriction proposal for per- and polyfluoroalkyl substances (PFAS) represents a significant step towards reducing the environmental and health impacts of these persistent and harmful chemicals. The proposed restriction is a comprehensive measure that covers a wide range of products and applications and sets strict limits on the use and release of PFAS. However, implementing the proposed restriction will pose significant challenges for affected industries, including compliance costs, technological barriers, and the need for safer alternatives. At the same time, the proposed restriction also presents opportunities for innovation, sustainability, and stakeholder engagement.

As the EU moves towards finalizing the restriction, it will be essential for businesses, policymakers, and other stakeholders to collaborate and navigate this rapidly evolving regulatory landscape in a responsible and proactive manner. By doing so, we can ensure a more sustainable, healthy, and equitable future for all.

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