AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

REACH universal PFAS restriction proposal

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Executive summary

In February 2023, the European Chemicals Agency (ECHA) started discussing the universal per- and polyfluoroalkyl substances (PFAS) restriction put forward by relevant authorities from Denmark, Germany, the Netherlands, Norway and Sweden.

The restriction's framework should take a proportionate approach to both protect human health and the environment and achieve the ambitions laid out in wider EU policy, including the Net-Zero Industry Act (NZIA) and the Clean Industrial Deal. The Commission can accomplish these goals by:

- **Regulating based on evidence and risk assessment**. In particular, the restriction should be based on smaller groups of substance-specific risk assessments, exclude PFAS with properties predictive of low hazard, assess life cycle impacts and consider existing risk management measures that already address the release of emissions into the environment.
- **Increasing regulatory predictability.** The Commission should provide longer, well-defined derogations when no viable or available alternatives exist and full derogations for essential industrial applications, aligning the restriction with existing legislation and broader EU policy objectives like the Competitiveness Compass and the Clean Industrial Deal.
- **Ensuring coherence and enforcement**. To do so, the restriction must be coherent with other existing and future regulatory requirements and legislation such as the Fluorinated Gass (F-gas) Regulation, the Industrial Emission Directive (IED), the Packaging and Packaging Waste Regulation (PPWR) and the Waste Framework Directive (WFD). It should establish practical and enforceable thresholds and concentration levels for PFAS in products, develop standardised testing methods for PFAS presence, consider the complexity of global supply chains and include a review clause to assess the restriction's effectiveness and adjust it based on technological advancements and the availability of alternatives at the market level.

Introduction

ECHA and its committees continue to review a proposal for a universal PFAS restriction. This position paper responds to the ECHA progress update reported on 20 November 2024 and recommends restriction options other than a ban, that account for different PFAS properties and risk profiles. In light of the upcoming Chemicals Industry Package and the revision of the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), the Commission must establish a more proportionate, predictable and enforceable restriction. It should be risk based, assess in-depth the available scientific evidence on polymeric and non-polymeric PFAS and consider the socio-economic value of certain substances in the scope of this proposal and their contribution to the EU's competitiveness.

Regulating based on evidence and risk assessment

Protecting human health and the environment is crucial. However, the proposed blanket ban on PFAS lacks scientific specificity, as it groups over 10,000 substances without differentiating their distinct hazard profiles. To strike the right balance between promoting safety and fostering competitiveness, the EU needs a more science-based and risk-oriented approach that focuses on specific substances

which pose an actual threat. For example, fluoropolymers, which are not mobile in the environment, not bio-accumulative, unable to bioconcentrate and have low hazard potential, should not be included in a broad ban. Instead, these should be regulated separately. Another example is refrigerants that are regulated by the F-gas Regulation. The restriction, as currently written, is application based, which would lead to inconsistent regulation of specific substances. For example, a molecule could be banned in one application but given a long derogation in another.

The restriction should assess the necessity of different high-performing PFAS like fluoropolymers and refrigerants in critical technologies where there are no suitable alternatives currently available or the viability of potential alternatives remains to be determined. These include PFAS in medicinal products, medical devices (insulin pumps, patient monitoring equipment etc), complex industrial equipment, (equipment used to detect PFAS contamination), semiconductors, energy production (photovoltaic front sheet protection, wind turbines paint and coating, coating, hydrogen, nuclear etc), aerospace and defence (high-performance lubricants, sealing applications, composites processing etc), cellular communications, wireless connectivity and automotive and energy transition (geothermal energy and carbon capture use and storage).

Key recommendations:

- Provide more guidance – with clear definitions and methods – on practically demonstrating compliance with the restriction.
- Base the restriction on smaller groups of substance-specific risk assessments to determine the substances to be included.
- Exclude from the ban PFAS with properties predictive of low hazard, such as fluoropolymers and internal or inaccessible components of complex durable goods.
- Assess lifecycle impacts, considering both health and technological needs.
- Use well-founded, substance-specific risk or hazard criteria within other regulatory frameworks to determine appropriate PFAS standards eg implement appropriate emissions limits and risk management measures under the F-Gas Regulation and IED or suitable environmental quality standards in the WFD.

Increasing regulatory predictability

The current PFAS restriction proposal hampers regulatory predictability and creates uncertainty in many sectors. Supply chains rely on chemical names and Chemical Abstract Service (CAS) numbers to communicate restrictions, so any PFAS regulation should include a specific list of chemicals and CAS numbers within scope, rather than vague chemical descriptions. Without clear scope and timelines of derogations where no alternatives exist, industries relying on PFAS face disruptions in production, supply chains and investment. To foster a stable regulatory environment as well as predictability for businesses, the European Commission must provide clear and enforceable derogations within a shorter timeframe. Additionally, time limits for derogations should reflect the complexity of transitioning to alternatives, product re-designs and timelines for production at scale.

For some applications, alternatives are yet to be developed, meaning a timeline for their availability is uncertain. For example, in the aerospace and defence, information technology and electronics sectors,

as well as specific heating and cooling applications, all products must fulfil significant technical, reliability and safety requirements, so-called type approval process, and undergo a strict qualification process, which lengthen substitution timelines. The process of redesigning, retesting and recertifying equipment is resource and time intensive. For some components, technology development through the relevant stages can take at least 10 to 15 years, including research and development, requalifying the materials, purchasing new manufacturing equipment with training, requalifying new equipment and performing field trials.

To comply with the PFAS restriction, international, regional and national regulatory entities and standard-setting organisations will need to revise a wide of range of standards. This review usually takes between three to five years and requires significant technical resources to develop and implement. This is the case of pharmaceutical products for instance, where no viable alternatives are available to meet pharmaceutical legislation's strict patient safety, quality and efficacy requirements. Following the review of the mentioned standards, testing and completing the qualification programme to meet a given standard can take an additional three to five years. It is not possible for business to re-engineer substitute compounds in all products by the proposed deadlines, even if industrial manufacturers were to cease all other research and rededicate all resources to the sole task of developing products with PFAS-free alternatives. The rush to qualify materials and associated products under applicable standards would overwhelm the capacity of qualified laboratories.

Key recommendations:

- Provide longer, well-defined derogations where no current proven alternatives currently exist or possible alternatives are far from full market deployment, and full derogations for essential industrial applications.
- List regulated PFAS by name and CAS number, not by chemical description.
- Align the restriction with broader EU policy objectives like the Competitiveness Compass, the Clean Industrial Deal and the NZIA, also considering the social-economic impacts.

Regulatory coherence and enforcement

The REACH universal PFAS restriction proposal must be coherent with other existing EU legislation, such as the Classification Labelling and Packaging Regulation, the F-gas Regulation, the PPWR, Urban Waste Water Treatment Directive and the Ecodesign for Sustainable Products Regulation (ESPR), among others. Currently, these regulatory frameworks are not coordinated, which could result in conflicting requirements and compliance challenges. For example, the concept of the 'right to repair' has been widely included in EU legislation and should encompass the ability to repair items that contain PFAS. EU legislators have broadly incorporated into other EU substance restrictions and other REACH restrictions the right to repair via the concept of 'repair as produced'[1] and the resale of pre-owned products. However, they are not included in the current version of the PFAS restriction. It is essential that Commission include them in the PFAS restriction to avoid major market disruptions.

[1] For instance, the well-established 'repair as produced' principle allows finished electronic products already on the market before a compliance enforcement date to be repaired using spare parts that were compliant before that enforcement date.

In addition to conflicting requirements, the restriction should not impede EU objectives. For example, the F-gas Regulation is successfully reducing emissions; regulating F-gases again under REACH unnecessarily duplicates regulation and increases costs and administrative burdens.

The broad scope of the restriction makes enforcement difficult, particularly in complex global supply chains eg, in the electronics pharmaceuticals, or machinery sector or with Fluoropolymers products in a chain involving producers, converters, equipment manufactures and end users. Monitoring compliance with such a wide-reaching ban would require new testing methods and calibrated equipment, which are currently unavailable and consequently, could further undermine the EU's competitiveness. Such a ban can only considered valid where there is evidence proving the need and where the cost to society is too great. In this respect, companies need more guidance on appropriate due diligence for compliance.

Key recommendations:

- Ensure alignment with existing or upcoming legislation that regulates PFAS – such as the PPWR, the WFD, the IED, the Toy Safety Regulation and the ESPR – and industrial emissions, F-gases and circular economy principles. In particular, the Commission should avoid double regulation with the F-gas regulation.
- Support the circular economy, avoid premature obsolescence and support product longevity by incorporating the 'repair as produced' principle for the repair of spare parts of products already placed on the market and the re-supply of pre-owned products.
- Establish practical and enforceable thresholds for PFAS in products in the scope of the REACH universal PFAS restriction.
- Encourage innovation by allowing for the advent of new and innovative technologies and processes that may incorporate PFAS in the future.
- Develop standardised testing methods for PFAS' presence, considering the complexity of global supply chains.
- Include a review clause to assess the effectiveness of the restriction and make adjustments based on technological advancements and availability of alternatives.

Conclusion

A more targeted, science-based approach to regulating PFAS is essential to protecting human health and the environment, as well as achieving long-term European competitiveness. This approach should exclude substances that do not pose a risk or pose a negligible risk to health and the environment, be controlled by appropriate risk management measures and incorporate clear and predictable derogations.