

Dear Sir or Madam:

We appreciate the opportunity to participate in the public consultation on the proposed restriction on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS).

1. Comments regarding Scope of PFAS Definition

The proposed restriction has defined the chemical scope of PFAS as: 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), with a few exceptions. This definition is aligned with the Organisation for Economic Co-operation and Development (OECD) chemical definition for PFAS, which states that “fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), that is, with a few noted exceptions, any chemical with at least a perfluorinated methyl group (-CF₃) or a perfluorinated methylene group (-CF₂-) is a PFAS” (OECD 2021).

The PFAS definitions adopted in the proposed restriction and OECD are based solely on chemical structure and does not take into account the wide range of structures and properties or risks of PFAS. As a result, it covers approximately 10,000 substances with very diverse physical, chemical and biological properties and behaviour. This broad definition does not take into account the specific, distinct properties of different individual PFAS or PFAS subgroups and is therefore not suitable for regulatory risk management purposes. OECD itself acknowledges that this definition “does not conclude that all PFASs have the same properties uses, exposures and risks” and that it can only serve a starting and reference point as it “may be viewed as too broad” (OECD, 2021, Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance). In particular, the very broad scope of the PFAS definitions adopted by the proposed restriction and OECD does not enable a legally and scientifically sound risk assessment. By grouping all PFAS together in a single group, the proposed restriction fails to identify and consider the specific, distinct properties of each individual PFAS or PFAS subgroup and, in turn, it cannot be used to assess or characterise the hazards and risks related to those properties.

For example, fluoropolymers and fluoroelastomers are thermally, biologically, and chemically stable, barely soluble in water, immobile, insoluble in many common solvents such as water and octanol, and too large to migrate to cell membranes, so they are not incorporated into the body and are considered low concern from a human and environmental health perspective¹. Review of the toxicity data, human clinical data, and physical, chemical, thermal, and biological data for fluoropolymers has found that fluoropolymers satisfy widely accepted assessment criteria to be considered as “polymers of low concern”². These findings demonstrate that fluoropolymers and fluoroelastomers are distinct groups from other classes of PFAS such as PFOA and PFOS and should not be combined with them for hazard assessment or regulatory purposes.

Article 68(1) REACH provides that substance(s) can be restricted if they pose an unacceptable risk to human health or the environment. This unacceptable risk must be positively demonstrated by conducting a risk assessment that follows the conditions of Annex XV to REACH (and by cross-reference of Annex I

¹ Stephen K et al, Integrated Environmental Assessment and Management, Vol19(2),p326–354
<https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4646>

² Barbara H et al., Integrated Environmental Assessment and Management, Vol14(3), p316–334.
<https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035>

and Annex XIII). Such risk assessment comprises hazard identification and characterisation, exposure assessment and risk characterisation.

The proposed restriction applies to the entire range of substances falling within the broad definition for PFAS, including fluoropolymers and fluoroelastomers. However, fluoropolymers and fluoroelastomers have been demonstrated not to possess harmful properties to human health or the environment as discussed above. As such fluoropolymers and fluoroelastomers fail to meet the criteria for restriction under Article 68(1) REACH, and therefore, they should not be encompassed within the scope of the proposed restriction.

Based on the foregoing, we believe that, at minimum, fluoropolymers and fluoroelastomers should be excluded from the scope of the proposed restriction. We also believe that several other classes of PFAS would be required to be similarly evaluated against the criteria of Article 68(1) prior to any restrictions being proposed against such substances.

2. Comments regarding information on alternatives and socio-economic analysis (SEA) issues

PFASs have properties such as repelling water and oil, being resistant to heat, chemicals, and not absorbing light, and have been widely used in water repellents, surface treatment agents, emulsifiers, fire extinguishers, coatings, etc., and in a wide range of industrial applications such as semiconductors, automobiles, and batteries. Many of these applications and uses are considered "essential uses".

The applications in which PFAS are used are also critical for achieving the European Green Deal, which is a comprehensive initiative that includes a range of policies in different areas aimed at making Europe climate-neutral by 2050. For example, the Horizon Europe program funds research and innovation activities in transportation, including batteries, clean hydrogen, low-carbon steel manufacturing, the cyclical bio-based sector and the built environment.

Many of these industries require the use of certain PFASs, such as fluoropolymers and fluoroelastomers, to continue their operation and to reduce their emissions. In many instances, fluoropolymers and fluoroelastomers are some of the only materials that simultaneously possess heat resistance, weather resistance, chemical resistance, water repellency, lubricity, and unique optical/electrical properties, and they have become indispensable materials in many fields, including the energy field (fuel cells and lithium-ion batteries), semiconductor field (fluorinated coatings, etching gas), electrical and electronic communications field (wire cladding and liquid crystal materials), transportation field (cars, airplanes, railroads), and medical field (catheters, protective clothing). We therefore believe that the proposed recommendation to classify all PFAS for all uses as "toxic", including uses that are critical to fulfilling climate plans and targets, would significantly hamper efforts towards achieving the objectives under the European Green Deal.

Advanced manufacturing processes often require the use of PFAS due to their unique properties, such as resistance to heat, chemicals, and water. The use of PFAS is unavoidable for many chemical and/or physical processes during advanced manufacturing, due to the harsh conditions that are required in advanced manufacturing. It is noted that these processes are most commonly carried out under well-controlled environments, whether in lab or production settings due to compliance with numerous regulations (OSHA) and industry-standards (GMP, ISO, etc.), which significantly minimizes possibilities of environmental release or human exposure of such PFAS use.

Advanced manufacturing in Europe is of significant importance to the European economy, not only for export of products and services to international markets, but also for the critical role it plays in enabling

other technology sectors to continue their operation and innovations. Moreover, the proposed restrictions would hamper importation of articles and products made outside of Europe using such advanced manufacturing technologies, materials and processes if they contain even trace amounts of PFAS.

Implementing strict restrictions on PFAS and PFAS-containing articles may: (i) render certain processes or products infeasible to manufacture due to the lack of non-PFAS alternatives; (ii) increase manufacturing costs due to the need to find suitable alternatives (if they exist) or invest in development of replacement technologies; (iii) limit the availability of certain raw materials or components, leading to disruptions in the supply chain for manufacturers and companies who rely on such supply; (iv) where alternatives to PFAS exist, they are generally not as effective, and thus manufacturers may face challenges in developing products with similar performance attributes, potentially impacting the competitiveness of their offerings in the global market; and (v) unduly restrict European industries and consumers' access to existing and new products and technologies.

Therefore, we strongly advocate against implementing broad restrictions against every use of every PFAS, such as the approach being considered under the proposed restrictions.

3. Comments regarding Request for Exemption in Certain Industrial Sectors

We believe that restrictions on some uses of certain PFAS classes would be justified if there exist documented and substantiated risks posed to human health and the environment. Restrictions of PFAS in uses which have been shown to cause significant environmental or human exposure to harmful and persistent chemicals may yield more impactful results than implementing a broad restriction on PFAS as a whole, irrespective of its use. Uses of PFAS which may pose significant exposure risks include firefighting foams, textiles (including carpets and clothing), cosmetics, and paper food packaging.

However, it is important to acknowledge that certain industrial sectors, such as electronics, semiconductor, automotive, advanced manufacturing, and pharmaceuticals, among others, employ relatively small amounts of PFAS with limited potential for environmental release or harmful human exposure. Due to their controlled usage and minimal availability, the risks associated with these specific applications are comparatively lower than many other use cases of PFAS. For example, fluorinated coatings play critical roles in these industrial sectors due to the unique characteristics of fluorine. They are indispensable industrial materials/sub-materials in these industrial sectors. Implementing targeted restrictions while permitting the continued use of PFAS in these sectors ensures a balanced approach that prioritizes risk reduction without hampering critical technological advancements.

In view of the foregoing, we respectfully request the ECHA Committees to reconsider the proposed broad restrictions against all PFAS.