May 25, 2026

Stéphane Sejourne
Executive-Vice President for Prosperity and Industrial Strategy
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels
Belgium

RE: Response to Socio-Economic Analysis Committee (SEAC) Draft Opinion and Risk Assessment Committee (RAC) Evaluation on Proposed PFAS Restriction

Dear Executive-Vice President Sejourne:

The undersigned organizations appreciate the opportunity to provide comments on the draft SEAC opinion and associated RAC conclusions regarding the proposed restrictions on per- and polyfluoroalkyl substances (PFAS) under REACH. We support the objective of accelerating cleanup and controlling emissions of PFAS in the environment, based on the best science and risk management. At the same time, we must maintain access to essential chemistries in critical sectors across the economy. We respectfully submit that the proposal would benefit from further refinement to ensure that regulatory outcomes are scientifically grounded, proportionate, and practically implementable.

We urge that any final approach does not include broad product bans from commerce without consideration of risk, unavoidable use, or available replacements. Proposed derogations are merely delays in the implementation of such bans and often are not sufficient for transition to alternatives to occur. This approach also fails to consider systemic impact on the supply chain —too narrow derogations would likely lead to suppliers exiting the market and lead to unintended consequences such as critical products shortages or reinforcing reliance on sole suppliers based in third countries, in direct contradictions with the EU strategic autonomy and simplification objectives. Instead, the proposal should focus in a more targeted way on chemistries used in applications with high potential for exposure to actual hazardous materials.

Our comments focus on several key areas:

Need to Reevaluate the Science Based on Risk and Potential Exposure

The current proposal is fundamentally driven by a class-based approach, treating all PFAS as exhibiting equivalent risk due to persistence and potential for long-term accumulation. All PFAS are not the same. While persistence is a legitimate concern especially for legacy chemistries, a risk-based framework—integrating hazard, exposure, and use conditions—is essential to ensure proportionality and effectiveness.

We note that SEAC itself highlights significant uncertainties, data gaps, and limited quantification of both costs and benefits across sectors. These uncertainties extend to exposure pathways, emissions, and actual risk profiles, yet the proposal applies sweeping restrictions across thousands of substances.

Key considerations:

- Exposure variability: PFAS are used across diverse applications with vastly different exposure profiles (e.g., closed industrial systems versus consumer uses).
- Emission-based risk proxy limitations: The proposal relies heavily on emissions as a proxy for risk due to their persistence. However, this approach does not distinguish between tightly controlled uses and diffuse emissions.
- Lifecycle considerations: RAC and SEAC acknowledge emissions occur across manufacture, processing, use, and end of life (e.g. recycling or disposal) stages. This limitation further underscores the need for targeted controls rather than blanket bans.

Accordingly, we recommend:

- A refined, risk-based prioritization of PFAS uses based on essentialness to the economy, alternative product availability, national security, and actual exposure and emission potential.
- Greater reliance on lifecycle risk assessments and use-specific exposure data.
- Expanded consideration of emission control measures and technologies where risk can be effectively managed without eliminating critical uses. This approach can be applied, for example, to both fluoropolymer manufacturing and F-gas uses/applications:

    - In the case of fluoropolymers, the established framework of the Industrial Emissions Directive (IED) provides a mechanism for managing risks associated with emissions. The IED sets permitting conditions and emission limit values based on Best Available Techniques (BAT/BREF), which provides certainty for manufacturers to align their voluntary emission reduction efforts with official EU standards.
    - In the case of F-gases, a more proportionate and risk-based approach is to allow for a continued use of F-gases for controlled/contained uses (e.g., leak rates below a defined threshold) and for those uses for which non-fluorinated alternatives trigger an operational safety concern.
- Chemistries for which EU REACH duplicates existing regulations, such as the EU's Persistent Organic Pollutants (POP) and the IED should be exempt or at the very least the EU should clearly explain how the "dual regulatory control" would practically work. For instance, the POP already covers:
    - PFHxS, it's salts and related compounds.
    - PFOS, it's salts and related compounds.
    - PFOA, it's salts and related compounds.

Moreover, PFAS are used in a whole range of critical industrial equipment at manufacturing sites, including in the chemicals industry, where they meet critical performance needs around resistance to temperature, stress and corrosion. Examples include gaskets, sealings, pipe linings, membranes and other types of industrial machinery. As these applications are integral to the safety and operations of entire manufacturing sites, a full, time-unlimited derogation is needed.

Such an approach would align regulatory action more closely with measurable risk, while maintaining environmental protection and economic growth goals.

Development of a Practical, Risk-Based Definition of PFAS

The proposed definition—covering any substance containing at least one fully fluorinated carbon —captures more than 10,000 substances under a single regulatory umbrella. This definition introduces significant challenges:

- It does not differentiate functional or environmental behavior among PFAS subgroups.
- It risks capturing substances with low hazard or controlled exposure profiles.
- It complicates enforceability, monitorability, and innovation pathways.

The RAC rejected an exclusion for certain degradable structural groups on the basis of insufficient evidence. This suggestion underscores the importance of robust, risk-based definition, rather than treating all PFAS the same and proposing a binary inclusion/exclusion framework.

It should be also stated that several U.S. government agencies, including the Department of War, Department of Energy, the Environmental Protection Agency, and the Food and Drug Administration have raised the importance of a risk-based definition and the essentiality of fluoropolymer and fluorinated gas applications.[1][2]

We recommend that the EU:

- Build on existing structural-based definitions[3]used in other jurisdictions such as the U.S., which incorporate:
    - Functional subgroup distinctions.
    - Consideration of polymeric vs. non-polymeric substances.
    - Recognition of degradation behavior and environmental fate and transport.
- Develop a tiered definition framework that distinguishes:
    - Persistent, bioaccumulative PFAS of highest concern.
    - Low-emission or polymeric PFAS and fluorinated gases with minimal exposure pathways
- Align definitional scope with risk-relevant attributes rather than a single broad chemical criterion.

A more refined definition would improve regulatory clarity, enforceability, and scientific credibility, while avoiding unintended consequences such as over-regulation of low-risk applications, including fluoropolymers and fluorinated gases. Rather than the time limited derogations, which are nothing more than a delay of the proposed

[1] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.denix.osd.mil/cmrmp/denix-files/sites/14/2025/07/2025-DoD-Update-on-PFAS-Critical-Uses.pdf

[2] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.osti.gov/servlets/purl/2370520

[3] For example, the Delaware PFAS definition: (4) “PFAS” means non-polymeric perfluoroalkyl and polyfluoroalkyl substances that are a group of man-made chemicals that contain at least 2 fully fluorinated carbon atoms, excluding gases and volatile liquids. “PFAS” includes PFOA and PFOS.
(5) “PFOA” means perfluorooctanoic acid and its salts.
(6) “PFOS” means perfluorooctanesulfonic acid or perfluorooctane sulfonate and its salts

broad bans, appropriate consideration of low-risk chemistries and associated essential products would better enable a viable and workable framework.

Proportionality

The EU REACH effort contrasts with the risk-based approach that has been the foundation of chemicals regulations in all major economies for decades. Such broad-based restrictions require a strict application of the proportionality principle, and all efforts must be deployed at the technical and political levels to consider alternative approaches to support the most balanced and targeted approach. Sweeping bans are never the right solution, and thus far, ~~no~~ efforts ~~have been made~~ to address potential concerns by considering alternative approaches that are more balanced and targeted have been limited, focusing on restricting all PFAS, rather than examining in better detail mechanisms under other Directives or Regulations, like the EU's Industrial Emissions Directive mentioned above. We are concerned that the methodology applied by ECHA could lead to burdensome restrictions too broadly and too quickly, without a consistent reliance on good data and the best science to justify its determinations. This approach would be inconsistent with the SEAC discussion of proportionality of the needed responses.

Economic Impacts on Critical Sectors and Essential Uses

The current scientific limitations highlighted above should further strengthen a strict application of the proportionality principle – and ensure that socio-economic data provided across sectors heavily influence final decision-making in favor of appropriate consideration of critical and unavoidable uses.

SEAC acknowledges that costs of a full PFAS ban are likely significant, and that data limitations prevent a comprehensive assessment. The evidence provided in the attached economic study further illustrates the scale of potential disruption, particularly for essential uses.[4]

Across key sectors—including aerospace, defense, energy transition, healthcare, semiconductors, and transportation —essential fluorochemistries underpin critical performance, safety, and reliability functions.

[4] https://www.uschamber.com/environment/essential-chemistries-providing-benefits-across-the-u-s-economy

- These sectors collectively support approximately:[5]
    - 6.1 million jobs
    - $2.4 trillion in output
    - ~$1 trillion in GDP

In many applications:

- No viable alternatives currently exist, or substitutes may take as much as 20 years or longer to develop, qualify, and deploy.
- Considerations regarding regulatory and litigation driven obsolescence that will make the transition that much more challenging. The most recent Department of War report supports this issue. "An increasing number of mission critical PFAS and PFAS-enabled products are at risk for obsolescence due to market phase outs; manufacturer liability; complex geopolitical escalation dynamics; and regulatory complexity, uncertainty, and inconsistency which impact all levels of the PFAS supply chain. Major shifts in PFAS manufacturing decisions result in the chronic loss of products before alternatives can be qualified and the increased likelihood of substitution regret—factors that contribute to the growing and impending risks to mission readiness and national security."[6]
- Alternatives may introduce new environmental, safety, performance, or regulatory risks.
- Substitutions could undermine strategic priorities, including:
    - Advanced manufacturing
    - Chemical manufacturing
    - Electronics
    - Energy transition technologies (e.g., batteries, renewables).
    - Semiconductor manufacturing and digital infrastructure.
    - Life sciences manufacturing.
    - Lubricants
    - Medical devices and pharmaceuticals.
    - National security and defense capabilities.
    - Water treatment technologies that contribute to environmental security for cities (through potable water, wastewater management, and water

[5] https://www.uschamber.com/environment/essential-chemistries-providing-benefits-across-the-u-s-economy

[6] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.denix.osd.mil/cmrmp/denix-files/sites/14/2025/07/2025-DoD-Update-on-PFAS-Critical-Uses.pdf

reuse) and industries (e.g., pharmaceutical, chemical, food and beverage, and semiconductor).
    - Various complex durable goods, including automotive and aviation solutions.
    - Horizontal sectors such as sealing and lubricants that have applications across key verticals.

SEAC itself recognizes low substitution potential in several uses and recommends use-specific derogations to maintain proportionality.

Given these realities, we strongly support:

- A clear framework for identifying and preserving essential uses.
- Realistic transition periods aligned with innovation timelines and the inclusion of a review clause in the restriction text which would allow an efficient procedure to prolong any exemptions or derogations in the absence of suitable alternatives at the end of the derogation timeline.
- Recognition that premature substitution could lead to unintended environmental or societal trade-offs.
- While we believe that derogations are the wrong public policy, if the EU provides such a time limited approach, a formal review mechanism is essential to avoid a regulatory cliff and give business certainty. Where alternatives cannot be qualified within standard derogation timeframes, a transparent and defined process for requesting and reviewing extensions should be established, incorporating both technical and socio-economic considerations. This could be modelled on the review obligation introduced in the restriction of PFAS in firefighting foams under Commission Regulation (EU) 2025/1988.

Key Sector-Based Rationale

Aerospace Manufacturing

- Economic impact: High-value contributor within a ~$1 trillion GDP footprint across sectors; supports significant advanced manufacturing employment, including 510, 400 workers in aircraft manufacturing.[7]

[7] https://www.ibisworld.com/industry-statistics/employment/aircraft-engine-parts-manufacturing-united-states/

- Replacement challenges: No viable alternatives for many safety-critical applications (e.g., insulation, hydraulic systems).

Clean Energy Technologies

- Economic impact: 212, 300 jobs; critical to renewables, batteries, and EV supply chains supporting decarbonization investments.
- Replacement challenges: Limited substitutes for batteries and renewable components; replacements likely >10 years and could slow deployment.

Data Centers

- Economic impact: 655,600 jobs supported; fast-growing sector (~$99B market) critical to digital infrastructure and AI-driven growth.
- Replacement challenges: Cooling and fire suppression alternatives would require redesign, with performance and reliability tradeoffs.

Defense Equipment & Systems

- Economic impact: 242,700 jobs supported; essential to national security industrial base and high-value manufacturing output.
- Replacement challenges: No viable substitutes for many mission-critical uses; alternatives may take 5–20 years and pose safety risks.

Health Care

- Economic impact: 365,400 jobs; supports critical medical device, pharmaceutical, and health supply chains contributing to national GDP.
- Replacement challenges: Many uses beyond pluoropolymers (sterilization, packaging, refrigeration, device performance) are irreplaceable or only partially substitutable. The updated DoW PFAS critical use report indicated that "PFAS are critical to medical applications—devices, pharmaceuticals, and equipment—due to their unique thermal stability, chemical resistance, low friction, and biocompatibility properties. Medical devices account for a small share (~2%) of the total PFAS market. Based on what is currently known, PTFE, ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), and polyvinylidene fluoride (PVDF) account for 90% of the fluoropolymers used in medical devices. Expanded polytetrafluoroethylene (EPTFE) and hydrofluoroethers (HFEs) are also used. Currently, there are no functional

alternatives for PFAS in medical devices, and it is estimated that to go from conception to market for a viable PFAS alternative would take 10 to 15 years. "[8]

Life Sciences Manufacturing

- Economic Impact: ~2.1 million U.S. jobs (~$48 billion EU bioprocessing market) fast-growing sector (~$73 billion by 2027) critical to healthcare, biomanufacturing and R&D supply chains.[9]
- Replacement challenges: No viable substitutes for many mission-critical uses; approved alternatives likely to exceed 13.5-year derogations.

Military, First Responder & Medical PPE Textiles

- Economic impact: ~453,000 jobs supported; essential to national security and the protection of frontline military, first responder and medical personnel.
- Replacement challenges: No viable substitutes for many mission-critical uses including barrier protection in chem/bio suits, defense hazardous materials handlers' uniforms; medical infectious protective gowns, masks and gloves. DoW stated that "DoD is currently tracking over 100 fielded items that are or will be affected by PFAS regulations and/or voluntary PFAS manufacturer market exits. The objectives of this work are to determine the functionality PFAS provides, identify timelines and manufacturer alternatives, track regulatory waivers, evaluate non-PFAS alternatives and monitor the research, development, test, and evaluation (RDT&E) of PFAS alternatives – both repellent finishes and barriers for protection." [10]

Mobility (Automotive & Transportation)

- Economic impact: Largest sector impact (~2.6 million jobs); foundational to U.S. economy, logistics, and consumer mobility.
- Replacement challenges: No viable substitutes for key components (EV batteries, semiconductors, seals); transition estimated at 15+ years.
- All applications relevant to the vehicle should be included in the proposed overall vehicle type approval derogation, with no exclusions.

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[8] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.denix.osd.mil/cmrmp/denix-files/sites/14/2025/07/2025-DoD-Update-on-PFAS-Critical-Uses.pdf

[9] https://intuitionlabs.ai/articles/us-biotech-job-market-2025 and https://www.cbre.com/insights/reports/us-life-sciences-talent-trends-2025

[10] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.denix.osd.mil/cmrmp/denix-files/sites/14/2025/07/2025-DoD-Update-on-PFAS-Critical-Uses.pdf

- All forms of EU vehicle type approval – including small series and individual approval – should be included in the scope of general type approval derogation.

Oil & Gas / Industrial Energy Systems [11]

- Economic impact: The proposed PFAS restriction (RO2) could result in estimated annual turnover losses ranging from approximately €25 billion to €165 billion across the upstream O&G, refining, renewable fuels, and fuel distribution sectors between 2041–2055. Associated employment impacts are estimated at roughly 41,000 to 271,000 direct jobs lost relative to baseline conditions, with broader potential risks including facility shutdowns, supply disruptions, higher costs, weakened EU competitiveness, and reduced CCS investment and deployment.
- Functional role of PFAS: Fluoropolymers and related PFAS chemistries are essential to upstream, midstream, and downstream oil and gas operations, particularly in applications requiring extreme durability, corrosion resistance, and chemical stability. These materials are widely used in:
    - Piping, linings, and vessels handling aggressive chemicals.
    - Seals, gaskets, and fluid-handling components
    - Coatings and cable insulation in high-temperature or high-pressure environments
    - Filtration and containment systems

  These applications are critical for:
    - Preventing leaks and unintended emissions
    - Maintaining system integrity in corrosive environments
    - Enhancing operational safety and reliability
    - Reducing maintenance requirements and downtime
- Fluoropolymers specifically contribute to corrosion prevention and containment performance, which are essential given the significant economic and operational risks associated with corrosion in industrial systems. Even marginal loss of performance could lead to increased equipment failure risk, higher emissions, and elevated safety concerns. Replacement challenges:
- In many oil and gas and industrial process applications, PFAS are not interchangeable materials but are embedded in system design and performance requirements.

[11] https://iogpeurope.org/resource/socio-economic-analysis-for-a-reach-restriction-proposal-on-pfas-in-the-upstream-oil-gas-oil-refining-and-fuel-distribution-sectors-and-in-carbon-capture-and-storage/

- Substitutions would require system redesign, requalification, and extensive testing, particularly for safety-critical and high-pressure applications.
- Alternative materials may lack equivalent chemical resistance, durability, or lifecycle performance, increasing the risk of corrosion, leaks, and operational failures.
- Premature substitution could result in higher emissions, reduced efficiency, and unintended environmental or safety trade-offs, contrary to regulatory objectives.

Residential and Commercial Heating and Cooling (Fluorinated Gases) [12]

- Economic Impact: 519,927 jobs and more than $68 billion in GDP.
- Replacement challenges: Any replacements from current low global warming potential refrigerants are not drop in with significant infrastructure and safety concerns.

In addition, "increased electricity demand due to restrictions on fluorochemistries in the first year is roughly 2.6 million megawatt-hours ("MWh") per year in the residential sector, 8.5 million MWh in the commercial sector, and roughly 1 million MWh from alternative building materials."

We are proposing a more proportional response on the approach to fluorinated gases or f-gases as they are already regulated under the Kigali amendment to the Montreal Protocol providing more Low Global Warming Potential solutions to reduce greenhouse gas emissions. See Appendix A for an alternative proposal.

Semiconductors

- Economic impact: ~1.35 million jobs; ~$275 billion industry and leading export category underpinning advanced technology and innovation.
- Replacement challenges: Core manufacturing processes depend on unique chemistries; many alternatives are not viable or require >15 years (or longer).

The sector specific examples above show that, in highly specialized and multi-tier supply chains for safety-critical, performance-critical, and strategically important

[12] chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.uschamber.com/assets/documents/Essential-Chemistries-Economic-Benefits_-Part-2-Impact-on-Heating-Cooling-Building-Materials_2025-03-18-190749_bmbe.pdf.

applications, substitution is not a simple “drop in” product replacement, but a complex process requiring raw material availability, engineering redesign, qualification, certification, and end-use deployment. In many cases, viable alternatives take substantial time and investment to develop and scale, and some applications currently have no technically or operationally feasible alternative at all. Broad or premature restrictions that fail to reflect sector-specific realities therefore risk disproportionate impacts, including disruption to advanced manufacturing, delays in clean energy deployment, impairment of digital infrastructure, and harm to defense readiness and transport reliability.

Conclusion

We respectfully urge the Committees and decision-makers to ensure that any PFAS restriction:

1. Applies a risk-based approach grounded in exposure and lifecycle considerations.
2. Adopts a practical, risk-informed definition of PFAS reflecting scientific diversity.
3. Fully accounts for the economic and societal importance of essential uses, ensuring proportionality and feasibility.

A targeted, science-based policy framework is achievable under EU regulation, and deploying such an approach, rather than the very wide and highly complex restriction under REACH will better achieve the shared objective of reducing environmental and human health risks while safeguarding innovation, critical infrastructure, and economic resilience.

We appreciate the opportunity to contribute to this important process and remain available for further engagement.

Sincerely,

Aerospace Industries Association
Airlines for America
Alliance for Automotive Innovation
Alliance for Chemical Distribution
American Coatings Association
American Fuel & Petrochemical Manufacturers
American Petroleum Institute

Fuel Cell & Hydrogen Energy Association
Fluid Sealing Association
Medical Device Manufacturers Associations
National Council of Textile Organizations
PRINTING United Alliance
U.S. Chamber of Commerce
Valve Manufacturers Association of America