July 21, 2023

Dr. Sharon McGuinness
Executive Director
European Chemicals Agency
Registry of the Board of Appeal
P.O. Box 400
FI-00121 Helsinki
Finland

RE: Consultation for European Chemicals Agency Phase 1 Restrictions on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS).

Dear Dr. McGuinness:

1) Overview

The U.S. Chamber of Commerce and our coalition of companies and trade associations appreciate the opportunity to comment on the EU Universal PFAS restriction proposal published February 7, 2023 (https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b).

- We oppose the approach that dossier submitters are taking in proposing to ban products and broad substance categories from commerce without consideration of risk, unavoidable use, or available replacements. Instead, the dossier should focus in a more targeted way on substances used in consumer applications with high potential for exposure to actual hazardous materials.
- Any action should be based on the best available science, take a risk-based approach, and utilize a sound cost-benefit analysis.
- Any action should be balanced with other EU policy priorities that may be negatively affected by these restrictions, including the European Chips Act.
- The coalition is proposing time-unlimited exemptions for substances, products, and sectors that are already highly regulated and/or for which there is significant risks of human health exposure.
- There will be broad economic effects across many sectors that will result in costs, impacts, and unintended consequences, including banning products and chemistries for which there are no replacements for critical and valuable societal uses.
- The restrictions will create reporting burden on uses of fluoropolymers for important societal uses, such as in public and industrial safety.
- Similar to previous REACH restrictions, the Universal PFAS restriction should exempt industrial uses (e.g., in pipes, gaskets, membranes, and diaphragms) of materials meeting the broad PFAS definition envisaged in the Annex XV dossier, provided that manufacturers supply information on risk management measures and emissions controls.

This is the approach taken, for example, in the REACH restriction on intentionally added microplastics.

2) Priorities

There are existing regulatory frameworks and industry-led standards, grounded in sound science that govern many PFAS chemistries across the broad economy— underscoring that bans are not needed:

- Existing approaches to evaluate substances (and articles) of very low regulatory concern by virtue of their lack of release to the environment already exist. The underlying science for these assessments is common to any/many applications and need not be specified in a time-limited manner.
- Reasonable proof is already available to demonstrate safe uses of fluoropolymers (e.g., PTFE, FKM, FFKM, and Viton) and low global warming potential (GWP)F-Gases (e.g., hydrofluorocarbons (HFCs) and hydrofluoroolefin (HFOs)), etc., such that the RAC should take into account the large body of evidence that negligible environmental impact comes from these substances.[1]
- Common themes grounded in science across many industries' derogation or exemption requests underscore that these PFAS are used to make products safer via longer life. Reductions to design life ratings and/or reduction in reliability/availability, an increase in occurrence of leakage, and increased maintenance/intervention frequency would be expected for all uses of PFAS-containing seals (e.g., items such as O-rings and gaskets) across all industrial sectors.

We urge time-unlimited exemptions and request better definitions on many of the proposed derogations (or exemptions) for the following applications as these applications are highly regulated and the qualification process is extensive:

- **Lubricants.** We note that there is already a proposed derogation for "lubricants where the use takes place under harsh conditions" or the use is needed for safe functioning and safety of equipment until 13.5 years after EIF. This time frame may not be sufficient to address these applications.
- **Fluoropolymer manufacturing.**

[1] Henry, Barbara J., Joseph P. Carlin, Jon A. Hammerschmidt, Robert C. Buck, L. William Buxton, Heidelore Fiedler, Jennifer Seed, and Oscar Hernandez. "A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers." *Integrated Environmental Assessment and Management* 14, no. 3 (2018): 316-334. **[REVIEW]**

https://doi.org/10.1002/ieam.4035

Korzeniowski, Stephen H., Robert C. Buck, Robin M. Newkold, Ahmed El kassmi, Evan Laganis, Yasuhiko Matsuoka, Bertrand Dinelli et al. "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: fluoroplastics and fluoroelastomers." *Integrated Environmental Assessment and Management* 19, no. 2 (2023): 326-354. **[REVIEW]**

https://doi.org/10.1002/ieam.4646

- **Materials used at industrial sites**. Accompanied by reporting requirements on risk management measures and emissions controls, exemptions should be similar to the approach taken in the REACH restriction on intentionally added microplastics.
- **Military and defense (not covered currently).**
- **Petroleum (oil and gas) and mining.** The Federal Energy Regulatory Commission (FERC) and the Bureau of Safety and Environmental Enforcement (BSEE) are two agencies that regulate oil and gas companies.
  - At present, the American Petroleum Institute (API) has over 50 industry standard specifications that reference specific PFAS for their beneficial safety-driven properties, including requirements that critical (pressure- or temperature-protective) components include superior properties provided by PTFE (e.g., Teflon), fluoroelastomers (e.g., FKM and FFKM), fluoropolymers in general, or PVDF.
  - We note that there is already a proposed derogation for "fluoropolymer applications in the petroleum and mining industry until 13.5 years after EIF." This time frame is not sufficient for certain applications and is not needed due to API's standard-setting process and the highly regulated nature of the oil and gas sector. In addition, it seems this derogation does not cover the whole oil & gas sector – and refers only to parts of the exploration/production process, and not the refining, petrochemicals or distribution parts of the oil & gas sector. The scope of the derogation should be extended and clarified.
- **Electronics and semiconductors.**
  - Spare parts for repair of finished electronic equipment already placed on the market.
  - Resupply of articles already placed on the market (preowned products).
    - As mentioned in comments from the Information Technology Industry Council, "The concepts of 'right to repair' and allowing resale of preowned products have been broadly incorporated into other EU substance restrictions and other EU REACH restrictions, and it is essential to incorporate them into the EU PFAS restriction to avoid major market disruptions."
  - Materials used in photolithography, etch, deposition, cleans, and other unit processes that are deemed essential for the manufacture of advanced semiconductors.
  - Articles used in the manufacturing of semiconductors.
- **Energy applications, including batteries and hydrogen.**
- **Transportation (manufacturing of transportation, safety, and emissions controls technologies of vehicles).**
  - Currently, alternative solutions for PFAS are poorly understood with respect to several key technical automotive applications. Identifying and validating alternatives take a considerable amount of time. Additionally, reporting requirements for PFAS substances are a recent development. Resultingly, the development of an exhaustive PFAS inventory of the global automotive supply chain is ongoing and will likely take many years. Therefore, the 18-month time limit after entry into force for applications without a derogation is *far* too short and exemptions should be considered.
  - The maintenance and repair of vehicles no longer in production are critical factors to ensuring that customers can continue to get high-quality, reliable parts throughout the

life cycle of their vehicles. Redesigning replacement parts for vehicles no longer in production would not be feasible due to technical, economic, and logistical barriers. Replacement parts must function identically to the original part to ensure that vehicle functionality and safety are not adversely impacted. Therefore, a derogation for replacement parts, specifically designed for the service, repair, and maintenance of vehicles is critical.

- Fluoropolymers and fluoroelastomers should be excluded from the scope of the restriction. Currently, there are no known alternatives available that can provide the desired durability, chemical resistance, temperature resistance, and surface tensions of fluoropolymers. Furthermore, fluoropolymers are vital in the development of electric vehicle battery and hydrogen fuel cell technologies, which both support EU decarbonization policy.
- In particular, according to the most recent study *"Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions"* conducted by Karlsruhe Institute of Technology (KIT) in cooperation with Société Générale de Surveillance (SGS) (study summary is provided below):

  > *"There were no short chain PFAS detected post incineration. The results confirm that fluoropolymers at their end of life when incinerated under representative European municipal incinerators conditions do not generate any measurable levels of PFAS emissions and therefore pose no risk to human health and the environment."*

- Exemptions, derogations, and longer transition timelines are required for the vehicle battery industry to allow it to identify and implement alternative non-PFAS solutions.
- Potential replacements for R-1234yf do not have the same or better global warming potential (GWP) value. The use of CO_2, propane, or ammonia as a potential substitute also have concerns. Switching away from R-1234yf will require extensive redesign of existing vehicle platforms and the servicing of approximately 1.5 billion vehicles already in commerce to utilize the new refrigerant. Unlimited derogations are also required for existing internal combustion engine (ICE) vehicles and existing fleets due to the lack of alternative options.
- The automotive industry will require derogations and longer transition timelines for the use of refrigerants for thermal management on battery and e-powertrain equipment, technology that supports EU decarbonization policy. Unlimited derogations are also required for existing ICE vehicles and existing fleets due to the lack of alternative options.
- Automotive electronics applications such as cables, cable harnesses, printed circuit boards, brackets, touch panels, wires, electronic components, and semiconductors rely on PFAS materials, mainly fluoropolymers. This is because of their unique combination of properties, including temperature performance, durability, and chemical stability. There are no known suitable alternatives with the same level of lifetime performance available at this time.

- Requirements for the safe dismantling of vehicles exist, which minimize the environmental PFAS risks.

- **Aerospace.** The aerospace industry should be recognized as a separate sector with a time-unlimited derogation. For space applications in particular, the National Aeronautics and Space Administration implements standards on U.S. industry.
- **Aviation (individually and as part of aerospace).** The European Union Aviation Safety Agency (EASA), the U.S. Department of Defense, the U.S. Federal Aviation Administration, and the U.S. Environmental Protection Agency are examples of primary agencies responsible for regulating different aspects of the aviation sector. The FAA, for example, ensures that commercial aircraft are certified to meet the safety requirements.
  - As discussed in the recent GCCA white paper (excerpt follows), many considerations must be taken into account when designing or changing the design to any part, component, system, subsystem, or full aerospace product.
  - *The A&D companies that design and integrate the products (e.g., aircraft, engines, radar systems, missiles), are each responsible for their own product qualification, validation and certification, according to airworthiness regulations or defense/space customer requirements. Within a single A&D company, even seemingly 'similar' components or hardware used in different systems/models have unique design parameters and performance requirements, driven by the system-level requirements of the final delivered product. A&D products cannot be placed on the market without going through this demanding process irrespective of any REACH legislation. The same rigorous process is in place to approve materials used for the repair and maintenance of these products.* Aerospace and defense chemical substitution timelines can vary from a few years under the most optimum conditions (e.g., simple change with full interchangeability with the original design) to multiple decades (e.g., where performance requirements are not fully met by candidate alternatives, such as hexavalent chromium (Cr(VI) or halon fire protection replacement activities).
- **Industrial applications (not covered currently).**
  - Hard chrome plating industry: Implementation of an exemption or extension of the derogation to 13.5 years to avoid conflicting with EU persistent organic pollutants and other elements of EU REACH.
- **Chemical processing industry (not covered currently).**
- **Medical devices and medical products.** The Food and Drug Administration (FDA) governs medical devices and medical products.
  - We urge exemptions for two medical propellants currently used in MDIs: HFC-134a and HFC-227ea consistent with the one granted to other medical device sectors. The proposed time frame—18 months after finalizing the proposal—is not technically or economically feasible and would risk the health of patients in Europe and around the world. Prematurely banning these essential products could lead to drug shortages of essential lifesaving medicines. A significant proportion of medicines manufactured in Europe are exported around the world. Adequate time must be provided to allow replacement products to be developed, tested, and approved by medicines' regulators and for patients to be safely and seamlessly transitioned. Companies are developing

next- generation more sustainable propellants to mitigate climate impact. One of these propellants, HFC 152a, is not classified as a PFAS. The current proposal recommends a 12-year derogation for MDI coatings given "the lack of technically feasible alternatives and the high societal value of the medicinal products indicates that a full ban would be associated with high socio-economic costs." The precise same rationale applies to the existing medical propellants for MDIs.

- We respectfully request a permanent exemption for HFO 1234ze as a medical propellant for MDIs. As outlined below (and to be supplemented in the future), HFO 1234ze represents an important alternative option to accomplish the phasedown of the existing medical propellants and will have a long-term role as a potential option for transitioning MDIs away from the existing medical propellants, HFC-134a and HFC-227ea.
- We request a permanent exemption for PFAS used in membranes for dialysis equipment and as coatings for medical implants and coatings for surgical instruments as there are no other materials to which blood platelets and pathogens do not adhere.
- We urge exemptions for fluoropolymers present in the plant, equipment, and consumables used in pharmaceutical manufacturing facilities. In chemical synthesis facilities PFA, PTFE, PVDF, and ETFE lined components provide corrosion protection against aggressive process solutions. While in biotechnology manufacturing facilities fluoropolymers (FEP, PTFE, EFTE, ECTFE, PCTFE, PFPME, and PFA) are used extensively because these materials are chemically inert, stable, and of very high purity, characteristics that are necessary for aseptic and low bioburden processing. In short, EU manufacturing facilities would not be able to function without fluoropolymers and if these facilities are global suppliers of APIs (active pharmaceutical ingredients), the security of the supply of multiple medicines will be put at risk by the EU PFAS Restriction.
- The coalition urges an exemption for Polychlorotrifluoroethylene (PCTFE)-based materials. PCTFE is used as a noncontact layer in prescription and over-the-counter (OTC) pharmaceutical packaging, as well as in medical device packaging applications. PCTFE is imported as a finished film for the above applications and is marketed under the trademark Aclar©.
- Although considered very persistent (vP) by design, PCTFE is a fluoropolymer that satisfies all internationally recognized criteria of Polymers of Law Concern (PLC). PCTFE does not exhibit the hazards identified by the Dossier Submitters as "supporting concerns" that they have identified as applicable to all PFAS, e.g., bioaccumulation, mobility, long-range transport potential (LRTP), accumulation in plants, ecotoxicity, endocrine activity/endocrine disruption, effects on human health, and concerns triggered by a combination of these properties. In section 1.1.4 of the proposal, the dossier submitters erroneously attributed these hazards to all substances in the "PFAS group," including PCTFE. Grouping PCTFE with all other PFAS for REACH read across and restriction processes purposes is scientifically unjustified and contrary to the provisions of Annexes I, XI, and XV REACH.

- **Refrigerants, Heating, Ventilation, and Air-Conditioning and use of fluorinated gases.** Having two regulatory frameworks for the same chemical substance(s) is considered at the practical level untenable.
  - We, therefore, urge exemptions for low and ultra-low global warming potential HFCs and HFOs for various refrigeration and HVAC applications, including HFO 1234yf for use in light, medium, and heavy duty vehicles and electric vehicles.[2]
  - We urge exemptions for Trifluoroacetic acid (TFA), which is formed in the atmospheric degradation processes for some HFCs and HFOs fluorinated gases. Emissions of TFA-yielding F-gases lead only to increases in TFA concentrations that safely remain at orders of magnitude below scientifically established DNEL/PNEC levels and/or food intake or water quality standards for TFA.[2], resulting in a de minimis risk to human health and the environment, as also highlighted by UNEP: "The margin of exposure between the distribution of No Observed Effect Concentrations (NOECs) and the observed and expected concentrations in the oceans and endorheic basins is several orders of magnitude and is indicative of de minimis risk" (REF: UNEP EEAP Report, pg. 290).
  - According to the REACH registration dossier and Chemical Safety Report (CSR) for trifluoroacetic acid (TFA), [3] this substance does not fulfill the criteria for a PBT or vPvB substance under Annex XIII REACH. Neither does it raise equivalent levels of concern as a PBT or vPvB. ECHA has already evaluated the TFA dossier without concluding that further regulatory actions were needed.
  - Polyurethane foam systems, which are formulated with nonozone depleting and low GWP HFO foam blowing agents. Polyurethane foam systems formulated with HFOs are generally used as insulation for buildings and appliances. Polyurethane foam insulation is a vital tool to ensure that the EU and its member states can meet their climate goals. HFO foam blowing agents are not "forever chemicals." They are not persistent, bioaccumulative or toxic.[4] HFO foam blowing agents are designed to break down in the environment into naturally occurring substances.
- **Water and Protection (not covered currently).**

3) Impact

- Each of the applications mentioned has a beneficial societal impact. We highlight some examples of impact based on the current proposal. For instance, all commercial airplanes use PFAS materials in safety functions such as in engine fuel line sealing (prevents fuel leaking in air and fire) and in hydraulic equipment to help land safely. Water and protection applications use PFAS, such as PVDF, in water filtration membranes to provide access to clean drinking water. This use supports the UN Sustainability Goal to "ensure availability and sustainable management of water and sanitation for all" (UN Sustainable Development Goal 6). In the semiconductor industry, PFAS is used in chip

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[2] Response to the public consultation on the PFAS restriction proposal, AmCham EU, June 2023.?

[2] See recent *Mammalian toxicity of trifluoroacetate and assessment of human health risks due to environmental exposure*, Dekant *et al.,* 17 February 2023; and all relevant previous UNEP (EEAP and SAP) reports.

[3] Trifluoroacetic acid, EC no: 200-929-3, CAS no: 76-05-1, Molecular formula: C2HF3O2.

[4] F-gases in the PFAS restriction file.

manufacturing and in devices such as cellphones. Another UN Sustainability goal is to "significantly increase access to information and communications technology and strive to provide universal and affordable access to the internet" (UN Sustainable Development Goal 9). A restriction on PFAS would also impact the ability to achieve the European Chips Act as manufacturing would move out of the region. PFAS are also used in membranes for dialysis equipment, as well as coatings for implants and surgical tools. These are essential uses because blood platelets and pathogens do not adhere to the surface coating, which greatly reduces the risk of blood clots and pathogen-borne infections, supporting UN Sustainable Development Goal 3.

- For instance, in the aerospace sector—
  - Fluoropolymers are essential to the aircraft industry. The properties of fluoropolymers are unmatched by other polymers and are required for the operation of today's aircraft systems. Replacements for the fluoropolymers that are used by the aircraft industry are not readily available with other polymers.
  - Fluoroelastomers, such as those meeting the requirements of SAE Aerospace specification AMS7287, are used to provide sealing of aircraft fluid systems like aircraft engine oil and aircraft jet fuel. These fluoroelastomers provide a combination of long-term compression set resistance at elevated temperatures and resistance to aircraft engine oils and aircraft jet fuels that are not available with other polymers.
  - Fluoroplastics, such as those meeting the requirements of SAE Aerospace specification AMS3678, are used to support fluoroelastomer seals and to function as bearings in aircraft engine oil and aircraft jet fuel systems. These fluoroplastics provide a combination of friction and wear properties and resistance to aircraft engine oils and aircraft jet fuels at elevated temperatures that are not available with other polymers.
  - As an example, the aerospace and defense industry has spent several decades to develop and implement alternatives to Cr(VI). At this time, there is still no universal replacement for any of these coating and surface treatments (Aerospace & Defense Qualification Process Impacts).

Members of the U.S. Chamber and our coalition are participating in Socio-Economic Analyses (SEAs) and utilizing research by the Fluoropolymer Product Group (FPG), the European Sealing Association (ESA), and an economic assessment with CEFIC. These documents and an executive summary will be submitted in a second submission to support derogations and exemptions for key sectors and product categories.

Sincerely,

Aerospace Industries Association
Airlines for America
The Alliance for Automotive Innovation
American Forest & Paper Association
American Fuel and Petrochemical Manufacturers
American Petroleum Institute

Fluid Sealing Association
National Association of Chemical Distributors
National Association for Surface Finishing
National Council of Textile Organizations
National Oilseed Processors Association
Plastics Industry Association
PRINTING United Alliance
U.S. Chamber of Commerce
Valve Manufacturers Association

Cc: John Thompson, Deputy Assistant Secretary, Bureau of Oceans and International Environmental and Scientific Affairs, State Department

Appendix 1: One for PTFE and for each of the key PFAS that needs a broad exemption and for which derogations could be unbound by time limit.

Attached is Henry et al. (2018) Supplemental Material (58 pages) and the 2023 SOT abstract/ poster/table driving home the fact that PTFE need not be "banned" if RAC would evaluate the scientific proof.

The High Stability of Polytetrafluoroethylene (PTFE) Does Not Imply Toxicity or Bioaccumulation, Future Degradation, and Release or Transformation into a Source of Substances of Concern. Authors: B. J. Henry[1], H. S. Adragna[1], and P. D. Drumheller.[2] [1]*W. L. Gore & Associates, Elkton, MD; and* [2]*W. L. Gore & Associates, Flagstaff, AZ.*

The European Chemicals Agency considers persistence to be the key marker of high risk in the hazard assessment of all PFAS. To determine if PTFE's high stability results in or is correlated with hazard, fine powder PTFE (meeting ASTM D4895-18, made with a non-PFOA fluorinated polymerization aid) was subjected to standard OECD eFate studies at Charles River Labs (Den Bosch, the Netherlands). Following the current risk assessment paradigm with these data, we pose questions for a new paradigm for persistent compounds differing from traditional POPs. Studies to investigate air, water, soil partitioning, and biodegradability included melting point/range OECD 102, molecular weight (MW) and MW weight distribution OECD 118, vapor pressure OECD 104, Henry's Law constant, thermal gravimetric analysis, octanol-air partition coefficient, thermal stability in air OECD 113, solution/extraction behavior in water OECD 120, water solubility OECD 105, partition coefficient OECD 107 and OECD 117, ready biodegradability OECD 301B, inherent biodegradability OECD 302C, biodegradability in seawater OECD 306. Vapor pressure was <1 x 10-10 mm Hg at 20°C. Thermal gravimetric analysis showed no decomposition or chemical reaction <150°C and 5% weight loss at 549°C. Fine powder PTFE was thermally stable at continuous use processing temperature of 260 °C. The melting transition temperature of ~350°C was determined using differential scanning calorimetry, with no further melting/decomposition below 400°C, showing stability at environmentally relevant temperatures. These results demonstrate low volatility or partitioning to air at <150°C. Fine powder PTFE was not sufficiently soluble to be evaluated using GPC even after sonication and stirring (19 hours) in representative solvents. Standard Specific Gravity and Melt Flow Rate are used to determine fluoropolymers MW rather than rheological and dynamic light scattering methods. By alternative methods, the molecular weight was >500,000 Da. Fine powder PTFE was not dissolvable in water (OECD 105, 120). The lack of solubility in octanol or water (OECD 107, 117) prevented determination of octanol/air or octanol/water partition coefficients. The Henry's Law constant was not determined due to the insolubility of fine powder PTFE. Fine powder PTFE was not readily (OECD 301B) or inherently (OECD 302C) biodegradable. ISO 10993-1, Biocompatibility of Medical Devices testing (cytotoxicity, irritation, sensitization, implantation, acute and subchronic toxicity, material-mediated pyrogenicity, hemocompatibility, genotoxicity (in vitro and in vivo) on fine powder PTFE was performed in compliance withgood laboratory practices. The results demonstrate the biocompatibility and low toxicity of fine powder PTFE. The data generated on fine powder PTFE, from the standard OECD eFate studies under environmentally relevant conditions, support that this PTFE does not partition to air, water, or soil. PTFE was biotically/abiotically stable and not transformed to perfluoroalkyl acids, which are substances of toxicological concern. PTFE has inherently low toxicity as demonstrated by OECD eFate studies and ISO 10993-1 testing. These studies confirm that PTFE does not degrade nor release/transform into a continuous source of PFAS substances of concern. The high stability of PTFE does not imply hazard."

Appendix 2: Similar reporting-based exemptions could be implemented for industrial uses of PFAS: Didn't edit this section since all quoted.

> *"1. [Microplastics] shall not be placed on the market as substances on their own or, where the synthetic polymer microparticles are present to confer a sought-after characteristic, in mixtures in a concentration equal to or greater than 0,01 % by weight. […]*
>
> *4. Paragraph 1 shall not apply to the placing on the market of:*
> *(a) synthetic polymer microparticles for use at industrial sites.*
>
> *[…] manufacturers and industrial downstream users of synthetic polymer microparticles in the form of pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites, and [..] other industrial downstream users using synthetic polymer microparticles at industrial sites shall submit the following information to the Agency by 31 May of each year:*
> *(a) a description of the uses of synthetic polymer microparticles in the previous calendar year.*
> *(b) for each use of synthetic polymer microparticles, generic information on the identity of the polymers used.*
> *(c) for each use of synthetic polymer microparticles, an estimate of the quantity of synthetic polymer microparticles released to the environment in the previous calendar year."*