2225 W. Chandler Blvd | Chandler, AZ USA

White Paper for EU Annex XV Restriction Report and under REACH

Rebecca Agapov, Ph.D., Scott Eastman, Ph.D., William F. Scholz, Ph.D., Peter Walsh, Ph.D.

I. Scope: Exclude Fluoropolymers from the Proposed Restrictions on PFASs

The current Annex XV Restriction Report ("Annex XV Report") proposes to restrict "any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-)" (Agency, 2023). This definition is used due to concern with safety profiles of these **per- and polyfluoroalkyl substances ("**PFASs"). Specifically, that they are, or ultimately transform into, persistent substances; are soluble and mobile in water and thereby able to contaminate surfaces, ground- and drinking water or soil; and are toxic and/or bio accumulative, both with respect to human health as well as the environment (Agency, 2023).

This definition of PFASs communicates that the compounds under this term share the same structural trait of having a fully fluorinated methyl or methylene moiety. However, it does not inform whether a compound presents risk or not. In this broad definition, there are distinct substances with very different properties: polymers and nonpolymers; solids, liquids, and gases; persistent and nonpersistent substances; highly reactive and inert substances; mobile and insoluble; eco-toxic and nontoxic chemicals. In addition, this definition covers a broad range of molecular structures- neutral, anionic, cationic, aromatic, low or high molecular weight- and therefore diverse physical, chemical, and biological properties. It is for all of these reasons that the definition of PFASs is too broad, and the chemicals it covers should be considered in separate groups for risk assessment and management.

One unique category that should be separated out for risk assessment and management is fluoropolymers. Fluoropolymers are a class of materials with high molecular weight. Examples of fluoropolymers are: polytetrafluoroethylene ("PTFE") CAS # 9002-8-0 $(CF_2CF_2)_n$; perfluoroalkoxy alkane ("PFA") CAS # 26655-00-5 $(CF_2CF_2)_n$-$(CF_2CF(OCF_3))_m$,; fluorinated ethylene propylene ("FEP") CAS # 25067-11-2 $(CF_2CF_2)_n$-$(CF_2CF(CF_3))_m$; polyvinylidene fluoride ("PVDF") CAS # 24937-79-9 $(CH_2CF_2)_n$; and combinations thereof. Fluoropolymers have unique properties that are a result of their very high molecular weight, generally over 100 kg/mol. Each repeating unit of a fluoropolymer has an extremely strong carbon-fluorine (C-F) bond, in fact the strongest bond that can exist between C and another atom, making them highly stable materials over a very wide temperature range (Olabisi & Adewale). In addition to thermal stability, fluoropolymers also have high chemical, oxidative, hydrolytic, and biological stability. PTFE is inert inside the body, without degradation, and is commonly used in heart stents and hernia meshes (Ünek, et al., 2019). The size of the molecule makes it impossible for the fluoropolymers to cross cell membranes. In addition, fluoropolymers are inherently non-flammable, and are highly resistant to degradation. The polymeric materials have negligible residual monomer and/or oligomer content, and low to no leachable materials (Gangal & Brothers), making the risk of ground water contamination negligible. As a result, fluoropolymers do not present significant toxicity concerns and cannot degrade into other PFASs.

It has been widely recognized that certain chemical properties, specifically molecular weight, limit the ability of a chemical to cross the cell membrane and therefore limit its bioavailability. Examination over time has resulted in a collection of data to relate the chemical properties and structure of a given chemical to its hazard potential. These factors support the "polymers of low concern" (PLC) criteria as defined by the Organization for Economic Cooperation and Development (OECD) (Development, 1993 Apr), which have been accepted by Australia, Canada, China, Japan, Southern Korea, Philippines, New Zealand, Taiwan, and the United States (Deloitte, 2015). The PLC criteria are detailed in cited references, (Development, 1993 Apr) (Deloitte, 2015), but include molecular weight, ionic character, reactivity, and residual monomer content, to name a few. Fluoropolymers satisfy the PLC criteria and are as such considered to be "low concern" to human health and the environment (Henry, et al., 2018).

The physical-chemical properties of fluoropolymers prevent bioavailability, bioaccumulation, toxicity, and degradation. Fluoropolymers are also not water soluble, and not subject to long-range transport. Due to the large size of these molecules, fluoropolymers cannot cross the cell membrane (Henry, et al., 2018). Based on review and assessment of fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal, and biological data, research has concluded that fluoropolymers are distinctly different from other nonpolymeric PFASs (Korzeniowski, A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers, 2023).

Grouping fluoropolymers together with all classes of PFASs for a single approach to structure-hazard assessment based on persistence alone is therefore not scientifically appropriate. For this reason, we strongly believe that a distinction must be made within the definition of PFAS included in the PFAS Proposal, and that the following fluoropolymers should be excluded from the proposed restrictions:

- **I.** **polytetrafluoroethylene ("PTFE") CAS # 9002-8-0 $(CF_2CF_2)_n$;**
- **II.** **perfluoroalkoxy alkane ("PFA") CAS # 26655-00-5 $(CF_2CF_2)_n$-$(CF_2CF(OCF_3))_m$,;**
- **III.** **fluorinated ethylene propylene ("FEP") CAS # 25067-11-2 $(CF_2CF_2)_n$-$(CF_2CF(CF_3))_m$**;
- **IV.** **polyvinylidene fluoride ("PVDF") CAS # 24937-79-9 $(CH_2CF_2)_n$**; and
- **V.** **blends, mixtures, composites, alloys, co-polymers, terpolymers, and other combinations of the above.**

This distinction is scientifically supported as large molecule fluoropolymers have been demonstrated to be safe and do not pose significant risk to human health (Korzeniowski, A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers, 2023)**.**

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II. Specific Uses of PFASs: Request for a Temporary Exemption for the Use of Specific Fluoropolymer PFASs in Semiconductor Applications

PFAS, and in particular fluoropolymers, are ubiquitous throughout the semiconductor sector. Polytetrafluoroethylene ("PTFE"), perfluoroalkoxy alkane ("PFA"), fluorinated ethylene propylene ("FEP"), polyvinylidene fluoride ("PVDF") , and fluorinated polymeric hydrophobic coatings are used: (1) in the distribution and storage of hazardous chemicals required for semiconductor production, (2) as protective coatings and wrap for wire, cable, sensors, and dip tubes, and (3) as ultrapure polymeric materials for piping, tubing, and other infrastructure necessary to keep water and chemicals pure down to parts per billion ("ppb") and eventually parts per trillion ("ppt") purity levels. **As such, fluoropolymers are an essential enabling technology in the manufacture of semiconductors by current modern day methods to achieve the performance expected from nearly every end use market including those critical to economic growth and quality of life (i.e. medical, aerospace, automotive, personal electronics, telecommunications, and defense). Furthermore, major legislative and industrial objectives will be at substantial risk of not achieving their global goals of electrification, CO2 emissions reduction, semiconductor supply security, manufacturing job retention/creation and others. The European and US Chips Acts, The Clean Sky Initiative, The Electric Vehicle Initiative, The Green New Deal, and The Infrastructure Investment and Jobs Act, will all be at risk of not achieving their important aims if fluoropolymers are prohibited from use in the semiconductor industry.**

Key Functionalities provided by PFASs: Semiconductor Industry

The Annex XV Report acknowledges that PFASs are commonly used in the production process of semiconductors as well as in the incorporation of semiconductor end use articles (packaging). However, for these applications, it should be emphasized that specific PFASs (PTFE, PFA, FEP, and PVDF) and fluorinated polymeric hydrophobic coatings, are the key materials contributing to the sub-uses mentioned in Annex XV: wire and cable, coatings, and electronic components. Annex XV fails to point out two other critical sub-uses of fluoropolymers, (1) chemical distribution and storage infrastructure, and (2) ultra-high purity processing, both of which are paramount for high yield, high performance semiconductor production. PTFE, PFA, FEP, and PVDF are the key enabling constituents of the performance required for semiconductor manufacturing and packaging due to their unique combination of properties:

I. High chemical and permeation resistance enabling safe transport and storage of harsh chemicals.
II. Low dielectric constant and low dissipation factor enabling superior performance as wire & cable insulation.
III. High dielectric strength enabling superior performance as wire & cable insulation as well as coatings for sensors and semiconductor dip tubes.

IV. Stable over a wide range of environmental conditions such as, high humidity, high UV and oxidative stability, and use temperatures from -50C to 130°C, enabling stable performance during environmental excursions.
V. High purity resins enable ultra-high purity water and chemical transport essential for achieving next generation, 0.5nm node size semiconductors.
VI. Inherently flame retardant.

Explained further below are specific uses of fluoropolymers as key constituents to enable the manufacture and performance of semiconductors of the semiconductor manufacturing and packaging with evidence describing that there **no current alternative materials that have been demonstrated to have all properties necessary to achieve the chemical resistance, dielectric strength, use temperatures, and purity needed for safe manufacturing of high yield, high performance semiconductors.**

PFASs Missing Application: Semiconductor hazardous chemical distribution and storage.

The U.S. Department of Labor outlines the major steps necessary in the manufacturing of silicon devices which are listed below for convenience (Labor, 2023).

Device Fabrication

- Oxidation
- Cleaning
- Photoresist Application
- Soft Bake
- Mask Alignment and Photoexposure
- Developing
- Hard Bake
- Etching
- Photoresist Stripping
- Doping (Junction Formation)
- Deposition

In nearly all of these steps, harsh chemicals and aggressive processing conditions are necessary to effectively produce high yield, high performance semiconductor articles. Due to these conditions, highly chemical resistant materials such as fluoropolymers are necessary to enable these processes and no other polymer has the same level of chemical resistance as outlined in Figure 1 below (CPLabSafety, 2023). In Figure 1, the first four (left most) material columns are all fluoropolymers, which are currently included in the Proposal's definition of PFAS. It is clearly apparent that these materials are superior to other polymers for a broader range of chemical resistance. It should also be noted that Figure 1 is based on testing that is only carried out at 20°C for 30 days, which is much less aggressive than standard use conditions. Materials need to withstand years of exposure to harsh chemicals above room temperature; for instance, 40-90°C is typical in the semiconductor wet etching process. Fluoropolymers have demonstrated their capability beyond anything else available today in the conditions necessary for semiconductor processing.

Overview of Chemical Resistance of Resins to Chemicals at 20°C:

E	30 Days of constant exposure causes no damage. Plastic may tolerate for years.
G	Little or no damage after 30 days of constant exposure to the reagent.
F	Some effect after 7 days to the reagent. The effect may be crazing, cracking, loss of strength or discoloration.
N	Not recommended. Immediate damage may occur. Depending on the plastic, the effect may be severe crazing, cracking, loss of strength, discoloration deformation, dissolution or permeation loss.

	ETFE	FEP/ TFE / PFA	FLPE	FLPP	HDPE	LDPE	PC	PETG	PP	PVC	TPE***
Acids, dilute or weak	E	E	E	E	E	E	E	G	E	E	G
Acids,** strong / concentrated	E	E	G	G	G	G	G	N	G	G	F
Alcohols, aliphatic	E	E	E	E	E	E	G	G	E	G	E
Aldehydes	E	E	G	G	G	G	G	G	G	G	G
Bases/Alkali	E	E	F	E	E	E	N	N	E	E	F
Esters	G	E	G	G	G	G	N	G	G	N	N
Hydrocarbons, aliphatic	E	E	E	G	G	F	G	G	G	G	E
Hydrocarbons, aromatic	G	E	E	N	N	N	N	N	N	N	N
Hydrocarbons, halogenated	G	E	G	F	N	N	N	N	N	N	F
Ketones, aromatic	G	E	G	G	N	N	N	N	N	F	N
Oxidizing Agents, strong	E	E	F	F	F	F	F	F	F	G	N

*not for tubing chemical resistance (except pvc)
**except for oxiding acids (see Oxidizing Agents, strong)
*** TPE gaskets

Figure 1. Chemical Compatibility Chart - LDPE, HDPE, PP, Teflon Resistance (calpaclab.com)

As mentioned previously, it is the strength of the C─F bond compared with the C─C bond that leads to the intrinsic and superior chemical stability and environmental persistence of fluoropolymers. Due to this chemical and temperature stability, PTFE and other fluoropolymer are chosen for chemical distribution tubing, flex hoses, lined reaction vessels, gaskets & seals, and filters, among other critical components. Fluoropolymers replaced stainless steel, polyvinyl chloride ("PVC"), high molecular weight polyethylene ("HDPE"), and many other materials as the transport system for semiconductor chemicals due to their superior performance. Fluoropolymers have demonstrated far superior reliability, durability, corrosion resistance, and total equipment and facility operating costs, despite fluoropolymers being substantially more expensive than the original metal components they replaced (Jones, 2023).

PFASs Missing Use Application: Semiconductor protective coatings and wraps for wire, cable, sensors, and dip tubes.

In addition to the chemical and temperature resistance described above, the inherent high dielectric strength and superior electrical insulation properties of PTFE and other fluoropolymers enables their use as protective coatings and wraps for wire, cable, sensors, and dip tubes. These protective coatings prevent degradation and thus prolong the longevity of coated components in the manufacturing process. Furthermore, the semiconductor manufacturing process is extremely sensitive to contamination. SEMI F5783 outlines the requirements for ultra-pure water ("UPW") systems for the manufacture of semiconductors, specifying limits of metals <0.05 ppb, ion contaminants (>19 Mohm/cm resistivity), total organic carbon <1.0 ppb, dissolved oxygen of <5 ppb, low particulate matter with no particles greater in size than 0.2 microns, and <10 particles/mL of particles greater than 10 nm diameter. The historic move from PVC to PVDF to meet these criteria took 47 years to fully complete (1948-1995) (Jones, 2023).

High purity PTFE is imperative to capacitive-type sensors shielded in dip tubes or on tank walls to monitor critical manufacturing processes such as fluid level, temperature, and flow rate among others. High purity PTFE-jacketed electrical cables are also used throughout the manufacturing process for additional protection against contamination.

III. Socioeconomic Impact to the EU

According to market reports, the current European Electrical Market size is estimated to reach €335 billion by 2027. This market space covers industrial manufacturing, automotive, healthcare, and aviation, to name a few (Europe Electrical Components Industry Outlook - Forecast (2022-2027), 2022). This industry has a direct impact of €3.8 trillion, which is approximately 20% of European GDP (Mitchell, 2021).

Elimination of PFAS from the semiconductor industry would require innovations that would fundamentally change the semiconductor fabrication infrastructure with cost implications of >$15B for a new fab facility, >$0.5B for each new semiconductor chip architecture, and an unknown amount of R&D investment costs to come up with robust and globally cost competitive alternatives especially compared to regions that would not embrace the proposed elimination of PFAS (Jones, 2023). In addition, it is very unlikely that a "one size fits all solution" will be identified as a PTFE-replacement, as it is a very unique material and used in a variety of semiconductor processes and applications. Some of the authors, along with the rest of the industry, have been evaluating PTFE alternatives for over 30 years and have not found suitable replacement products meeting all the requisite application needs. It is highly uncertain that replacement materials can be developed or found for these applications if PFAS (in this specific case PTFE and PFA) is banned from use in semiconductor manufacturing and applications.

IV. Comment on Annex Proposal Derogations

For semiconductor manufacturing, a 12 year derogation is currently proposed in the REACH proposal, however this derogation seems limited to the manufacturing process alone and not the articles produced from this process. **This is untenable, as alternative materials are not currently available for these applications described herein and 12 years is not nearly long enough to develop an entirely new manufacturing process and chip architecture that can achieve**

current state performance let alone performance and throughput targets currently being estimated over the next decades.

Therefore, we request:

I. **The exclusion of the following fluoropolymers from the proposed restrictions of the Annex XV Report on PFASs:**
   I. polytetrafluoroethylene (“PTFE”) CAS # 9002-8-0 $(CF_2CF_2)_n$;
   II. perfluoroalkoxy alkane (“PFA”) CAS # 26655-00-5 $(CF_2CF_2)_n$-$(CF_2CF(OCF_3))_m$,;
   III. fluorinated ethylene propylene (“FEP”) CAS # 25067-11-2 $(CF_2CF_2)_n$-$(CF_2CF(CF_3))_m$;
   IV. polyvinylidene fluoride (“PVDF”) CAS # 24937-79-9 (CH2CF2)n; and
   V. blends, mixtures, composites, alloys, co-polymers, terpolymers, and other combinations of the above.

As a result of their very high molecular weight, generally over 100 kg/mol, fluoropolymers have unique properties that distinguish them from all other PFASs. Fluoropolymers s have a low impact to human health and the environment, as was further detailed this attached white paper. Thus, grouping fluoropolymers together with all other classes of PFASs for a single approach structure-hazard assessment based on persistence alone is not scientifically appropriate.

II. **Request for a temporary exemption for use of specific fluoropolymer PFASs in semiconductor applications and articles processed from semiconductor manufacturing processes.**

We request that the proposed restrictions on PFASs provide a temporary exemption for “semiconductor manufacturing and applications” of at least 12 years for:

I. polytetrafluoroethylene (“PTFE”) CAS # 9002-8-0 $(CF_2CF_2)_n$;
II. perfluoroalkoxy alkane (“PFA”) CAS # 26655-00-5 $(CF_2CF_2)_n$-$(CF_2CF(OCF_3))_m$,;
III. fluorinated ethylene propylene (“FEP”) CAS # 25067-11-2 $(CF_2CF_2)_n$-$(CF_2CF(CF_3))_m$;
IV. polyvinylidene fluoride (“PVDF”) CAS # 24937-79-9 (CH2CF2)n; and
V. blends, mixtures, composites, alloys, co-polymers, terpolymers, and other combinations of the above.

The semiconductor industry and the articles produced therefrom are the keystone to growth in several other industries that are expected to grow substantially and with a greater presence of semiconductor components. Medical, aerospace, automotive, personal electronics, telecommunications, and defense are just a few of these industries where electrification, efficiency, durability, and longevity are paramount to their success, rely increasingly on semiconductor technologies, and are enabled by fluoropolymers to do so.

The fluoropolymers listed above are critical to the yield, efficiency, performance, and longevity of semiconductor articles (chips, boards, electronics, etc.) due to a unique combination of the following properties:

I. High chemical and permeation resistance enabling safe transport and storage of harsh chemicals.
II. Low dielectric constant and low dissipation factor enabling superior performance as wire & cable insulation.
III. High dielectric strength enabling superior performance as wire & cable insulation as well as coatings for sensors and semiconductor dip tubes.
IV. Stable over a wide range of environmental conditions such as, high humidity, high UV and oxidative stability, and use temperatures from -50C to 130°C, enabling stable performance during environmental excursions.
V. High purity resins enable ultra-high purity water and chemical transport essential for achieving next generation, 0.5nm node size semiconductors.
VI. Inherently flame retardant.

Due to this unique *combination* of properties, PTFE, PFA, FEP, and PVDF are extremely difficult to substitute in specific data communications components without significant tradeoffs in performance and lifetime, and there are no known alternatives that meet all of these performance criteria.

Significant invention is required to identify, and then qualify, each specific PFAS-free solution and there is no guarantee that such efforts will be successful. To date, no other class of materials has been able to demonstrate the collective performance benefits of PTFE stated above. Typical qualification and test cycles for semiconductor applications and manufacturing processes are in the fifteen-to-twenty-five-year range for incremental advances in this industry. A limitation or outright exclusion on the use of fluoropolymers in semiconductor technology without suitable alternatives standing by would have dire consequences not only in the semiconductor industry but also in the many other industries that depend on reliable semiconductor components and technologies. Medical, aerospace, automotive, personal electronics, telecommunications, and defense are just a few of these industries dependent on the electrification, efficiency, durability, and longevity obtained from fluoropolymer-enabled semiconductor technologies.

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