<u>To Eminent ECHA – European Chemical Agency's Committees</u>

<u>23 May 2023</u>

<u>SUBJECT: PFAS RESTRICTION Public Consultation SECTION IV. Non-confidential attachment</u>

Dear Mr or Mrs,

On 7 February 2023 was pre-issued the UE restriction proposal of PFASs, notified by national Authorities of Germany, Denmark, Netherlands, Norway and Sweden, targeted to reduce or eliminate the environmental PFASs presence, under Regulation (EC) No. 1907/2006 ("REACH").

The final version of restriction - "Restriction on the manufacture, placing on the market and use of PFASs" – was issued on 22 March, with the Annex XV report, 7 Attachments and 4 Appendixes.

The restriction proposal defines PFASs (Per- and polyfluoroalkyl substances) as substances which "contain at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I atom attached to it)", on the base of definition expressed by OECD (Organisation for Economic Co-operation and Development) in 2021 for those substances.

With this Attachment, we would like to give our contribution to the topic in the subject; the content of this contribution is related to the following points of SECTION III_Non-confidential comments:

- Scope or restriction option analysis
- Hazard or exposure
- Environmental emissions
- Baseline
- Information on alternatives
- Information on benefits
- Request for exemption

The main goal of our contribution is related to bring information supporting an exemption request of the **FLUOROPOLYMERS** substances category of PFASs, due to their unique characteristics and their importance for the entire society.

1. Scope or restriction option analysis

Fluoropolymers are a distinct class of per- and polyfluoroalkyl substances (PFAS), high molecular weight (MW) polymers, with fluorine attached to their carbon-only backbone. Fluoropolymers possess a unique combination of properties, they enable functional performance critical to many products and manufacturing processes and are irreplaceable in many uses. Although fluoropolymers fit the PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS.
Fluoropolymers are a distinct and different group of PFAS and should not be grouped with other PFAS for hazard assessment or regulatory purposes. Grouping fluoropolymers with all classes of PFAS for "read across" or structure–activity relationship assessment is not scientifically appropriate.

(1) (2)

2. Hazard or exposure

Fluoropolymers have documented safety profiles; are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic and they satisfy, themselves and in-use, the widely accepted polymer hazard assessment criteria to be considered polymers of low concern (PLC). By 2007, the OECD Expert Group on Polymers agreed that "Polymers of low concern are those deemed to have insignificant environmental and human health impacts".
The PLC criteria include:

- Polymer composition
- Molecular weight, number average molecular weight, MW distribution, and % oligomer <1000 Da
- Electrical charge (ionic character)
- Reactive functional groups (RFG) and RFG ratio to MW
- Low MW leachables
- Particle size
- Structural and elemental composition
- Water and lipid solubility and the octanol–water partition coefficient
- Stability
- Abiotic stability
- Biotic stability
- Thermal stability

These considerations refer to well-known commercial fluoropolymers as:

- Polytetrafluoroethylene (PTFE)
- Fluorinated ethylene propylene (FEP)
- Ethylene tetrafluoroethylene (ETFE)
- Tetrafluoroethylene copolymers with perfluoroalkyl vinyl ethers (e.g. perfluoroalkoxy polymer, PFA)
- Polyvinylidene Fluoride (PVDF) homopolymer and copolymer
- Polychlorotrifluoroethylene (PCTFE)

Due to their physical–chemical properties, PLCs are not bioavailable to cause toxicity or to bioaccumulate and, although fluoropolymers are persistent, they are not bioaccumulative or toxic, and therefore do not meet the PBT "Persistent, Bioaccumulative and Toxic" criteria.

The assessment for the representative fluoropolymer Polytetrafluoroethylene (PTFE) shows that:

- ✓ Polymer composition:
  Polytetrafluoroethylene is a homopolymer of tetrafluoroethylene (TFE), contains only C and F having a $–CF_2–$ backbone terminated on both ends of each polymer chain with $–CF_3$, and meets the compositional criterion to be a PLC (must have C, H, Si, S, F, Cl, Br, or I covalently bound to C);

- ✓ Molecular weight, number average molecular weight, MW distribution, and % oligomer <1000 Da: PTFE, as a very high molecular weight polymer, cannot cross cell membranes, is not bioavailable, and cannot bioaccumulate or be toxic, has a narrow MW distribution and negligible oligomer content (<<1%);

- ✓ Reactive functional groups (RFG) and RFG ratio to MW:
  PTFE most typically has a terminal $–CF_3$ group that is not an RFG, and have a very high MW, which set an RFG ratio to MW on the order of 10^5 or more, well beyond the FGEW (functional group equivalent weight) threshold of concern;

- ✓ Low MW leachables:
  Concentration of leachables from fluoropolymers, particularly PTFE "fine powder" (ASTM [2015] 4895-16 Type I fine powder definition), are typically very low (<1 ppm);

- ✓ Structural and elemental composition:
  fluoropolymers are not subject to degradation into small, mobile, and persistent substances;

- ✓ Water and lipid solubility and the octanol–water partition coefficient:
  Fluoropolymers, such as PTFE, are not soluble in octanol or water, therefore, it is not possible to measure or calculate a K_{OW}. Because solubility in octanol is predictive of lipid solubility, PTFE cannot dissolve in cell membrane lipids to gain access to cellular contents;

- ✓ Stability, Abiotic stability, Biotic stability, Thermal stability:
  PTFE has the best chemical resistance of all currently known polymers and is insoluble in all known solvents, including water; It is resistant to photolysis, hydrolytically stable, water resistant, not subject to hydrolysis catalyzed degradation, not subject to chemical oxidation; It is biologically inert and not degraded by microorganisms under oxygenated (aerobic) or anoxic (anaerobic) conditions; It is one of the most thermally stable polymers with a continuous processing temperature at 260 °C (SPI 2005).

(1) (2)

3. Environmental emissions

At the end of industrial or consumer use, fluoropolymers may be disposed via the following routes: landfill, incineration (e.g. waste-to-energy [WTE] facilities), or reuse/recycling. There is considerable data demonstrating that fluoropolymers such as PTFE do not degrade in the environment or release substances of toxicological or environmental concern.

Fluoropolymers are chemically, thermally, and biologically stable and therefore are not expected to transform to dispersive nonpolymeric PFAS when disposed of in a landfill; a recent study demonstrates that PTFE is stable and does not degrade under environmentally relevant conditions. Further, fluoropolymers that meet the criteria to be considered PLC, have negligible leachables, unreacted monomers, and oligomers most likely destroyed in fluoropolymer use processing and would therefore not be expected to significantly contribute to landfill leachate.

Available data reveal that fluoropolymers are mineralized (i.e. all C–F bonds broken, hydrofluoric acid generated, and scrubbed to calcium fluoride) under commercial WTE incineration operating conditions. In recent pilot scale studies representative of full-scale WTE facilities, the most common form of end-of-life destruction conducted on PTFE found that combustion converted the fluorine into controllable hydrogen fluoride gas and that, of the 31 PFAS studied, no fluorine-containing products of incomplete combustion were produced above background levels.

(2)

4. Baseline

Plastic finished technical articles, produced by mechanical processing form semi-finished plastic shapes such as tubes, rods, or sheets, are used in many crucial application sectors. Fluoropolymers plastic items have unique properties of durability, mechanical strength, inertness, thermal stability in foreseeable use conditions, and resistance to chemical, biological, and physical degradation, and corresponds to the 100% of plastic items productions, and of the company turnover, of some industries in the specific sector.

The following table shows performance characteristics required in various commercial fluoropolymer applications:

	Fluoropolymer characteristics									
	Durable		Inert		Functional			Stable		
Commercial application	Mechanical strength	Low particulation	Resistance to chemicals	Nontoxic, biocompatible, biological degradation resistant	Flexibility	Friction resistance	Low dielectric constant	Low leachables	Resistance to photolysis, oxidation, hydrolysis	Stability
Aerospace	X	—	X	—	X	X	X	—	X	X
Automotive industry	X	—	X	—	X	X	X	—	X	x
Medical devices	X	X		X	X	X	—	X	X	X
Pharmaceutical manufacture	X	X	X	X	X	—	—	X	—	X
Consumer outdoor apparel	X	—		X	X	—	—	X	—	—
Technical clothing (military, firefighters, first responders, medical personnel)	X	—	X	X	X	X	—	X	X	X
Consumer electronics	X	—	X	—	X	X	X	—	X	X
Wireless communications	X	—	X	—	X	X	X	—	X	X
Satellite navigation systems	X	—	X	—	X	X	X	—	X	X
Semiconductor industry	—	X	X	—	—	—	X	X	—	—
Building construction	X	—	—	X	X	—	X	—	X	X
Energy production and storage	X	X	—	—	—	—	X	X	X	X
Food and beverage production	X	X	X	X	X	X	—	X	X	—
Food protection and packaging	X	X	X	X	X	—	—	X		—
Drinking water filtration	—	X	X	X	—	—	—	X	X	—
Environmental protection	—	X	X	X	—	—	—	X	X	X

(1) (2)

5. Information on alternatives

Fluoroplastics, Polytetrafluoroethylene (PTFE) in particular, are the only plastics that combine both the broadest chemical resistance with the highest operating temperature and are the preferred material of choice because of their unique combination of properties, which are not achievable from other materials or via other functions.
As such, Fluoropolymers have become a critical mainstay for society and are useful to modern living, as they provide vital, reliable functionality to a broad range of industrial and consumer products. *(2)*

Chemical resistance and operating temperature are shown in tables below:

Classes of Substances at 20°c, Chemical Compatibility Chart. *(3)*

	ETFE	FEP/TFE/FPA	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 oxidizing acids (See oxidizing agents, strong) ***TPE gaskets

EXCELLENT	GOOD	FAIR	NOT RECOMMENDED
30 days of constant exposure causes no damage. Plastic may tolerate for 30 years.	Little or no damage after 30 days of constant exposure to the reagent.	Some effect after 7 days of constant exposure to the reagent. The effect may be crazing, cracking, loss of strength or discoloration.	Immediate damage may occur. Depending on the plastic, the effect may be severe crazing, cracking, loss of strength or discoloration, deformation, dissolution or permeation loss.

Chemical Resistance of High-Performance Polymers. *(4)*

Chemcial compound	PTFE	PVDF	PSU	PPSU	PPS	PPA	LCP	PEEK	PI	PAI	PBI	PEI
Acid, diluted	+	+	(+)	(+)	+	(+)	+	+	(±)	+	±	+
Acid, concentrated	+	+	±	±	+	(+)	(+)	(+)	(±)	+	-	+
Bases, diluted	+	+	+	+	+	+	+	+	-	±	±	+
Bases, concentrated	+	±	(+)	(+)	(+)	+	(+)	+	-	-	-	-
Hydrocarbons, aromatic	+	(+)	-	(±)	+	+	+	+	+	+	+	-
Hydrocarbons, aliphatic	+	(+)	+	+	+	+	+	+	+	+	+	+
Esters and Ketones	+	+	-	-	+	(+)	+	+	+	+	+	(±)
Ethers	+	+	±	±	+	(+)	+	+	+	+	+	+
Solvents, chloride based	+	+	±	-	±	+	+	+	+	+	+	(±)
Alcohols	+	+	±	±	+	+	+	+	±	+	+	+
+: resistant; (+): partially resistant; ±: conditionally resistant; (±): partially not resistant; -: not resistant												

Heat-resistant plastics available on the market. *(5)*

Symbol	Material name	Working temp. [°C]	Temporary temp. [°C]
PTFE	Polytetrafluoroethylene	260	290
PEEK	Polyetherketone	250	310
PVDF	Polyvinylidene fluoride	150	150
PEI	Polyetherimide	170	210
PPS	Polyphenylene sulfide	240	270
PFA	Perfluoroalkoxy polymer	150	240
PSU	Polysulfone	150	180

For many critical applications, fluoropolymers are the material of choice because alternatives are unable to provide the full complement of performance and functionality required. As such, there are currently no viable commercial alternatives to fluoropolymers in virtually every critical application in which they are used. *(2)*

6. Information on benefits

Fluoropolymers have substantial, unique societal value: Fluoropolymers possess a remarkable combination of properties and functional characteristics, that make them valued materials of choice in a broad range of industries and applications critical to life and sustainable environment in the 21st century. Their unparalleled combination of properties and performance characteristics deliver functionality to a wide variety of products and systems critical to achieving important societal goals. They are strategically important to innovation in vital sectors of the global economy requiring high-speed, high-volume data transmission, miniaturization, or operations in extreme temperatures. Moreover, they are crucial to achieving important societal goals such as decarbonization, renewable energies, and/or competitiveness in the digital transition.

- ✓ Aviation & Aerospace sector:

The thermal stability of PTFE and FEP fluoropolymers provides improved fire risk safety over other polymers when used in plenums and structural geometries in aviation and standard building construction.
The low dielectric constant of PTFE ensures the integrity of high speed–low signal loss systems as employed in the aerospace industry for flight controls, communication, and protection from extreme cold, moisture, and altitude changes. These are lifesaving applications that are used in satellite systems for navigation, wireless communications, in-flight navigation, and shielding from electronic interference. Civil and military aviation depends on reliable performance of these systems for long service hours with minimal maintenance down times.

- ✓ Medical sector:

Medical devices are successful when they are made from “biocompatible” biomaterials, that is, materials able to perform with an appropriate host response in a specific situation. The inertness of PTFE allows for its acceptance into the body. Moreover, PTFE flexibility and durability deliver mechanical integrity for the device’s lifetime.
The International Organization for Standardization (ISO) 10993 Biocompatibility of Medical Devices standards describe a broad array of biocompatibility tests that require consideration for each new device or significant changes to existing devices (ISO 2009). Over the years, medical devices containing PTFE (or expanded PTFE) have been evaluated using ISO 10993 and US Pharmacopeia (USP) Class VI standards (USP 2011) and have been determined to be biocompatible in their intended uses.

- ✓ Energy sector:

Chemical resistance to acids, bases, solvents, and chemical attack, combined with its unique conformable strength, makes PTFE an ideal coating for chemical process equipment, lining for process piping, sealants for gaskets and hoses, and fabricated parts for pumps, gears, and other mechanical parts that need extreme resistance for functionality.

- ✓ Food & Beverage sector:

The EU food contact regulation requires that monomers, other starting substances, and additives used to produce food contact polymers should be risk assessed and authorized (EU 10/2011): the regulation lists authorized substances which are permitted to have food contact. The monomers, other starting substances, and additives used to produce fluoropolymers for food contact (e.g. PTFE, FEP, and PFA) have been authorized for food contact uses.

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7. Request for exemption

Because of the points expressed in the explanations above:

- Fluoropolymers are a distinct class of per- and polyfluoroalkyl substances (PFAS)
- Fluoropolymers are polymers of low concern (PLC)
- Fluoropolymers have become a critical mainstay for society
- Fluoropolymers have substantial, unique societal value

an exemption of Fluoropolymers from the PFAS restriction proposal needs to be requested.

REFERENCES:

[1] Henry B., Carlin J., Hammerschmidt J., Buck R. C., Buxton L., Fiedler H., Seed J., and Hernandez, O. (2018); "A critical review of the application of polymers of low concern and regulatory criteria to fluoropolymers". Integrated Environmental Assessment and Management, Vol. 14(3), pp. 316-334.

[2] Korzeniowski H., Buck R. C., Newkold R. M., El kassmi A., Laganis E, Matsuoka Y., Dinelli B., Beauchet S., Adamsky F., Weilandt K., Soni V. K., Kapoor D., Gunasekar P., Malvasi M., Brinati G., and Musio S. (2022); "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers". Integrated Environmental Assessment and Management, Vol. 19(2), pp. 326–354.

[3] Chemical Compatibility Chart - LDPE, HDPE, PP, Teflon Resistance (calpaclab.com)

[4] https://www.findoutaboutplastics.com/2020/05/design-properties-for-engineers.html

[5] Design and Manufacturing of Micro-Turbomachinery Components with Application of Heat Resistant Plastics