

General Comments for Annex XV restriction report on Per- and polyfluoroalkyl substances (PFAS)

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We welcome the opportunity to contribute to the public consultation initiated by the European Chemicals Agency regarding potential restriction of Per- and polyfluoroalkyl substances (PFAS) according to Regulation (EC) No. 1907/2006 ("REACH").

We support the implementation of the regulation to restrict the manufacture and use of certain hazardous PFAS such as PFOS, PFOA. However, we believe that the proposed restriction should not regulate all substances defined as PFAS, but rather identify more detailed substance groups which have similar toxicity profiles based on scientific evidence and should establish appropriate restrictions for each substance-groups based on their human health and environmental impacts.

We have prepared our **General Comments** on fluoropolymers, particularly PVDF, as follows.

1. Scope or restriction option analysis

Fluoropolymers (PVDF, PTFE, etc.) are structurally classified as PFAS because they have a -CF₃- or -CF₂- group, but their properties are fundamentally different from those of low molecular weight PFAS: Fluoropolymers are stable, non-mobile, and do not enter the metabolic system of the human body. Therefore, they are basically harmless to human health and the environment.^{2, 3}

Among more than 11,000 PFAS, only about 40 fluoropolymers should be clearly distinguished from other PFAS and should be exempted from this PFAS restriction proposal in terms of their human health and environmental impact.

Also, we support the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV.

2. Hazard, Exposure, and Environmental emissions (Safety of Fluoropolymers in each stage)

2.1 Safety in the production stage

Now it is expected that close to 83 % of the global production of fluoropolymers will not require the use of short-chain PFAS such as fluorinated polymerization aids (FPAs). Especially, it is to be noted that the three main fluoropolymers by volume

(PTFE, PVDF and FKM) will shortly be manufactured fully without the use of FPAs.¹

In parallel, there has been progress in development of technologies to recover more than 99% of the emitted PFAS during fluoropolymer production.⁵

2.2 Safety in the use stage

Existing scientific data demonstrates that, because of their unique characteristics such as negligible solubility in water or the high molecular weight, fluoropolymers cannot enter or accumulate in the human bloodstream. Therefore, fluoropolymers do not pose a significant risk to human health or the environment. This allows to conclude that fluoropolymers meet the criteria to be identified as Polymers of Low Concern (PLC).^{2, 3}

The recent studies show that all the fluoropolymers evaluated (covering approximately 96 % of the global fluoropolymer market) fulfill the PLC criteria, and therefore can be negligibly soluble, not mobile, not bioavailable, not bioaccumulative, and not toxic.^{2, 3}

2.3 Safety in the End-of-Life stage

Fluoropolymers have a very long-life span in their applications of use (in many cases going above 30 years). This means that the rate of generation of fluoropolymer waste is significantly lower compared to other polymers (plastics). Indeed, based on recent studies that have evaluated available data from 2020, it is anticipated that less than 0.01 % by weight of fluoropolymers entered relevant waste streams in Europe. This is significantly lower to other plastics that are estimated at 4.8 %.¹

Regarding incineration, a Study shows that PTFE, the most stable fluoropolymer, completely pyrolyzes at 800 °C.⁶ It is therefore assumed that the other fluoropolymers also thermally decompose completely at a temperature of 800 °C. Since temperatures at the pyrolysis front and the combustion front in the waste-burning bed range from 900 to 1100 °C, all of fluoropolymers can be decomposed completely on this temperature range.¹

Regarding landfills, fluoropolymer waste is chemically inert as it meets the criteria of PLC. Therefore, if properly landfilled, fluoropolymers pose less concern to human health and the environment than other commodity plastics. Based on this, fluoropolymers should be managed appropriately within the same legal framework as other commodity plastics.

Regarding recycling of fluoropolymers, PVDF and its copolymer (poly (VDF-co-HFP)) can be decomposed and recovered as fluoride ions in water by heating at

250 °C with a low-concentration aqueous alkaline solution (1.0 mol/L) such as potassium hydroxide. The obtained fluoride ions can be reacted with calcium hydroxide to obtain high-purity calcium fluoride, or artificial fluorite, which is the raw material for PVDF.⁴

3. Information on benefits and socioeconomic analysis (SEA) issues

Fluoropolymers are used in critical applications related to health, environment, and safety. Examples include binders for lithium-ion batteries which are also used in EVs, water treatment membranes, the semiconductor industry, and aircraft components. Many of these applications cannot be substituted by other materials in terms of function and properties.

Thus, fluoropolymers are used in critical applications that help deliver strategic EU and UN climate objectives and are an enabler of "the European Green Deal", "the Chips Act", "Hydrogen Strategy", "Sustainable and Smart Mobility Strategy" and "the Net-Zero Industry Act". The proposed PFAS restriction creates general uncertainty that would undermine investment decisions and innovation in these and other important EU ambitions.

4. Request for exemption

As mentioned above, fluoropolymers are fundamentally different in physical properties from low molecular weight PFAS. Fluoropolymers are polymers of low concern (PLC) that are insoluble in water, non-mobile, and non-bioaccumulative. When they are incinerated at an appropriate temperature (800 °C or higher), they are decomposed completely and neither PFAS nor other toxic substances are generated. When they are landfilled, they are insoluble in water and non-mobile, so it does not diffuse into soil or water systems. In other words, fluoropolymers do not have human health or environmental impacts that exceed those of other plastics. Therefore, it is desirable to manage fluoropolymers in the same legal framework as other plastics.

From a socioeconomic viewpoint, fluoropolymers are used in critical, irreplaceable social applications as mentioned above. Therefore, eliminating their production and use would be a major loss to the EU society and economy. It would reduce the EU's competitiveness in the world and would also be a negative move for the implementation of the EU Green Deal.

As a conclusion, fluoropolymers (PVDF, PTFE, etc.) should be exempted from the proposed PFAS restriction from the standpoints of both human health and

environmental impact, as well as socioeconomic impact.

<References>

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- (4) J Hamaura et al, 'Efficient fluoride recovery from poly(vinylidene fluoride), poly(vinylidene fluoride-co-hexafluoropropylene) copolymer and poly(ethylene-co-tetrafluoroethylene) copolymer using superheated water with alkaline reagent.' *European Polymer Journal* **2023**, 182, 111724-111734.
- (5) R Dams and K Hintzer, 'Industrial Aspects of Fluorinated Oligomers and Polymers, in Fluorinated Polymers' (2016) *Polymer Chemistry Series* Volume 2: Applications, 1-31.
- (6) Rijksinstituut voor Volksgezondheid en Milieu, 'Per- and polyfluorinated substances in waste incinerator flue gases' (2021).