22 August, 2023

To

European Chemical Agency (ECHA)

Telakkakatu 6, P.O. Box 400, FI-00121 Helsinki, Finland

Reference: Public Consultation on Annex XV report on Per- and polyfluoroalkyl substances (PFAS)

Gujarat Fluorochemicals Limited (GFL), as a leading manufacturer and a global supplier of fluoropolymers with its European subsidiary based in Germany (Gujarat Fluorochemicals GmbH, Esplanade 40, 20354 Hamburg), welcomes the opportunity to provide input to the public consultation of the PFAS restriction proposal under EU REACH. GFL understands the need for regulating some PFAS that pose an unacceptable risk to human health and the environment but respectfully disagrees with the inclusion of fluoropolymers in the proposal and advocates that fluoropolymers should be exempted from the current PFAS restriction proposal under EU REACH.

First and foremost, Fluoropolymers are safe, high molecular weight group of 38 substances that are inert, non-soluble in water, non-mobile, non-bio accumulative and non-toxic. Dossier Submitters have concerns related to the lifecycle of fluoropolymers mainly during manufacturing and end of life fate. In the manufacturing of fluoropolymers, the development of non-fluorinated polymerization aids and greater implementation of efficient abatement technologies ensure minimal emissions of small-molecular weight PFAS. Nonetheless, GFL supports regulating Fluorinated Polymerization Aids (FPAs) used in the manufacturing of fluoropolymers that are the true and main source of PFAS pollution associated to fluoropolymers. At the end of its life, 85% of fluoropolymer applications end up in waste-to-energy incineration plants in EU; experimental data from a recent study demonstrates that fluoropolymers achieve complete thermal destruction resulting to Hydrogen Fluoride (HF) and Carbon-di-oxide (CO_2) under standard incineration operating conditions.

As these measures ensure meeting the final objective of achieving negligible emissions of small-molecular weight PFAS associated to fluoropolymer life cycle, the restriction proposal under EU REACH has become disproportionate as per Ramboll's Impact Assessment and Proportionality Assessment on Fluoropolymers, especially considering that fluoropolymers are used in critical industrial applications and are irreplaceable. Below we elaborate on this position and refer to recent studies including experimental data developed specifically for public consultation and scientific literature that supports it.

Most of the information presented is based on data and reports recently prepared by independent agencies and other stakeholders to support public consultation.

A. Fluoropolymers pose no risk to human health and environment

A.1. Fluoropolymers are Polymers of Low Concern (PLC)

Fluoropolymers meet the criteria of polymers of low concern as established by the OECD[1,2]. Fluoropolymers have thermal, chemical, photochemical, hydrolytic, oxidative, and biological stability. Fluoropolymers are practically insoluble in water and not subject to long-range transport. With a molecular weight well over 100,000 Da, fluoropolymers cannot cross the cell membrane. Fluoropolymers are not bioavailable or bio accumulative, as evidenced by toxicology studies on polytetrafluoroethylene (PTFE): acute and sub chronic systemic toxicity, irritation, sensitization, local toxicity on implantation, cytotoxicity, in vitro and in vivo genotoxicity, hemolysis, complement activation, and thrombogenicity. They have negligible residual monomer and oligomer content and low to no leachables. Since risk is defined as hazard in combination with the level of exposure, the absence of hazard means risk cannot be directly attributed to fluoropolymers, let alone an unacceptable risk.

References:

1. *A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and Fluoroelastomers - Korzeniowski et al. 2022.*
2. *A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers - Henry et al. 2018.*

A.2. Persistency alone is not a REACH risk criterion

Fluoropolymers are very stable materials, but persistency alone is not an appropriate measure of potential human health or environmental risk. Persistence in the environment does not indicate that the substance would accumulate in organisms, nor that environmental levels would rise to such an extent that exposure would result in toxicity. The PBT criteria established under REACH has always considered the characteristics of both persistency and bioaccumulation together, as indicators of potential risk (i.e., toxicity), which is not the case in fluoropolymers. Moreover, persistency, or stability, is the characteristic behind the much sought after properties that fluoropolymers bring to numerous industrial applications (e.g., related to chemical and temperature resistance or durability of products). Furthermore, any alternative substances that may be considered as potential substitutes for fluoropolymers, and which should perform at levels at least close to those of fluoropolymers are likely to be persistent too. This is further described in a recent report that provides information on the lack of concerns related to fluoropolymers[3].

References:

3. *Technical Support Document in Response to ECHA Annex XV Restriction Proposal for PFAS - GSI Environmental*

B. Proportionality

B.1. Quantification of risk by estimating PFAS emissions during fluoropolymer lifecycle

Manufacturing Phase

Most fluoropolymers can be manufactured (e.g., 100% of PTFE, PVDF, FKM) without fluorinated (PFAS) polymerization aids[4]. This has been made possible due to the recent developments in hydrocarbon surfactants replacing fluorinated surfactants. The use of non-fluorinated technology does not result in increased concentration of fluorinated residuals, which can be kept within environmentally sustainable concentration limits at which there is no adverse effect on humans[5]. Moreover, considerable progress has been made over the last years in the implementation of abatement technologies that allow for significant reduction of emissions of fluorinated compounds during manufacturing.

References:

4. *Developments in fluoropolymer manufacturing technology to remove intentional use of PFAS as polymerization aids – Ameduri et.al., 2023*
5. *Responsible manufacturing of fluoropolymers without the use of fluorinated polymerization aids (FPAs) – Report reviewed by Ramboll, 2023*

Use phase:

Fluoropolymers do not degrade under intended use conditions or under environmental conditions, as published by the Danish EPA in 2013[6]. It clearly states that, "the degradation of fluoropolymers cannot lead to the formation of long chain PFCAs, and they are not included in the OECD list of possible precursors of short chain PFAS". Fluoropolymers are polymers with carbon-only backbone with Fluorine atoms directly bonded to it. The exceptional strength of the C-F bond in fluoropolymers makes them not degrade to small molecular weight PFASs. This has been further elaborated in another publication confirming that fluoropolymers are not only different from non-polymeric PFAS, but they also exhibit completely different properties from other polymeric PFAS like side-chain fluorinated polymers, particularly in relation to possible environmental degradation into smaller PFAS[7]. Side-chain fluorinated polymers can degrade to hazardous non-polymeric PFAS during their intended use or under environmental conditions at the end-of-life phase of their applications due to their chemical structure. Moreover, these substances are mainly used in dispersive consumer applications like coatings on carpets, paper and textiles[8].

References:

6. *Survey of PFOS, PFOA and other perfluoroalkyl and polyfluoroalkyl sub-stances – Danish EPA 2013*
7. *Differentiation of fluoropolymers from other polymeric PFAS – Chemservice, 2022*
8. *Synthesis Report on Understanding Side-Chain Fluorinated Polymers and Their Life Cycle - OECD Series on Risk Management, No. 73, 2022*

i. Generation of microplastics:

Microplastics are generated typically due to friction between two moving surfaces and fluoropolymers have very low coefficient of friction. Fluoropolymers are typically used in non-abrasive applications that are either stationary or only rub against liquids and gases. Also, >99.5% of fluoropolymers are used as articles/components in industrial applications whereas <0.5% are used as powders/mixtures (declining use) in final application such as cosmetics, inks, ski waxes or bike chain lubricants and we support regulations on such dispersive uses of fluoropolymers. End of life disposal, typically landfills is unlikely to result in microplastic generation due to extreme stability and lack of physical ablation.

End of life phase:

Overall, fluoropolymers represent a tiny fraction of total plastics consumption globally (less than 0.5 million tons of fluoropolymers against 460 million tons of plastics). As per the Conversio report[9] on Fluoropolymer waste in Europe 2020, it is estimated that 84% fluoropolymer application waste ends up in energy recovery plants or hazardous waste incineration plants. Around 13% of the fluoropolymer waste is landfilled and 3% was recycled.

i. Thermal destruction of fluoropolymers in waste-to-energy incineration plants

As per a recent experimental study conducted by Karlsruhe Institute of Technology (KIT) in cooperation with Société Générale de Surveillance (SGS)[10], it has been established that Fluoropolymers are converted to Inorganic Fluorides and Carbon dioxide at standard incineration conditions. Inorganic fluorides mainly include Hydrogen Fluoride and Silicon tetrafluoride. Total organic fluorides (PFAS) were non-detectable with a reporting limit of 0.08 ppm and Trifluoroacetic acid (TFA) was also not detected with a reporting limit of 0.04 ppm. The results confirm that Fluoropolymers at their end of life when incinerated in waste-to-energy recovery plants do not generate any noticeable levels of PFAS emissions and therefore, pose no risk to human health and the environment.

The study involved application samples of the four most sold Fluoropolymers (PTFE, PVDF, PFA and FKM) provided by Pro-K (German association of polymer processors), which were incinerated under standard operating conditions for municipal and industrial waste incineration (850°C – 1100°C for two seconds residence time respectively) and consulted by the German Federal Environment Agency (Umweltbundesamt).

ii. Fluoropolymer application waste disposed of in landfills

Fluoropolymers waste is inert and does not degrade in the environment, it poses no risk during landfill[11]. To the contrary, fluoropolymers are used as an inert geomembrane in landfill infrastructure to prevent contamination of ground water and soil from the release of hazardous chemicals[12].

A set of studies was performed by independent laboratories to investigate the persistence, degradation, transformation to or release of substances of concern using standard OECD and US EPA Efate protocols. Studies include potential partitioning of PTFE into soil, water, air, and its leaching

potential. The set of studies conclude that PTFE does not partition to air, water, or soil. These results support the stability of PTFE and lack of transformation to other PFAS, such as perfluoroalkyl acids. Potential inhalation, oral or dermal exposure to PTFE for biota or the environment is unlikely based on this data.

iii. Recycling of fluoropolymers

Many studies have shown that fluoropolymers can be converted back to their monomers on a lab and pilot scale via CRM. A review paper[13] has brought together recycling (including PTFE micropowders and fluoropolymer recycled materials), reuse, closed loop systems, decomposition, and end of life of fluoropolymers. Recycling of clean fluoropolymers (e.g., PTFE), FEP, PFA and PVDF waste or scraps generated in the production has already been achieved[14] (e.g., by Dyneon on a pilot scale), at Karlsruhe Institute of Technology or by Arkema company). This approach is very critical in achieving closed loop economy and requires additional work and discussion in recycling and reuse of fluoropolymers in consumer articles since these fluoropolymers are typically contaminated by other fillers and substances, which makes recycling difficult.

An article on Chemical Recycling of PTFE[15] (as a Model for Other Polymers) discusses different recycling routes for fluoropolymers such as thermal, chemical (molecular recycling, monomer recycling and feedstock recycling), and mechanical recycling. With all the new recycling options, the fluoropolymer industry can establish closed loops throughout the whole value chain with close to zero emissions for perfluorinated polymers.

Recycling of fluoropolymers is technologically possible, but often there are economic hurdles.

References:

9. *Fluoropolymer Waste in Europe – 2020 – Conversio, 2022*
10. *Pilot-Scale Fluoropolymer Incineration Study-Preliminary report – Gehrmann et. al., 2023*
11. *Summary of the PTFE studies performed with independent laboratories to investigate Persistence, Degradation, Transformation to or Release of Substances of Concern*
12. *Contamination from a leaking geomembrane—A necessary and imminent evil? – Tippet et. al., 2023*
13. *Recycling and End of Life Assessment of Fluoropolymers: Recent Developments, Challenges and Future Trends – Ameduri et. al., 2023*
14. *Technical brochure – Recycling of Fluoropolymers, Fluoropolymergroup, Pro-K, 2018*
15. *Chemical Recycling of PTFE (as a Model for Other Polymers) - Achim Schmidt-Rodenkirchen, Klaus Hintzer, Thorsten Gerdes*

B.2. Socio-economic value of fluoropolymers

Fluoropolymers are indispensable for the functioning of modern society

Fluoropolymers are used in a wide variety of critical industrial uses. Fluoropolymers provide important benefits to the industry sectors where they are used, and to society, by contributing to safety and well-being, decarbonization, environmental safety and circularity, performance in critical technological sectors and comfort [16].

References:

16. *Critical use of fluoropolymers in the functioning of modern society – Sales et. al.,2023*

Irreplaceability of fluoropolymers - Analysis of alternatives:

Fluoropolymers provide a combination of functionalities for many industrial sectors. Fluoropolymers are high-cost materials, and they are only chosen where no other material is able to match the required combination of properties. Substitution by substances offering inferior performance would negatively impact the safety of people and the environment. It would also compromise key objectives of the European Union, such as the transition to a decarbonized and circular economy, Europe's technological leadership and its autonomy in key strategic sectors like semiconductors.

Potential alternatives to fluoropolymers are subject to unacceptable trade-offs that would negatively impact the functioning of European society from multiple perspectives, including safety standards, development of green energy sources, increased generation of waste streams and inability to maintain the high living conditions that European citizens enjoy[17].

References:

17. *Technical report on Analysis of Alternatives to fluoropolymers and potential impacts related to substitution in different sectors of use – Chemservice, 2022*

B.3. Socio-economic assessment and the Principle of Proportionality:

The PFAS restriction proposal is justified on the basis of "persistency and other concerns". As previously discussed, those "other concerns" do not apply to fluoropolymers, because they are Polymers of Low Concern; furthermore, most fluoropolymers can now be manufactured safely using non-fluorinated polymerization aids in combination to increased efficiency of abatement technologies, and they can be disposed of safely at the end of their life.

In addition to this, it needs to be noted that, as stated by the Dossier Submitters, the largest contribution to PFAS emissions (at least 75%) is related to fluorinated gases and side-chain fluoropolymers uses in the TULAC sector. Fluoropolymers are not involved in any of these sectors and therefore their potential contributions to emissions can be regarded as low.

Taking the above into consideration, restricting fluoropolymers would not be a proportionate regulatory option[18,19], as it would not result in additional significant reduction of PFAS emissions; combined with the significant negative impact to many critical sectors of the European economy, with great impact on safety, decarbonization, circularity and the working of key technological sectors in the EU, it is evident that restricting fluoropolymers is not necessary to achieve the desired end, while it would impose an excessive burden to society.

Moreover, a system based on multiple, time-limited derogations would not be workable, due to the high complexity of supply chains involving many SMEs and the high fixed cost-intensive processes associated to fluoropolymer manufacture.

In this regard, the conclusions from a Regulatory Management Option Analysis (RMOA) recently published by the UK Competent Authorities under UK REACH appear to be more pragmatic and

balanced[20]. The conclusions from the UK recommend a targeted approach for different sub-groups in the PFAS family, based on real concerns and risks from chemicals in each sub-group. This would allow to take regulatory action on substances that are truly of concern (focus on what matters) for human health and the environment, while allowing the continued use of low-risk chemicals (i.e., fluoropolymers); this does not exclude the possibility for regulators to improve areas that may require a more thorough assessment and implementation of best practices (e.g., via regulations on industrial emissions or waste).

References:

18. *Assessment of PFAS Emissions during the Lifecycle of PTFE: a case study – Report prepared by Ramboll, 2023*
19. *Inclusion of fluoropolymers in the scope of the PFAS restriction proposal under EU-REACH: Impact and proportionality assessment – Report prepared by Ramboll, 2023*
20. *Analysis of the most appropriate regulatory management options (RMOA) on Poly- and perfluoroalkyl substances (PFAS), UK HSE, March 2023*

In conclusion, **GFL requests that fluoropolymers be exempted from the EU REACH PFAS restriction.**

C. Legal observations on unfair inclusion of fluoropolymers in PFAS restriction proposal

A recent legal review [21] of the PFAS restriction proposal suggests that the inclusion of fluoropolymers may not be in line with the legal dispositions of the REACH Regulation and other pieces of European legislation. The memorandum summarizes the findings of the legal assessment with a special focus on general legal concerns as well as legal implications due to the intended restriction in general, and with respect to Fluoropolymers. The Proposal is based on the assumption that all PFAS qualify as persistent and do have other hazard properties in addition to their persistence. The Proposal, however, lacks a mandatory risk assessment to demonstrate that Fluoropolymers share the same or similar hazard properties with other PFAS. In particular it needs to be noted that Fluoropolymers do not meet the criteria for being bioaccumulative, mobile or toxic. Furthermore, the Proposal fails to demonstrate that there is an unacceptable risk to human health or the environment with respect to Fluoropolymers. Restricting Fluoropolymers as supported by the Proposal does also not align with the precautionary principle. Due to the fact that any emission in connection with the entire life-cycle of Fluoropolymers from manufacturing to processing until the end-of-life stages are to be considered *de minimis* if fluorinated polymerisation aids are restricted, a restriction of Fluoropolymers as such would not be necessary at all against the background of the principle of proportionality. Therefore, Fluoropolymers manufactured without the use of fluorinated polymerisation aids should be exempted from the scope of the Proposal.

References:

21. *Legal Observations on Proposal for a restriction of Per- and polyfluoroalkyl substances (PFAS) according to Regulation (EC) No. 1907/2006 (REACH) – Produktkanzlei, 2023*