

SECTION III. Non-confidential comments

General comments

1. Scope or restriction option analysis

- By including fluoropolymers, the principle of proportionality was disregarded.
- A variety of substances like fluopolymers, that are covered by the definition of the PFAS family, do not have hazardous properties of concern or entail unacceptable risks. Therefore, the definition of the PFAS family is too broad.
- The data presented demonstrate that the fluoropolymer class of PFAS is well defined, meets PLC criteria, and should be considered as distinctly different from other classes of PFAS.

The grouping of all PFAS together is not supported by the scientific data.

- Although fluoropolymers fit the PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS.

2. Hazard or exposure

- Fluoropolymers are considered Polymers of low concern.
- fluoropolymers are high molecular weight, have narrow molecular weight distribution, and have negligible oligomer content and organic and inorganic leachables.
- Data show that fluoropolymers have thermal, chemical, photochemical, hydrolytic, and biological stability
- Toxicology studies on PTFE demonstrate the absence of acute or subchronic systemic toxicity, irritation, sensitization, local toxicity on implantation, in vitro and in vivo genotoxicity, hemolysis, complement activation, or thrombogenicity
- Further, the study results demonstrate that fluoropolymers are a distinct and different group of PFAS and should not be grouped with other PFAS for hazard assessment or regulatory purposes

6. Information on alternatives

- Fluoropolymers possess a unique combination of properties and unmatched functional performance critical to the products and manufacturing processes they enable and are irreplaceable in many uses.
- Fluoropolymers are currently irreplaceable for many critical applications, and existing potential alternatives would be associated with significant trade-offs that could compromise safety of workers, general population, or the environment, either due to direct hazardous properties of the alternative, or by downgrading performance of key applications. As of today, it is not anticipated that viable alternatives offering equivalent performance could be developed in the near future.
- Under a situation in which fluoropolymers may no longer be available and downstream users would be forced to switch to alternatives, a relevant number of applications could be pushed backwards 50 years or more, in terms of technologies that would have to be used.

9. Transitional period

- Because the supply chain of fluoropolymers are very complex and the end uses, in which fluoropolymers are involved, are so broad, the restriction will be very hard to implement. That is even with the derogations, that are established in the restriction proposal.
- Fluoropolymers are very critical to the European society. Only a full exemption of fluoropolymers will guarantee the continuity of those critical applications for the European society.

10. Request for exemption

- Because the properties of fluoropolymers are so different, they pose a specific group of substances within PFAS
- They are considered polymers of low concern and therefore their use does not pose any risk to human health and the environment.
- Therefore, a broad exemption for this group should be considered.