

ABOUT GORE, THE USE OF FLUOROPOLYMERS AND WHY THEIR CONTINUED USE IS JUSTIFIED

Brussels, July 18, 2023

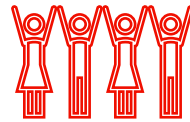
Together, improving life



About Gore | Global Facts & Figures



Founded in 1958



One of the 200 largest
privately held US companies



12,000+ Associates
(1,600+ in Bavaria)



1969: Discovery of
ePTFE



3,500+ unique inventions



12% of revenue
dedicated to R&D

Gore's Product Portfolio

Improving Lives and Industries through innovations



Globally recognized among 15+ industries





AEROSPACE

Reliable, time-tested solutions for the most challenging applications in the harshest environments – when failure is not an option.





INDUSTRIAL & CHEMICAL

Products that help protect the environment while increasing customer efficiency, productivity, or profitability.





PUBLIC SAFETY

High-performance technical fabrics for end-users in fire & rescue, law enforcement, defense, workwear and industrial environments.



Proposed EU PFAS Restriction

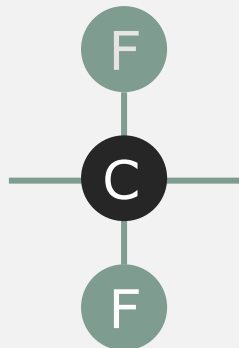
- Dossier **Submitters' Concerns** From Annex B:
 - The main concern for all PFAS and/or their degradation products is their **very high persistence** (vP).
 - Supporting concerns are their **bioaccumulation, mobility, long range transport potential** (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects.
 - High persistence in the environment will lead to **distribution of PFAS from one environmental compartment to another** (e.g. from soil to freshwater to marine environment).
 - Continued PFAS emissions will lead to an **increased environmental stock leading to increased exposures**. Increased exposures will exceed known/unknown PFAS thresholds to cause adverse effects at some point in time.
 - Therefore, PFAS should be treated as non-threshold substances like PBT/vPvB substances and **PFAS releases should be used as a proxy for risk**.
 - **Fluoropolymers** are indirectly of concern because **during their production and use, monomers, oligomers and by-products of processing "are emitted into the environment"** and during waste incineration at **end of life, other PFAS "may be formed and emitted"**.
- Grouping all PFAS together is based on structural similarity (common perfluoroalkyl moieties) that is considered to trigger equivalent hazards and risk, primarily related to the vP property.

Overview

Per- and Polyfluoroalkyl Substances (PFAS)

Thousands of PFAS

Similarities



1 fully fluorinated carbon

with a wide variety of properties

Differences

PTFE on the spectrum



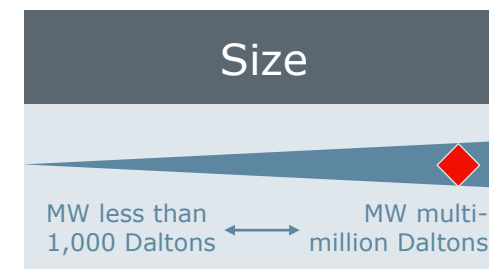
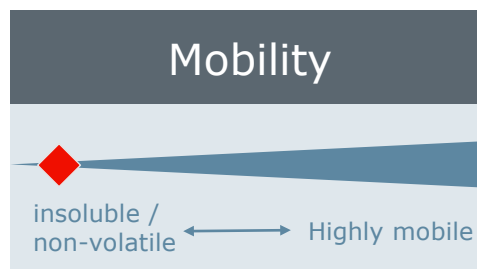
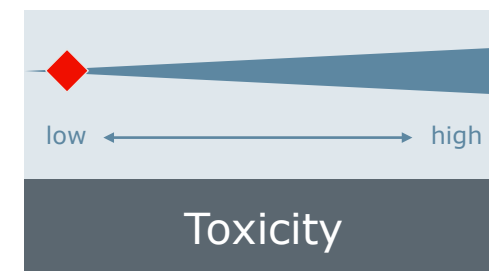
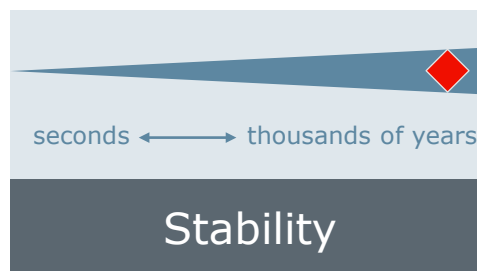
Gases



Liquids

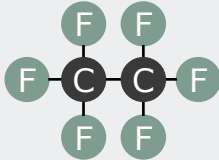
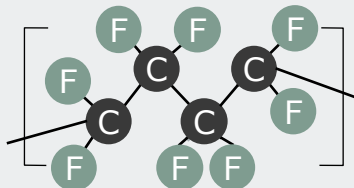
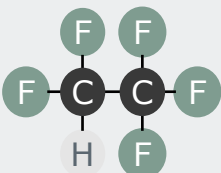
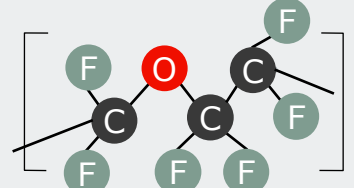
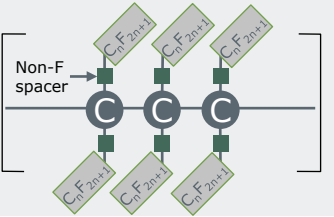


Solids



Overview

Per- and Polyfluoroalkyl Substances (PFAS)

1 Group			PFAS Per- and Polyfluoroalkyl substances
2 Categories		Non-Polymers	Polymers
5 Classes		<u>Perfluoroalkyl Substances</u> Compounds for which all hydrogens on all carbons (except for carbons associated with functional groups) have been replaced by fluorines 	<u>Fluoropolymers</u> Carbon-only polymer backbone with fluorines directly attached 
Perfluoroalkyl Acids (PFAAs) such as PFOA, PFOS, PFHxS, etc.		<u>Polyfluoroalkyl Substances</u> Compounds for which all hydrogens on at least one (but not all) carbon have been replaced by fluorines 	<u>Polymeric Perfluoropolyethers</u> Carbon and oxygen polymer backbone with fluorines directly attached to carbon 
			<u>Side-chain Fluorinated Polymers</u> Variable composition non-fluorinated polymer backbone with fluorinated side chains 

Fluoropolymers – Key properties



Durability



Inertness



Mechanical
strength

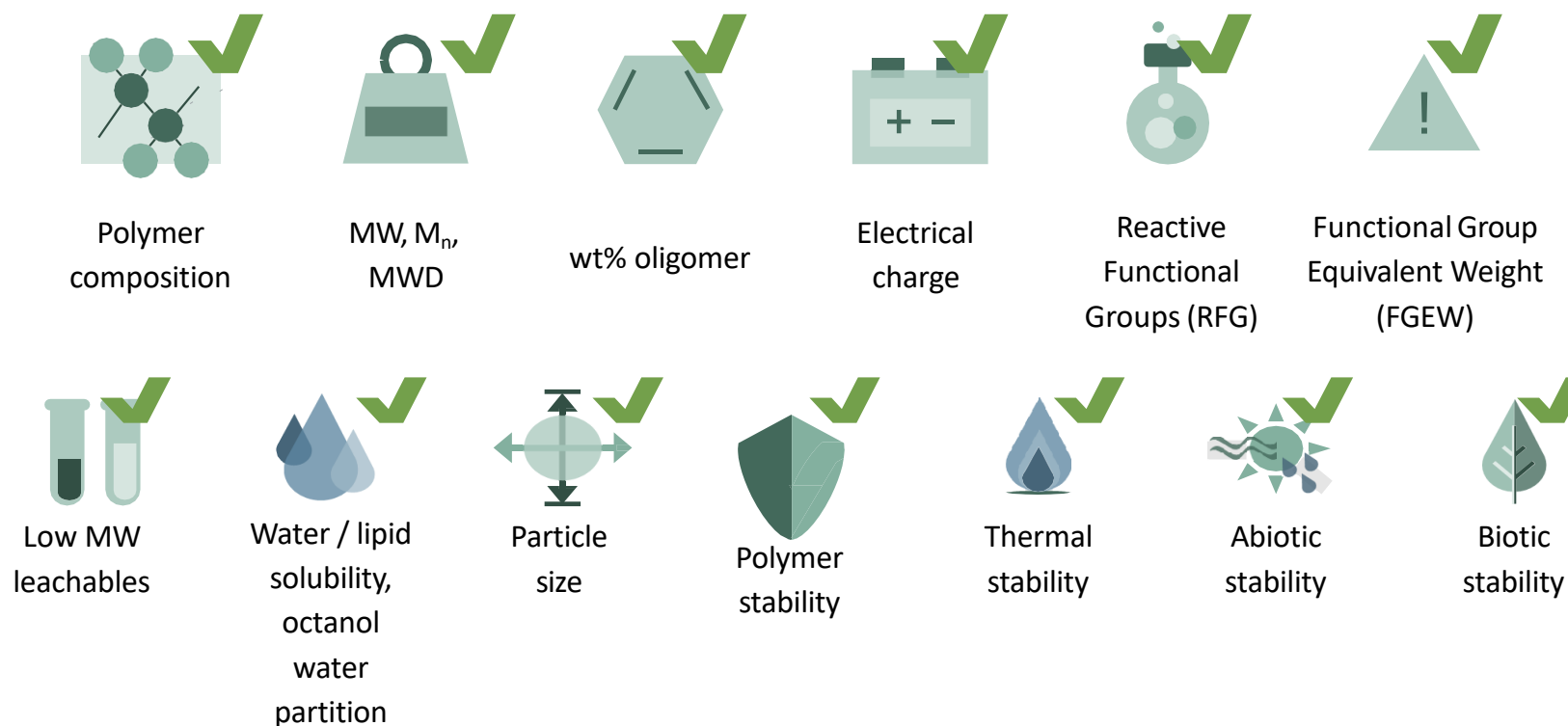


Thermal stability



Resistance to
degradation

Polymer Chemical/Physical Properties Predictive of Low Hazard



Fluoropolymers with these properties have demonstrated low health and environmental hazard.

Proposed EU PFAS Restriction

EU industries have already voiced constructive suggestions on how to improve the restriction proposal

- Call for exemption of PFAS that verifiably do not pose an „unacceptable risk“, e.g. fluoropolymers
- Strong support for:
 - Derogations for industries until socioeconomically sensible alternatives are available
 - Realistic transition timeline for those applications where socioeconomically sensible alternatives are available or at least foreseeable
 - Correction of technical misconceptions in the proposal



Proposed PFAS Restriction

Aviation | Need to reconsider proposed provisions

- Aviation requires combination of properties that can only be met by high-performance materials such as fluoropolymers
- Alternatives of lower quality is not an option in aviation sector, and it is considered unlikely that feasible alternatives will be found in the foreseeable future.
- Aviation not discussed as separate sector in PFAS restriction proposal. Time-limited derogation of 13,5 years for transport safety-related applications
- Other applications would no longer be available 18 months after EiF: significant negative impact on availability and supply
- It is vital to consider future aviation requirements that cannot be achieved without PFAS (e.g. higher voltages, increased electrical current, faster data rates, and improved sealing enable miniaturization, weight reduction, and fuel efficiency in conventional and more electric aircrafts)

Proposed PFAS Restriction

Aviation | Need to reconsider proposed provisions



Proposed EU PFAS Restriction | Fluoropolymers

Persistence and Related Concerns | Rebuttal based on scientific evidence

Key Take- away

Fluoropolymers are persistent, but not mobile, bioaccumulative, or bioavailable. They do not concentrate in environmental compartments.

The restriction proposal lacks a sufficient scientific basis with regard to risk assessment of fluoropolymers. It is not even clear from the proposal whether the dossier submitters associate any direct hazards with fluoropolymers.

A body of data demonstrates that regulators concerns about persistency of fluoropolymers, like PTFE, are absent.

Proposed EU PFAS Restriction | Fluoropolymers

Persistency and Related Concerns | Rebuttal based on scientific evidence

Stated Concern	Rebuttal	Evidence
High persistence will lead to distribution of PFAS from one environmental compartment to another Increased environmental stock...	PTFE is not volatile, is insoluble in water, does not adsorb to soil and does not partition to or concentrate in environmental compartments. It is not mobile and is not subject to long range transport.	Charles River Laboratories data
Resulting increase in exposure	PTFE is not bioavailable. The blanket assertion that long persistence leads to high-risk disregards risk being dependent on the quantity released, uptake in biota and toxicity. Assuming the total concentration is bioavailable overestimates risk. Need to quantify the bioavailable fraction and use it to get a more representative picture of the actual human and environmental risk. Only the bioavailable fraction of a chemical in the environment is available for uptake. Risk requires hazard and bioavailable exposure.	Beyer EC, 1993; DeMello WC, 1987; Alberts B, Bray D, Lewis J et al., 1994; Leeson, 2012.; ECETOC Special Report No.18. Brussels, July 2014; Ming-Qiang Zhang and Barrie Wilkinson, 2007.; Mackay D et. al., 2014; Ehlers and Loibner, 2006; Akkanen et al., 2012; Semple et al., 2004; Nat'l Research Council 2003
Exceeding thresholds that cause adverse effects	PTFE does not have hazards (persistence alone is not a hazard), therefore PTFE has no threshold for adverse effects to exceed	Henry et al., 2018 and Supplement; published literature; clinical trials;
PTFE releases can be a proxy for risk	Risk assumes hazard and bioavailable exposure, neither of which is present for PTFE.	Supplement to Henry et al., 2018,
Grouping all PFAS together is expedient because common moiety means shared hazard profile	The presence of a single fully fluorinated carbon is insufficient to describe all PFAS and their chemical, physical and biological properties. For example, the hazards of a perfluoroalkyl acid are not shared by a polymeric perfluoropolyether.	CEFIC fact sheet on grouping, May 2021; Anderson et al., 2022. Reg Tox and Pharm, Volume 134, October 2022.
Possible degradation products and/or leachables are otherwise a source of concern	The tested PTFE (fine powder PTFE meeting ASTM D4895) showed a lack of degradation and leachables; therefore, not a source of concern.	Charles River Laboratories data

Proposed EU PFAS Restriction | Fluoropolymers

Emissions and Related Concerns | Rebuttal based on scientific evidence

Key Take-away

The main concern is around environmental emissions from manufacturing and end-of-life. The right instrument to regulate emissions from manufacturing is emission control law, not a restriction.

Fluoropolymer manufacturing and processing emissions can be tightly controlled with BAT environmental control technologies. This applies to both exhaust air and the wastewater stream. Fluoropolymers manufactured under BAT have low to undetectable residual levels.

Residuals and contaminants impact PTFE performance and are undesirable from a quality perspective.

Note: To produce highly technical products, such as those Gore products enable, PTFE (made with no fluorinated PPAs) cannot achieve high enough molecular weight (MW) and processability as fine powder PTFE (which needs fluorinated PPAs to achieve high MW)

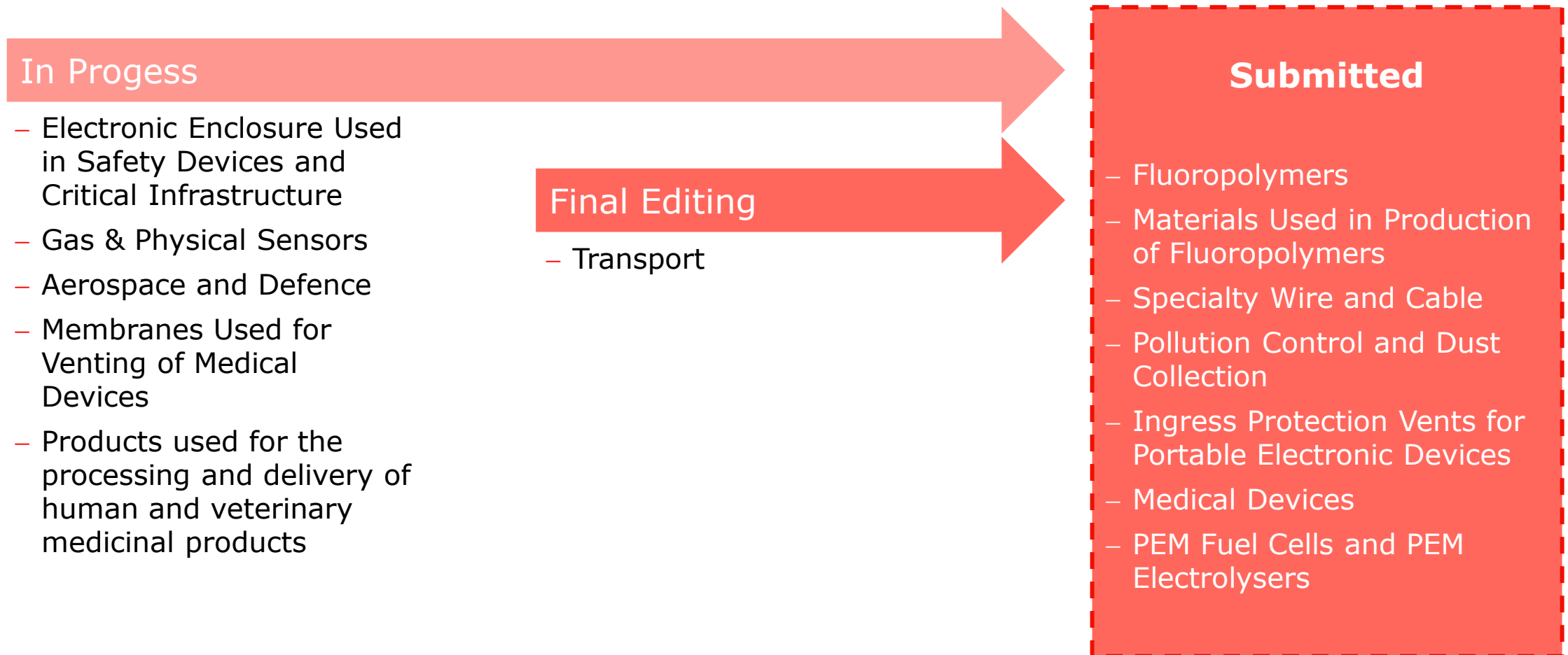
Proposed EU PFAS Restriction | Fluoropolymers Proposed EU PFAS Restriction | Fluoropolymers

Emissions and Related Concerns | Rebuttal based on scientific evidence

Stated Concern	Rebuttal	Evidence
Environmental release of PFAS (processing aids, monomers, oligomers, etc.) used or formed in the production of fluoropolymers...	The CAS# System is inadequate to differentiate between processing methods and key attributes that influence degradation products. Fluoropolymer manufacturing and processing emissions can be tightly controlled with BAT environmental control technologies. This applies to both exhaust air and the wastewater stream. Residual processing aids and other residuals are undesirable because contaminants impact or impair processing of fluoropolymer resins into final products, influence the attributes of the polymer, and impair polymer performance. Post polymerization finishing steps (e.g., washing, drying) reduce residuals. Processing steps to reduce residuals and volatiles in fluoropolymers, including PFAS-based processing aids and monomers, are undertaken as part of quality control. Poor quality materials may contain higher levels of impurities, residuals, and other contaminants. These materials would not be suitable for highly technical applications.	ECETOC-133, 2019; Korzeniowski, 2022; Henry et al., 2018 and Supplemental; Ebnesajjad, 2000; ASTM4895-16
...during product manufacturing and intended use...	When applying high manufacturing standards, residuals are reduced to trace levels in post-polymerization processing steps. For example, PTFE (fine powder PTFE meeting ASTM D4895-16) contains very low to undetectable (<1ppm) levels of processing aid residuals, as published data demonstrates.	Charles River Laboratories; Henry et al., 2018 Supplemental.
...during product disposal/end-of-life	Gore commissioned an incineration study to determine if any of 31 studied PFAS were released under typical municipal incineration conditions. PFAS compounds were chosen to represent a broad range of PFAS and were selected due to their occurrence in the environment, literature citations and availability of validated methods from commercial laboratories. Municipal incineration of PTFE showed no significant generation of the studied PFAS.	Alexandrov et al., 2019. Chemosphere Volume 226, July 2019, Pages 898-906.

Proposed EU PFAS Restriction | Gore's derogation requests

2 Broad, 22 End-use (1 Medical Products, 1 Fabrics, 20 Performance Solutions)



Thank you



"To some degree, each of us is a dreamer and a doer. I know that we will continue to *dream* and to *achieve* great and wonderful things."

Vieve Gore

