In review of the current ECHA dossier, there are significant concerns and impacts that Zeus Inc would like to comment on regarding the proposal as it currently stands. The majority of Zeus' fluoropolymer products are highly engineered extruded tubing, heat shrink, wire insulations, and monofilaments. They go into a variety of use sectors and sub-uses sectors, but they are chosen because of the combination of material properties including: high electrical resistance, high temperature resistance, excellent chemical resistance, tensile properties, low surface friction/high lubricity, and low flammability to name a few.

Although not every application and end use is currently known by Zeus, in review of the dossier, the majority of known uses already have been designated as having low-substitution potential. There is a proposed derogation based on sufficient evidence (5e, 6a, 6b, 6c, 6f,) or weak evidence (5ee, 6o) as outlined in the "Proposed restriction- Annex XVII entry PFASs (Restriction Option 2)" on pgs 4-8. Zeus wishes to share information regarding the low potential for harm throughout the lifecycle for fluoropolymers, particularly in the known uses listed above, provide additional support that the value of fluoropolymers is high, and comment on the insufficiency of the proposed derogations. Additionally, there is concern regarding supply availability in the proposed derogation for 5a, which will be expanded upon below. Zeus would also like to comment that the transportation sector (6o) is currently very broad as it applies to "applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers, or goods." Zeus has information regarding the use of fluoropolymers in aerospace applications, specifically aircraft, which have different performance requirements than other transportation vehicles.

The following information provides additional information that supports the position that Zeus' fluoropolymer products have low risk of harm, a lack of available replacements, and high societal value. Zeus recommends exempting fluoropolymers from the current restriction altogether.

1. Life-cycle of Fluoropolymers

   The life-cycle of fluoropolymers includes manufacturing, intended use, and end of life. The fluoropolymers that we receive have very low amounts of residual small-molecule PFAS the order of ppb or less. The source of most environmental contamination comes from dispersive applications[1], not via the trace amounts left in fluoropolymers.

   The intended uses for our fluoropolymer products fall into different a variety of use sectors and sub-classes, but regardless of application, fluoropolymers behave like other polymers. It is well-acknowledged that polymers do not behave like small-molecules, and as such often have their own separate classifications and designations. The OECD has developed a list of criteria that designated if a material can be considered "a polymer of low concern." [2] Two documents have been published indicating that 18 commercial fluoropolymers meet this criteria. [3, 4]

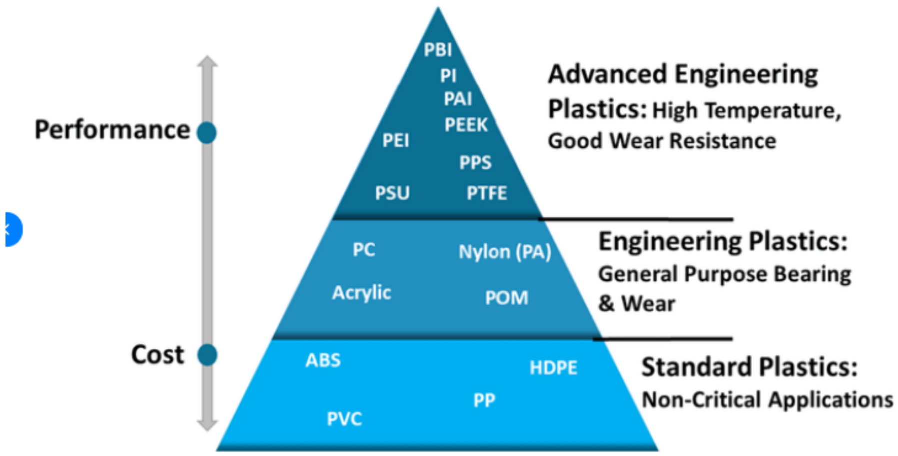
   The final concern is regarding the end-of-life for fluoropolymers. The Conversio Marketing & Strategy GmbH group has compiled a comprehensive detailing of the various waste streams that contain fluoropolymers. As this document shows, the majority of the fluoropolymer waste does not end up in a municipal waste stream[5]. Additionally, a study by the Karlsruher Institut fuer Technolgie, has shown that PTFE converts into fluorine and hydrofluoric acid and no small-molecule PFAS were generated when using the best available technology for municipal waste inceneration[6]. The study did note that there were small-molecule PFAS detected in the test, but it was present in statistically equivalent amounts in both the control and experimental tests. In conclusion, there is evidence that at the proper conditions fluoropolymers can be safely incinerated. It is our position that responsible manufacturing and disposal will further mitigate the already low risks of fluoropolymers.

2. Proposed derogations

The last point Zeus wishes to comment on is the lack of alternative materials and the insufficient time frame given to develop alternatives and the premature exclusion of a processing aid in the manufacture of PTFE fine powder.

a. The highest concern is that many of the applications that have low substitutions available with only a 13 years Entry info Force (EiF) time frame given to develop a solution. The requirements of fluoropolymers is usually based on several properties, so designing an alternative becomes more complex.
b. New material development has a relatively long and complex path from concept or discovery to market. As Commercialization of New Materials for a Global Economy succinctly states: "The process of developing and commercializing materials is a lengthy one, often requiring 10 years or even longer. A primary reason is that progressing through each phase of the development process requires increasing amounts of material to be processed and fabricated, followed by extensive testing to demonstrate that the properties that make the material desirable have not changed. Before full-scale application, it must be shown that the performance of the material is indeed reproducible, meets all of the necessary standards, and has the necessary life-cycle properties and integrity for the intended application. This process takes time and large capital investments, which is why automotive or airplane manufacturers, for instance, are reluctant to change from a known to a newly developed advanced material. Economics is a large driver in the process as development proceeds from laboratory to commercial quantities. In the final analysis, the materials supplier, component manufacturer, and final product manufacturer or assembler all must make returns on their investments, so materials commercialization ultimately must stand the test of profitability of the final manufactured product."[7]

The conditions mentioned above suggest that raw material replacement will be long and iterative between the different entities in the supply chain is likely to hold true for fluoropolymers. Currently, fluoropolymers are used in applications that have specific requirements that other materials cannot meet. As shown in the schematic below[8], there is economic incentive to choose lower cost alternatives where possible. And as a side comment, the other resins listed in the advanced engineering plastics have particular physical and chemical properties that differentiate it from the others in that group. For example, PEEK and PTFE are in the upper pyramid tier but have different combination of properties, as shown in the chart below.[9]



Polymer pyramid listing high performance polymers used in TS processes organized from amorphous to crystalline. Modified from Friedrich, K., 2018. Polymer composites for tribological applications. Advanced Industrial and Engineering Polymer Research 1, 3-39.

Specification	PTFE	PEEK
Chemical Resistance	Virtually Inert	Affected by Sulphuric Acid
Dielectric Strength	50-100 KV/mm	50 KV/mm
Tensile Strength	25-35 MPa	90-100 MPa
Coefficent of Friction	0.03-0.05	0.35-0.45
Temperature Resistance	Up to 250°C	Up to 250°C
Flexural Modulus	495 MPa	3900 MPa
Coefficient of Linear Thermal Expansion	14 x 10-5/K	5 x 10-5/K
Elongation	350-400%	30-40%
Compressive Strength	140 MPa	30-40 MPa
Machineability	Good	Very Good

These are two specific examples where fluoropolymers are recommended because of their unique performance characteristics:

i. PTFE is the desired material for catheter liners because it meets the requirements for lubricity that even the second-most lubricious material (FEP) cannot meet.[10] Additionally, catheter liners have other performance requirements such tight tolerances and specific mechanical properties that make developing a drop-in substitution very challenging.

ii. In aerospace applications, PTFE and FEP are often chosen in wire harnessing and safeguarding and have stringent performance requirements. For example, insulating heat shrink made from PTFE or FEP must meet all the required performance properties outlined in the

SAE standard AS23053. The properties include the ability to withstand and perform as expected under extreme chemical, thermal, and electrical conditions.

Finally, any new material would require stringent testing and regulatory approval before market acceptance. On the medical side, raw material safety must be demonstrated before it can be considered for use in a medical device. And then the device itself must undergo regulatory approval under EU-MDR. Likewise, the standards regulating aircraft would need to be updated to allow a new material to be used, which would require additional testing and approvals via the appropriate standards committees. The time and cost to develop and commercialize currently non-existent alternatives to fluoropolymers will be immense.

1. A recent example that highlights the challenges of bringing a new material to market within the current derogation timeframe is graphene. It was discovered in 2004, and its potential to replace metal in various applications was recognized shortly thereafter. Despite the EU committing 1 billion Euros in 2013 to speed up the development process with the program "Graphene Flagship", as of 2022, the material has yet to successfully be scaled up to an economically feasible commercial level.[11,12]

c. The other concern Zeus has related to the derogation timeframe is regarding the use of processing aides in PTFE. Essentially, 5a excludes any derogation for processing aids in certain fluoropolymers. "This derogation does not apply to the production of PTFE, PVDF, and FKM". While it is true that some PTFE can be made without processing aides, these grades are not suitable for use in producing the types of products Zeus manufactures.

Zeus requires PTFE fine powder made from emulsion polymerization. Currently, there are no commercially available grades of PTFE fine powder made via emulsion polymerization that do not use a fluoro-based polymerization aid. PTFE powders made from suspension without using processing aids are commercially available, but they cannot make the smaller tubing needed in the applications mentioned above. The inherent differences in particle shape due to the different formulations means the materials do not process equivalently. This derogation exception means that the resin for certain tubing sizes cannot be manufactured in the EU, which would push that demand for that resin to other manufacturer, who may or may not have the capacity to meet that demand.

i. The development time for an alternative processing aid is likely to be longer than the proposed 18 months EiF. Samples of PTFE made with a non-fluorinated surfactant have been trialed and found to be unsuitable to replace the current product made with fluorinated surfactants, due the high pressure it creates during processing. In addition to safety issues running at increased pressures, it impacts other critical extruded properties such as surface smoothness, mechanical properties, clarity, and tolerances. No other experimental resins are available, even as samples, from other resin manufactures. As far as acceptance/suitability in the supply chain, a non-fluorinated surfactant produced PTFE has not gone beyond the raw material supplier.

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