W. L. Gore & Associates' Comments on Dossier Submitters´ Draft EU REACH restriction on PFAS

Request for Derogation:
Materials used in the Production of Fluoropolymers

Public consultation

May 2023

Summary

Gore appreciates the opportunity offered by the public consultation process to provide comments on the Proposal for a Restriction of Per- and polyfluoroalkyl substances (PFASs) (hereinafter '**Restriction Proposal**').

Gore fully supports the stated objective of the Restriction Proposal to replace the use of fluorinated polymer processing aids (hereinafter also referred to as "PPAs"), where possible. However, currently available alternatives are not technically feasible for a large range of high technical applications. Besides fluorinated processing aids, other fluorinated materials and in particular monomers are needed for the manufacture of polymeric PFAS.

Based on our extensive knowledge of the PTFE fine powder resins available on the market and the requirements of the specific PTFE resin properties necessary to produce expanded PTFE articles with demanding performance requirements, W. L. Gore & Associates would like to request that paragraph 5.a. be amended to read:

> **"5.a. PFAS in the production of polymeric PFAS intended for uses where a derogation under this restriction applies."**

The rationale for the recommended changes includes:

1. The current state of **non-fluorinated polymer processing aid technology cannot produce all the necessary grades of fine powder PTFE**, including those necessary for many end-uses currently recommended for derogations. In addition to not meeting minimum performance requirements, currently available PTFE resin prototypes made with non-fluorinated polymer processing aids contain elevated levels of low molecular weight fluorinated residuals.
2. In addition to the references cited by the dossier submitters regarding PTFE that are addressed below, **there is no evidence cited to conclude that other fluoropolymer resins like FEP, PFA, and ETFE can be made without fluorinated PPA's and transitioned into products within 6.5 years.**
3. Real-world experience has demonstrated that it takes **greater than 7 years** to fully transition complex fluoropolymer-based products from fluoropolymer resins made with one polymerisation aid to fluoropolymer resins made using a new polymerisation aid, **after the new polymerisation aid was demonstrated to be technically feasible**. Non-fluorinated PPA technology to make fine powder PTFE has not yet reached that initial technical feasibility point, and the timeline for such advancement is not known.
4. We would also like to request clarification in the restriction to **explicitly allow the continued use of the PFAS necessary to produce and**

process fluoropolymers needed for derogated end uses. The inclusion of paragraph 5.a. in the initial dossier makes it unclear whether parties would be able to use other PFAS as raw materials or manufacturing aids besides polymer processing aids to produce finished products in the EU. The ability to manufacture fluoropolymers in the EU must be preserved, including the ability to produce or procure PFAS polymerization processing aids, raw materials (including monomers), and other manufacturing aids (such as processing solvents) necessary for the production of fluoropolymers. Otherwise, the fluoropolymers needed for the derogated uses would have to be imported into the EU, and as more fully described herein, Gore's ability to secure the fluoropolymers for its uses would not be possible.

1. About W. L. Gore & Associates

1.1. Background

W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Since 1958, Gore has solved complex technical challenges in demanding environments — from outer space to the world's highest peaks to the inner workings of the human body. With more than 12000 Associates and a strong, team-oriented culture, Gore generates global annual revenues of $4,5 billion. In Europe, Gore employs around 2300 Associates in manufacturing plants, sales offices and service centers.

Gore utilizes the unique properties of PTFE and other fluoromaterials to invent valuable products, from implantable medical devices such as vascular grafts and stents; technical applications such as components for aircraft, automobiles, mobile phones and computers; protective apparel for firefighters and first responders; high performance outerwear; to filters and seals that reduce emissions from power generation and industrial processes.

1.2. Gore has deep processing knowledge using many grades of fine powder PTFE

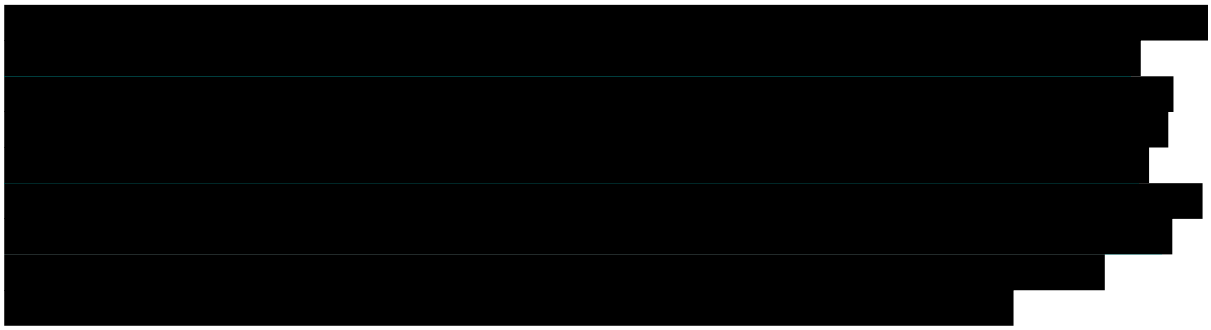
W. L. Gore & Associates is primarily a processor of fine powder PTFE resin. We have over 65 years of experience processing PTFE fine powder resin into a variety of articles and are recognized as the global leader in expanded PTFE technologies.

Over that period of time, Gore has sourced resin from multiple suppliers and developed an extensive understanding of how the characteristics of PTFE impact the ability to process it into finished articles. Furthermore, Gore has collaborated with many fluoropolymer suppliers to advance their technology over this time period.

Gore utilizes more than [redacted] distinct grades of fine powder PTFE resin to meet the unique needs of a wide variety of end uses. Different grades of PTFE are not chemically different, but have different material properties, such as [redacted], which impact conditions under which the resin can be further processed and the characteristics of the final products that use them. Many end use products require distinct combinations of properties from the fluoropolymer components, such as strength, thinness, porosity, and flexibility to name a few, which are derived from the physical form of a fluoropolymer article. These grades are not interchangeable and, in some cases, have been custom formulated to enable specific properties of finished articles. Using so many different grades of PTFE resin adds cost and complexity to Gore's supply chain, therefore it is only done because it is necessary to achieve properties for demanding end uses.

1.3. Gore has direct knowledge of small-scale fluoropolymer manufacturing

Gore operates a small polymerization facility in Gendorf, Germany. This facility was built to enable the production of small batches of custom grades of PTFE and other fluoropolymer resins which are not available from commercial suppliers, but are required to meet challenging performance requirements for a variety of end uses, including implantable medical devices and multiple other end uses which have been proposed for a derogation by the dossier submitters.



2. The Three Distinct Types of PTFE

There are three main types of PTFE: Granular PTFE, PTFE dispersions, and fine powder PTFE. PTFE dispersions and fine powder PTFE which are manufactured by process of emulsion polymerization require polymer processing aids during polymerization, while granular PTFE manufactured by way of suspension polymerization does not.

All of these forms retain the fundamental material properties of PTFE, such as chemical resistance, temperature resistance, UV resistance, biocompatibility and low coefficient of friction. However, the three types of PTFE are not interchangeable. Each one is suitable for different kinds of processing which are distinct from one type to the next. The selection criteria differ for each PTFE type and careful consideration is made for selection based on the needed form, performance, and processing requirements.

Fine powder PTFE is the most versatile in terms of the article forms that are possible. Most notably, only this form of PTFE can be expanded, which enables physical properties that are not achievable with other forms of PTFE. Expanded PTFE can be made into high strength tapes, membranes, rods, fibers and many other forms. These forms can be designed to have specific properties of thinness, strength, precisely controlled pore size, flex durability, and electrical insulative properties. When these physical properties are achievable in combination with the unique properties which are inherent to PTFE, as cited above, numerous combinations of properties are realized that are not available from other materials. It is these combinations of properties which make fluoropolymer-based articles suitable for so many demanding applications and likewise makes finding alternatives so challenging.

PTFE dispersion is used in particular for coatings and film castings and its production is also an intermediate step to producing fine powder PTFE resin.

Granular PTFE is suited for compression molding applications and can often be found used as liners for pipes carrying aggressive chemicals or as bearings and other friction reducing applications.

3. <u>The current state of non-fluorinated polymer processing aid technology cannot produce all the necessary grades of fine powder PTFE.</u>

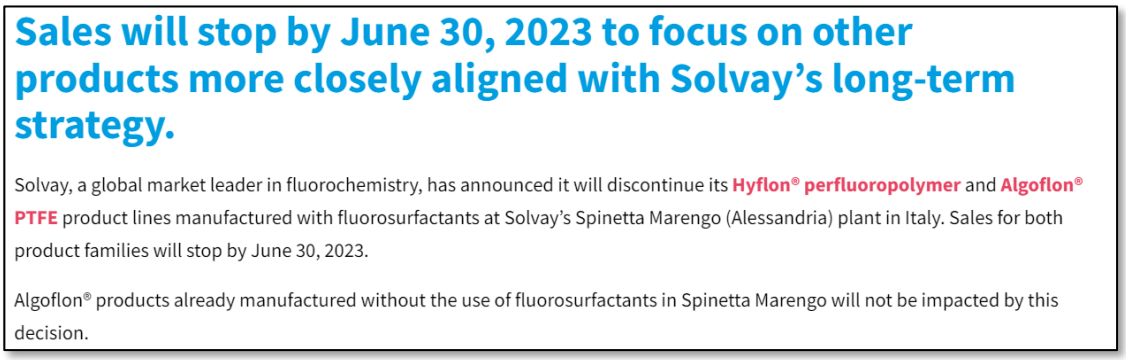
3.1. Evidence cited by Dossier Submitters

The dossier submitters cited five references as evidence that PTFE, PVDF and FKM could be made without fluorinated polymer processing aids currently and therefore no derogation was warranted. Only three of these references are related to PTFE. Gore would like to take this opportunity to explain that **not all grades of PTFE can be manufactured without fluorinated processing aids**. The conclusion that all types of PTFE can be manufactured with non-fluorinated processing aids is neither supported by the references in the Restriction Proposal or other announcements of manufacturers, nor Gore's direct experience with actively seeking fine powder PTFE resins made without fluorinated polymer processing aids from all known global suppliers for the last eight years. In Annex E, Section E.2.1.2.1, the dossier submitters acknowledge that it is not clear whether all PTFE can be produced without fluorinated polymerization aids.

3.1.1. Gore's understanding of announcement from Solvay

The first reference cited by the dossier submitters was from Solvay from June 2022[1]. This announcement is not evidence of a technological breakthrough in the feasibility of producing fine powder PTFE without the use of polymer processing aids. It is an announcement of a business decision to cease production of specific types of PTFE which still required fluorinated PPAs to produce them, as described in the reference below, also from June 2022. Note that the ALGOFLON® products reference below are not fine powder PTFE.

[1] https://www.solvay.com/en/article/eliminating-pfas



Sales will stop by June 30, 2023 to focus on other products more closely aligned with Solvay's long-term strategy.

Solvay, a global market leader in fluorochemistry, has announced it will discontinue its **Hyflon® perfluoropolymer** and **Algoflon® PTFE** product lines manufactured with fluorosurfactants at Solvay's Spinetta Marengo (Alessandria) plant in Italy. Sales for both product families will stop by June 30, 2023.

Algoflon® products already manufactured without the use of fluorosurfactants in Spinetta Marengo will not be impacted by this decision.

Source: https://www.solvay.com/en/news/solvay-discontinue-algoflon-ptfe-and-hyflon-perfluoropolymers-made-italy

3.1.2. The announcement from Gujarat Fluorochemicals Limited is not applicable to many grades of fine powder PTFE

The reference cited an announcement from Gujarat Fluorochemicals Limited (GFL) as strong evidence that PTFE can be made without fluorinated processing aids and a derogation is not necessary. While this statement may be true for the grades produced by a specific company, it is incorrect to conclude from this announcement that all fine powder PTFE can be made without the use of fluorinated processing aids. The range of fine powder PTFE grades that the cited technology can produce does not include most of the grades that are commercially available, and specifically not for many of the technically demanding applications which have been recommended for derogations.

The type of technology referenced in this announcement has been evaluated by multiple PTFE resin manufacturers, and in each case demonstrated to not be capable of producing the fine powder grades required for many applications and in particular expanded PTFE applications. Gore has also observed significant amounts of low molecular weight fluorinated residuals in resins made using this technology, as further described below.

3.1.3. Sales et al. Paper

The dossier submitters also referenced a paper by Sales et al.[2] as further rationale for both the current state of non-fluorinated PPA and the timing to develop additional advancements.

- Firstly, the paper states that new manufacturing processes without fluorinated PPA's result in technically equivalent fluoropolymer grades with no presence of unintended **fluorinated** by-products. To the contrary, as shown in the summary of our alternative assessment work spanning 8 years in Appendix 2, multiple evaluations from

[2] Sales J., Hernández F., Kapoor D., and van den Noort M. (2022): Fluoropolymers: The Safe Science That Society Needs. International Chemical Regulatory and Law Review 5 (1), 13-23. https://icrl.lexxion.eu/data/article/18603/pdf/icrl_2022_01-006.pdf (last accessed 16.02.2023)

multiple suppliers offering prototype fine powder PTFE resins have shown:
None of the available PTFE resins made without fluorinated PPA's are technically equivalent to the grades of fine powder resin needed to make most of our expanded PTFE intermediates and therefore products for many end use applications. **Not only are they not equivalent, but they do not meet the minimum requirements** for properties such as [redacted]. Our testing of multiple samples from multiple suppliers have all demonstrated that **the use of currently known non-fluorinated PPA results in the generation of significant levels of low molecular weight fluorinated residuals** in the fine powder PTFE resin. This appears to be occurring at a much higher level than when using fluorinated PPAs and also generates new compounds, including sulfonated chemistries, which are not present in fine powder PTFE made with fluorinated PPAs.

- Secondly, the authors suggest that within 10 years it will be possible to make all fluoropolymers without fluorinated PPAs. While we will continue to work with fluoropolymer suppliers to pursue this goal, currently it is only speculation, and the authors acknowledge the level of uncertainty. Furthermore, as shown in Section 4 below, the demonstration of technical feasibility of converting a fluoropolymer to a non-fluorinated PPA is one step in the development process, **but will require many additional years to develop, qualify and commercialize products made using the new resins.**

While we agree with many of the other conclusions of the paper which are supported by data, our testing and experience directly contradicts the conclusions about the current state of technology regarding non-fluorinated PPAs and the timing for substitution which are not supported by any data in the paper or elsewhere.

3.2. Gore's efforts to evaluate the technical feasibility of PTFE fine powder made without fluorinated processing aids

3.2.1. Throughout Gore's history, the company has continually evaluated new developments in PTFE resin which is supported by the high number of grades available on the market and in use across our product portfolio today. Further in 2016, Gore initiated a substantial technical project to seek out and evaluate PTFE resins which did not use any of the current fluorinated polymer processing aids. In short, [redacted], we have still **not** identified such a fine powder PTFE resin that

is technically feasible for any of our products without using a fluorinated polymer processing aid. Substituting a non-fluorinated surfactant for those used in industry today present a host of challenges that are not obvious.

With multiple approaches and significant investment, Gore and its suppliers have not yet been able to produce PTFE that meets the requirements of the majority of grades of commercially available fine powder on the market. The introduction of a new surfactant to the process adds unintended consequences, such as the generation of unwanted residuals in the polymerization process, or leaving unwanted non-PTFE materials in the fine powder that can disrupt downstream processing, add industrial hygiene challenges, add potential environmental impact, or render the material unfit for certain applications.

A timeline summary of the efforts to find a technically feasible PTFE fine powder made without fluorinated processing aids is shown in **Appendix 2**.

Gore is supportive of further development of PTFE fine powder made without fluorinated processing aids, and will continue to evaluate all samples available to us and invest in process development to adopt a new PTFE resins that meets our performance needs.

The summary of our alternative assessment is listed in **Appendix 1**.

4. Some other fluoropolymers, like FEP, PFA, ETFE, also require fluorinated PPAs

4.1. A 6.5-year transition is not sufficient for other fluoropolymers that use fluorinated PPA's today

The challenges highlighted above apply equally to other fluoropolymers like FEP, PFA, ETFE which require the use of fluorinated PPAs. The Sales et al. paper referenced by the dossier submitters acknowledges in the table on page 20 that these fluoropolymers and others require the use of fluorinated PPAs and makes no claims about the ability to eliminate their use. **There is no evidence presented in the paper or otherwise cited to conclude that these resins can be made without fluorinated PPA's within 6.5 years.** The experiences of Gore and fluoropolymer manufacturers over the last 8 years for PTFE would indicate it is expected to take longer than 6.5 years to develop the technology and then transition products to the new resins.

4.2. Statement from fluoropolymer industry association

The ongoing technical challenge is confirmed by the Fluoropolymer Products Group (FPG) of the business association Plastics Europe in their March 2023 statement on the restriction proposal where they state: "…it may be necessary to continue using fluorinated polymerization aids until non-PFAS polymerization aids are developed. Therefore, relevant derogations for fluoropolymers should be provided."[3] FPG represents all EU manufacturers of fluoropolymers.

5. Timeline for Substitution

5.1. Raw material transition requires development time for the new resin and development time for technically demanding products which use that resin.

Gore also has direct experience that highlights the significant amount of time needed to develop, qualify, and commercialize technically demanding products which can only occur after a new resin is commercially available.

We would like to share our experience which would inform a reasonable transition period once such a new resin was actually developed. Gore's experience was in response to the eight global fluoropolymer suppliers' participation in the U.S, Environmental Protection Agency's Voluntary Stewardship Program in 2006. This was when PTFE suppliers transitioned from their original polymer processing aid (PFOA) to the currently utilized fluorinated PPAs. Due to that change by our suppliers, it was necessary to convert our entire product portfolio to using new grades of fine powder PTFE resins.

5.2. Actual data on a similar, but simpler, fine powder PTFE resin transition

Our experience has shown that it took more than 7 years to transition the majority of our products from PTFE resins that used PFOA as a polymer processing aid to new PTFE resins that used different polymer processing aids. This timeline is a useful indicator for such a future transition; however it is important to note that a process change to using a non-fluorinated processing aid will be much more challenging and brings greater technical uncertainties than changing from one fluorinated PPA to another.

The first drum of new resin was processed at Gore in January 2007. We completed the majority of our transitions by the end of 2014 but did not completely convert 100% of products until 2019. [redacted] so our experience may be more optimistic than an industry average for such a transition.

[3]https://fluoropolymers.plasticseurope.org/application/files/8716/7991/0281/21_March_FPG_Statement_on_the_PFAS_REACH_restriction_report.pdf

A transition like this is much more complicated than simply purchasing from a new source and continuing production. It required material characterization testing, prototyping, and process development to make the PTFE components used in hundreds of complex products. Once the components were made, there were requirements for similar characterization, prototyping and process development to convert these components into finished products. When finished products were deemed to be suitable, many required extensive change notification, evaluation and qualification processes by end users. These uses include highly regulated and high reliability-oriented applications such as medical devices, pharmaceutical manufacturing, automotive, aerospace, chemical processing and semiconductor manufacturing applications, as examples.

The transition process was not linear or straightforward. There were numerous cases that required iteration and troubleshooting to achieve the performance requirements for such demanding applications. [redacted]

Change management and requalification requirements in many industries have become even more complex over the past decade, so there is no expectation that such a change would take less time now. Furthermore, a change from current processing aids to a non-fluorinated processing aid would be a more significant technical change than the prior example, leading to even more uncertainty about the timeline. With a more significant change to the manufacturing process for fluoropolymers, it is likely that more end product re-qualification and assessment would be required. This adds complexity for a single product, but more importantly has the potential to cause significant disruptions as a number of companies and industries all have a simultaneous increased demand for engineering, analytical and regulatory agency services all at once.

5.3. Time Estimated for Substitution to non-fluorinated PPA

As indicated above, substituting a new non-fluorinated polymer processing aid involves identification of a technically feasible solution followed by significant work on resin development, product development using that resin and qualification in end use products and the associated certification, regulatory approval and supply chain transition. We do not have a way to estimate the first step due to the current state of the technology but can estimate the subsequent steps based on the transition from PFOA to alternate PPA's and updated transition time which can be found in various use-based derogation requests. Our assessment indicates a transition time for end products of **8-20 years <u>after</u> a non-fluorinated polymerization aid has been demonstrated to be technically feasible in the production of PTFE, which has not yet occurred.**

Table 1: Substitution steps

Steps for substitution	What activities does this step entail?	Time required for step
1. Identification and development of new PPA	Developing a new non-fluorinated polymer processing aid. Ensuring new PPA has an equivalent or better hazard profile, in addition to technical feasibility.	**Unknown**
2. Resin processing development – R&D to develop new processes which use new resin to make articles which meet performance requirements.	Pilot scale and production scale process development. Development of specific resin grades to meet range of requirements. Confirm adequacy of industrial hygiene and emissions controls.	2-3 years
3. Product development – this involves an iterative stage of R&D, (re)formulation and lab testing	Product Development, testing in lab, and pilot scale, including modification of polymer to ensure performance needs. Prototyping and testing and process development for hundreds of distinct products.	2-5 years
4. Qualification and/or Validation – involves testing and validation with customers and/or external testers	Validation by OEM's and end users to be applicable, in hundreds of end use situations	1-3 years
5. Certification – this may be required, and could involve review and testing by standard setters and/or regulators	Certification by test institutes to national and international standards, or approval by relevant regulatory agencies.	1-4 years

6. Production – this would involve implementing the manufacturing plan for the alternative, including a possible pilot phase, regulatory approval, and modifications to the production line.	**Set up production, manufacturing capabilities. Conduct transition throughout the supply chain.**	**2-5 years**
Total	All steps	**Unknown** + 8-20 years

Appendix 1. Summary of Alternative Assessment

R&D activities conducted	Our R&D activities since 2016 have focused on an assessment of fine powder PTFE resins made without the use of fluorinated polymer processing aids. To date, we have invested approximately [redacted] combined with significantly more money invested by our suppliers. We have not yet identified any resin that meets the minimum performance requirements for processing and end use. See Section 5.2 and Appendix 2 for a more detailed description of activities.	
Performance requirements	Fine powder PTFE is the only form of PTFE that can be expanded, which enables physical properties that are not achievable with other forms of PTFE. Expanded PTFE can be made into high strength tapes, membranes, rods, fibers and many other forms. These forms can be designed to have specific properties of thinness, strength, precisely controlled pore size, flex durability, and electrical insulative properties. It is these combinations of properties in combination with the properties of PTFE itself which make fluoropolymer-based articles suitable for so many demanding applications.	
Products on market without use of fluoropolymers/ fluoromaterials	None of the available PTFE resins made without fluorinated PPA's are technically equivalent to the grades of fine powder resin needed to make most of our expanded PTFE intermediates and therefore products for many end use applications. The use of currently known non-fluorinated PPA results in the generation of significant levels of low molecular weight fluorinated residuals.	
Alternative cited in the Restriction Proposal and performance of such materials	Granular PTFE	Granular PTFE cannot be used as an alternative because it is suitable for different kinds of processing than fine powder PTFE; in particular, it cannot be expanded. Expanded PTFE is an essential aspect of the PTFE forms used by Gore and others to make the article forms necessary for many end uses include many proposed for derogations. For example, granular PTFE cannot be made into strong fibers or thin, strong membranes, nor can it be made microporous.

	Sales et al. 2022 paper	None of the available PTFE resins made without fluorinated PPA's are technically equivalent to the grades of fine powder resin needed to make most of our expanded PTFE intermediates and therefore products for many end use applications. Contrary to the statement in the paper regarding unintended fluorinated by-products, the use of currently known non-fluorinated PPA results in the generation of significant levels of low molecular weight fluorinated residuals. There is also no evidence presented, and no information otherwise known to Gore, to conclude that FEP, PFA, ETFE and some other fluoropolymer resins can made without fluorinated PPA's within 6.5 years.
	Chemours press release on fluoroelastomers	These resins are not relevant to for PTFE products and only relates to fluorotelomers. While the ability of Chemours to produce the referenced product without the use of fluorinated PPA is a notable technology advancement, it is indicative only of the willingness of industry to continue to invest in research and development in this area. It is not an indicator of likely success of being able to manufacture all needed grades of PTFE without the use of fluorinated PPA. See Section 5.2 and Appendix 2 for a more detailed description of R&D investments to-date at Gore.
	Arkema Press Release on PVDF	These resins are not relevant for PTFE and only relates to PVDF. While the ability of Arkema to produce the referenced product without the use of fluorinated PPA is a notable technology advancement, it is indicative only of the willingness of industry to continue to invest in research and

		development in this area. It is not an indicator of likely success of being able to manufacture all needed grades of PTFE without the use of fluorinated PPA. See Section 5.2 and Appendix 2 for a more detailed description of R&D investments to-date at Gore.
	Chemical Watch article on Gujarat Fluorochemicals Ltd.	These PTFE emulsion resins are not relevant to expanded PTFE products. While the ability of Gujarat to produce the referenced product without the use of fluorinated PPA is a notable technology advancement, it is indicative only of the willingness of industry to continue to invest in research and development in this area. It is not an indicator of likely success of being able to manufacture all needed grades of PTFE without the use of fluorinated PPA. See Section 5.2 and Appendix 2 for a more detailed description of R&D investments to-date at Gore.
	Solvay Press Release	In the press release, the product ALGOFLON® is refereced which is not a fine powder PTFE. Additionally, Solvay announced a market exit from PTFE fine powder products where they were unable to identify a technically feasible alternative to using fluorinated polymer processing aids.
Risk assessment for alternative materials	In addition to failure to meet the technical performance requirements, R&D conducted by Gore to-date suggests the possibility that generation of unintended fluorinated oligomers or other low molecular weight fluorinated residuals can be formed during manufacture of fine powder PTFE without the use of fluorinated PPA, which negatively impact the quality of the PTFE resin and need to be removed and treated/destroyed prior to further processing of the PTFE to limit the potential for release during downstream polymer processing operations.	

Appendix 2. Summary Timeline of Alternative Fine Powder PTFE Resin Assessment

Listed below is a summary of the work, in order to demonstrate the level of activity and diligence to identify and evaluate technical feasibility of the grades of PTFE required to make our products. Work continues, but thus far, the evaluation has not identified a viable candidate.

[redacted]

To date, we have not identified any resin that resolves the above issues of meeting the minimum requirements for the end use, having low unintentional fluorinated residuals and enabling processability into finished articles.