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

Public consultation

Request for Derogation: Food Contact Materials (including vents and filters) in Industrial Applications

August 2023

I. Summary of Contents

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

With this statement, Gore will provide information to support a time unlimited derogation for fluoropolymers used in food contact materials (Paragraph 6a), including vents and filters, in industrial applications. The current proposal for this sub-use is to restrict their use 6.5-years after EiF.

The conclusions from our statement are summarized as follows:

- The unique combination of fluoropolymer properties provides critical functionality in industrial applications. In the industrial food contact application where aggressive cleaning and sterilization are required, fluoropolymer properties such as chemical and thermal resistance, low levels of extractables, and a strong microporous structure are important to ensure filter function and protection from contaminants.
- There are no existing alternative materials that meet the stringent performance requirements and Gore is not aware of potential materials that could meet these requirements in the foreseeable future.
- Without a derogation for fluoropolymers in this application, the safety and efficacy of food and feed production and the stability of their global supply will be compromised.

II. Derogation Request

Gore respectfully recommends the following edits to the derogation in Column 2, paragraph 6a:

6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers or perfluoropolyethers for use in:

a. food contact materials for the purpose of industrial and professional food and feed production ~~until 6.5 years after EiF~~

- **in industrial applications (time unlimited)**
- **in packaging and other applications until 6.5 years after EiF**

III. Background

a. Description of the End Use

Equipment used in food processing includes components and systems used to cook, handle, package, prepare, and store food. This equipment can be designed to handle solid, semi-solid, and liquid products. However, the optimal design depends on the requirements of the particular food processing application.[1] In many process steps, it is necessary to vent or filter liquids or gases. Venting may be necessary to equalise pressure due to temperature changes, steam generation, or as by-products from chemical or biological processes. Filtration may also be necessary to separate materials or remove potential contaminants.

[1] https://www.plantautomation-technology.com/articles/types-of-food-processing-equipment

PTFE membranes (Figure 1, left) are used in vents and filters (Figure 1, right) for food and beverage production applications because their microstructure enables high air and liquid flow through the membrane, but prevents bacteria, viruses, and particles from contaminating the food product.

Figure 1. GORE® Microfiltration Media (left) and typical filter cartridges (right)

PTFE meets the criteria for Polymers of Low Concern (PLCs), under the definition provided by the Organisation for Economic Cooperation and Development (OECD) Expert Group on Polymers.

Table 1. Typical PFAS Materials used in Filtration Media for Food and Feed Applications

Product	Type of PFAS	CAS Number	Is this a PLC?
GORE® Microfiltration Media	PTFE	9002-84-0	Yes

b. References in Restriction Proposal

In Gore's examination of the Restriction Proposal, the following key references to filters used in food contact applications were found:

- Manufacture and Uses A.3.4.1.2. Industrial Applications (p. 40)

While many of the products cited in Industrial Applications use PFAS for their non-stick properties, it was acknowledged that PFAS are also used for sealing pressure bearing equipment and **as filters to capture contaminants**. These products enhance productivity by preventing clotting and enable hygienic conditions, for example, by enabling steam sterilization of food processing equipment.

- Impact Assessment E.2.3.1. Baseline (p. 141)

"For industrial applications of PFAS in the sector, some growth in the market for PFASs can be expected, particularly on the component side (rather than coatings) given stricter legislation on food quality and the use of more severe conditions for cleaning and sterilization of food processing equipment."

This statement acknowledges that PFAS materials are required for higher food quality by enabling better cleaning and sterilization of equipment.

- Impact Assessment E.2.3.2.6. Substitution Potential (p. 152)

“For Industrial applications, such as the use of fluoropolymers in seals, tubing etc. in production equipment where components need to address stresses from, for example, high temperatures and pressures and strong cleaning agents, it is concluded that there is sufficiently strong evidence for low substitution potential, and a derogation is therefore considered.”

This statement acknowledges the need for derogation; however, this document will demonstrate that there are no existing alternatives and, therefore, 6.5 years from EiF is not sufficient to bring a replacement to market.

c. Regulations

To ensure a high level of food safety, all food contact materials must comply with Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food when placed on the European market. In addition to this Regulation, all food contact materials must be manufactured in accordance with Good Manufacturing Practices (GMP, Commission Regulation (EC) No 2023/2006), and specific Union legislation on certain materials, including plastics (EU) No 10/2011, as well as with National legislation on other materials.[2] These regulations apply to all food contact materials including packaging materials, kitchen utensils and equipment in the food processing industry.

This means that food must be processed with a validated method that does not endanger human health, bring about an unacceptable change in the composition of the food, or bring about a deterioration in the organoleptic characteristics. Changes to the food contact materials used in the manufacturing process must be revalidated to demonstrate it is compliant to EU Food Contact requirements.

IV. Need and Justification for Derogation

a. Performance Requirements

As noted above, food contact material requirements are unique for each product and process. However, many of the requirements for filters used in food and feed production are similar to the requirements for filters used for the processing of human and veterinary medicinal products. These include the following:

Table 2. Performance Requirements for Filtration in Food and Feed Applications

Requirement	Description
Low levels of extractables	Extractables are compounds that can be removed from a material under aggressive conditions, which include solvent, time, and temperature. The test conditions and stimulants are determined by the food type (aqueous, acidic, alcoholic, dry and fatty) and exposure times. Low levels of extractables are a factor in the selection and qualification of materials used for food processing. Non-fluoropolymer materials are often

[2] https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials_en

	inadequate for meeting process and product design requirements because they either contain impurities or decompose in the presence of processing fluids which both may lead to contamination of food/feed. Extractables measurement is an industry requirement that is measured by the European Commission's Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food sets the specific provisions for certain materials and articles as well as the compliance testing required. • Overall Migration Limit (OML) measures for inertness of the material and aggregates the sum of all the non-volatile substances that migrate from the FCM into food. The OML threshold is 10mg/dm^2. • Specific Migration Limit (SML) quantifies the migration of one specific substance into food and is unique to that specific substance. That limit is set by EFSA and is specified in the Union list of the Regulation. • Maximum permitted quantity (QMA) applies to the residual content of a substance in the FCM and is also specified in the regulation for those specific substances.
Chemical and thermal resistance	The material must be highly resistant to aggressive chemicals, such as strong acids and bases, polar and non-polar solvents, and reactive gases that are used to clean and sterilize equipment. The material may not degrade in the presence of high temperatures, which are used to sterilize equipment. For example, references indicate steam sterilization temperatures up to 140°C. [3]
Contamination Prevention	Filters used in food processing must allow air and fluid flow while capturing particles, bacteria, and viruses to ensure food quality. Air hygiene and air quality is essential in food production and therefore high-efficiency filtration and media solutions are necessary in industrial food production process.
High strength and stability	The material has excellent strength and durability, even after exposure to aggressive chemicals and high temperatures, that enable it to withstand exposure to mechanical stresses, like pressure surges.

b. Alternative Assessment

Impact Assessment E.2.3.2.3 Alternatives (p. 149) discusses the wide variety of applications in this sub-use with differing potentials and options for substitution. It suggests that the selection of alternatives consider all performance requirements, such as temperature range, pressure exposure, and exposure to cleaning agents.

Filtration is a segment of the food contact market that requires the performance characteristics uniquely enabled by fluoropolymers. The products described in Section III.a meet customer's performance specifications that cannot be met by other materials. Many of our customers have

[3] STERILIZATION OF FOODS, Editor(s): Benjamin Caballero, Encyclopedia of Food Sciences and Nutrition (Second Edition), Academic Press, 2003, Pages 5593-5603

confirmed that they have investigated alternative materials but have been unable to identify feasible options. Fluoropolymers are generally more expensive than other polymers, so customers have an economic incentive to use other materials, when it is possible to meet their performance requirements.

Based upon Gore's nearly 50 years of expertise and deep knowledge of material science, established polymers cannot meet the vital functions needed to be suitable alternatives to fluoropolymers in the food contact market. Gore continually follows external developments of new materials while also pursuing an R&D program to develop novel materials that meet market needs. However, no materials that can replace the need for fluoropolymers in these applications have been identified. Alternative materials for filtration applications of food/feed industry are also not mentioned in the Restriction Proposal.

i) Contamination Prevention

Of the limited number of polymers that can be used in food contact applications, only a limited number can be processed into microporous structures that allow air and fluid flow while capturing particles, bacteria, and viruses. PTFE can be expanded to form customized porous structures to meet specific filtration and venting requirements. Non-fluorinated materials that can be made into microporous membrane have limitations, not only in their ability to meet the performance requirements describe above, but also in their ability to meet specific filtration requirements.

ii) Low Levels of Extractables

Unlike alternative materials, fluoropolymers do not require the use of additives (e.g., antioxidants, slip/mold release agents, UV inhibitors, plasticizers) to enhance their chemical, physical, and mechanical properties.

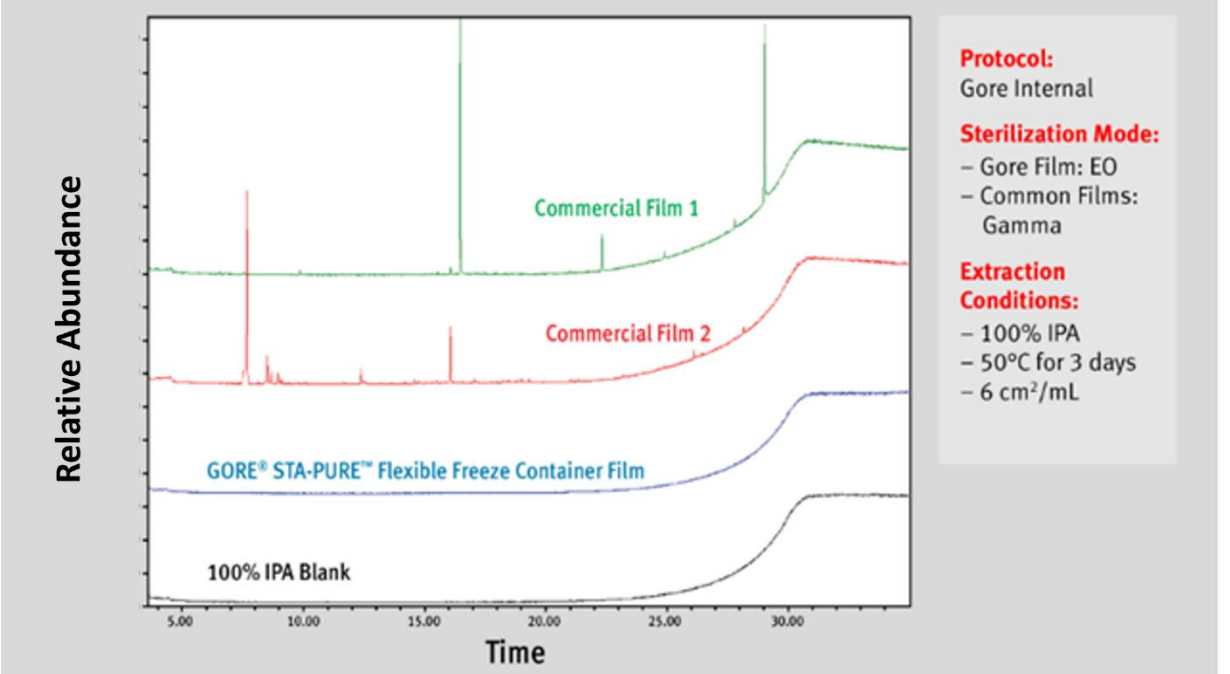
Figure 2, below, shows the stacked extractables comparison[4] of a fluoropolymer film (labeled as GORE® STA-PURE™ Flexible Freeze Container Film) to potential alternative materials:

- Commercial Film 1 [redacted]
- Commercial Film 2 [redacted]

Even though this is a different product than the GORE® Microfiltration Media covered by this derogation request, the data presented below are representative also for GORE® Microfiltration Media due to the comparable material composition of the products. The peaks seen in the Commercial Film 1 and Commercial Film 2 curves are due to impurities that have been extracted from the films. In contrast, the fluoropolymer film curve has the same shape as the control blank, indicating that no impurities were extracted from the material.

[4] Test performed according to the BioPhorum Operations Group Ltd "Best Practice Guide for Evaluating Leachables Risk from Polymeric Single-Use Systems used in Biopharmaceutical Manufacturing," July 2021 (https://www.biophorum.com/download/best-practices-guide-for-evaluating-leachables-risk-from-polymeric-single-use-systems/)

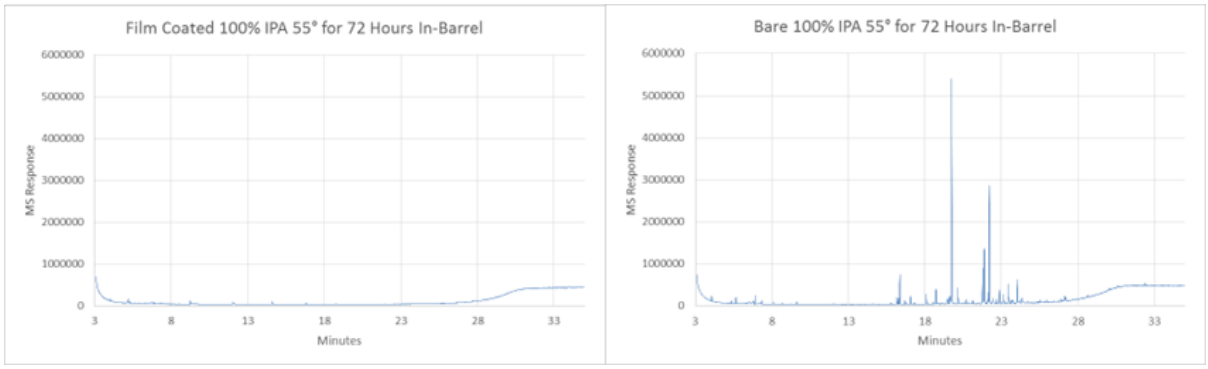
Figure 2. Extractables Comparison between Alternative Solutions and GORE STA-PURE® Flexible Freeze Container Film



Test Details: Following the recommended sterilization protocols for each, a 6cm²/mL sample of Gore film and commonly-used films were tested in 100% IPA at 50°C for 3 days. The impurities were measured using GC/MS.

Another example of low extractables can be seen in the comparison of the GORE® IMPROJECT® Plunger for Prefilled Syringes (rubber plunger with fluoropolymer barrier film) versus an uncoated rubber plunger. Again, as shown in Figure 3, the Gore fluoropolymer has no peaks, indicating that no impurities were extracted from the material, while the rubber plunger shows impurities that have been extracted by the solvent.

Figure 3. Extractables Comparison between Plunger with Fluoropolymer Barrier Film and Uncoated Rubber Plunger



Fluoropolymers are uniquely able to meet the requirements for low extractables in combination with other typical requirements for this sub-use.

iii) Chemical Resistance

Fluoropolymers, like PTFE, are chemically inert and, therefore, have a high degree of resistance to fluids used in food processing. This can be seen by analyzing the Labware Chemical Resistance Table[5], which assesses the effects of over 200 chemicals on common plastics used in the industry.

[5] https://tools.thermofisher.com/content/sfs/brochures/D20480.pdf.

PTFE shows no damage after 30 days of constant exposure to nearly all chemicals evaluated. Resistance to these chemicals enables fluoropolymers to maintain their structural integrity, which prevents the generation of contaminates and particulates and extends the usable life of the products. Materials like PE and PET show relatively poor resistance to a range chemicals.

Fluoropolymers are uniquely resistant to the broad range of chemicals that are relevant to this sub-use.

iv) Thermal Resistance

PTFE has maximum operating temperature of 260°C. Potential alternatives such as PE and PET have maximum operating temperatures at or below 110°C,[6] which is insufficient for the 140°C required by steam sterilization.[7]

PTFE is the only microporous material that is thermally resistant across the range of processing and sterilization temperatures that are relevant to this end use.

c. Timeline

Without a derogation recommendation for filtration applications, the use of PFAS-based components is proposed to be banned 6.5 years after EiF. We have demonstrated that there are no existing alternative materials that meet the stringent performance requirements, and we are not aware of potential materials that could meet these requirements in the future. Such a material could not be identified in the Restriction Proposal either. This section underlines the timeframe needed in the uncertain case that a new material would be discovered or invented for this application.

Due to the unique material properties described in the Alternatives Assessment, Gore, and other key actors in the supply chain, do not believe that alternative materials can be developed to replace fluoropolymers in these applications. This first step involves discovery, for which a specific timeline cannot be predicted.

Examples from the past, show that the time span to develop new materials can vary significantly. For example, the development of acrylic polymer took several decades. The process from the first synthesis of acrylic acid to the introduction of the commercial polymer, was an 85-year journey.[8] While the development of PTFE from the "accidental" discovery to a commercial product took about 10 years, from 1938 to 1948[9], and then decades more to mature that technology into the materials used today. Development advances over this time have had to occur in polymerization, finishing, lubrication and blending, pelletization, extrusion, etc. In absence of such an initial unexpected discovery, we can only speculate that developing a new polymer until commercial availability will take **more than 25 years**.

To estimate the time required to bring an unknown alternative to market, Gore has divided the effort into three phases:

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[6] https://omnexus.specialchem.com/polymer-properties/properties/min-continuous-service-temperature

[7] STERILIZATION OF FOODS, Editor(s): Benjamin Caballero, Encyclopedia of Food Sciences and Nutrition (Second Edition), Academic Press, 2003, Pages 5593-5603

[8] See https://www.ptonline.com/articles/tracing-the-history-of-polymeric-materials-part-20.

[9] https://www.teflon.com/en/news-events/history#:~:text=An%20Accidental%20Discovery&text=Roy%20J.,to%20form%20polytetrafluoroethylene%20(PTFE).

Table 3. Steps for developing an alternative to fluoromaterials in food contact materials in industrial applications

Phases	What activities does this step entail?	Time required for step
Time for Gore to develop alternative	For this application, Gore has shown that invention or breakthrough processing technology is required to develop an alternative. The likelihood of this is low and the timeline is long and unpredictable.	**Unknown** Estimate ›20 years
Time for Gore to Validate and Commercialize	Internal evaluations of material performance and process validations following GMP guidelines. Supply chain establishment.	›3 years
Time for Customer to Validate and Commercialize	This estimate includes performance validations, process integration validations, and regulatory submissions	› 2 years
Total		**Unknown** **›25 years**

d. Impacts

Without a derogation, there will be multiple types of impacts in the EU, impacting both quality of food products and costs.

Safety, Effectiveness and Availability

The use of inferior materials may increase the risk of contamination in food and feed production.

Financial Impact

A restriction on a critical component in food processing will also have financial implications to individuals, industry, and governments. Across a range of uses, costs may increase due to:

- Increased costs and reduced yield on food production due to components or quality control failures
- Increased food costs and decreased availability due to lower yield.
- Increased cost to industry for development, testing and validation of alternate solutions which are demonstrated not to meet all the performance requirements.
- Costs to industry, and eventually to consumers and governments, related to relocating manufacturing outside the EU where PFAS-based components remain available.

V. Gore's Derogation Request on Fluoropolymers

Additional information on biocompatibility, responsible manufacturing, processing, and disposal of fluoropolymers are provided in Gore's separate derogation request for fluoropolymers.