Questionnaire PFAS used for food and feed packaging and non-food packaging

Background

The authorities of five EU/EEA Member States are preparing a joint REACH restriction proposal on the manufacture and use of a wide range of per- and polyfluoroalkyl substances (PFAS). A public call for evidence took place which ended in July 2020 and generated some information. Responding to this questionnaire is a second opportunity for stakeholders to contribute to the restriction process and influence its outcome.

The five countries are basing their proposal on the high persistence of PFAS in the environment. The scope of the proposal is much broader than has previously been associated with PFAS in that PFAS are defined as substances that contain at least one aliphatic -CF2- or -CF3 element. As such, the proposal will include many sectors of industry, and substances not previously considered as PFAS.

The restriction proposal is expected to be submitted to the European Chemical Agency (ECHA) in the next two years with the aim of the restriction entering into force in 2025.

We are therefore gathering information to ensure the market and potential impacts of a restriction are described as accurately as possible. Specifically, we are gathering information on PFAS that are used in food contact materials and alternatives to PFAS. Some information has already been submitted through an earlier call for evidence in 2020, but further data is needed.

We would therefore be grateful if you could complete this questionnaire and return to [redacted]@exponent.com) and [redacted]@emrc.co.u.uk) by November 27th 2020.

Notes

The region under consideration

The restriction will focus on activities linked to the European Union (EU) and European Economic Area (EEA).

The EU contains 27 countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

The EEA contains the EU27 and three further countries: Iceland, Liechtenstein and Norway.

The United Kingdom (UK) left the EU in 2020. Please indicate whether any data that supply includes the UK.

Alternatives

We are interested in all alternatives whether they are:

- Direct replacements for PFAS ('drop-in' substitutes)
- Replacements of a broadly similar nature to PFAS, but requiring changes in technology
- Based on different approaches for providing the same service.

1. Please fill in the following information.

Contact name	[redacted]
Role in organisation	
Name of organisation	The Chemours Company
Preferred contact phone number	[redacted]
Email address	[redacted]@Chemours.com
Location of organisation	1007 N Market St, Wilmington, DE 19898
Main activity of organisation (manufacture/import/distribution)	Manufacturer
Are you willing to be contacted again to further discuss the proposed PFAS restriction?	Yes

2. Please briefly describe your or your members' activities that use PFAS (based on the definition of PFAS in the introduction to this questionnaire).

Function	Application and PFAS used (specify food or non-food)
Food and Non-Food Packaging	Chemours produces fluoropolymer resins, coatings formulations, and fluoroelastomers which are intended for sale to customers who produce the final Food and Non-Food packaging. An example are blown films, also commonly known as tubular films, that are created by extruding plastic through a tubular-shaped die and then stretched and blown with air to create a very thin-walled film. Polyethylenes such as LDPE, LLDPE and HDPE polymers are common resins that are used to create blown films. Common products created from blown films are food and non-food packaging. These products, as well as other fluoropolymer-enabled packaging takes advantage of fluoropolymers' extremely low permeability and resistance to corrosion and changes in temperature. Fluoropolymers have been used safely and effectively for decades in a wide range of industries, including food and medical packaging. While some chemistries might offer a similar performance to fluoropolymers for a particular parameter or property, it is the unique combination of properties that set fluoropolymers apart and make them vital to the sectors and industries they serve. Below are just a few of the multitude of examples of fluoropolymer packaging applications: 1. Oxygen and moisture barrier films for pharmaceutical blister packs that maintain the integrity of the medicine and extend its shelf life; 2. Films for septum liners used to store pharmaceuticals sensitive to moisture and oxygen; 3. Bags for storing cellular therapies and other medications that require cryogenic storage temperatures and no chemical contamination; 4. Shrink wrap packaging to prevent the contamination of endoscopic, laparoscopic or catheter-based surgery kits; 5. Bottles, tanks and trays used for storing and transporting high purity chemicals for semiconductor manufacturing;

	6. Integrated circuit packaging with superior dielectric and dissipation performance that ensures the longevity of electronic components by protecting microchips from moisture, heat stress and other environmental challenges. 7. Hundreds of additional applications where fluoropolymers are used as processing aids to produce tougher, stronger and lighter packaging that helps meet societal goals such as minimizing food waste, improving resource efficiency through less plastic and energy use, and reducing greenhouse gas emissions.

3. Please briefly describe your or your members' activities that use alternatives to PFAS. (see note in the introduction regarding the different types of alternative of interest).

Function	**Application and PFAS used (specify food or non-food)**
Food and Non-Food Packaging	Chemours produces fluoropolymer resins, coatings formulations, and fluoroelastomers which are intended for sale to customers who produce the final Food and Non-food packaging. The attached selection guide ("CHEMOURS_Section A - Specific Uses_Other_Chemical and Industrial Processes_Question 9_ Fluoroelastomer PPAs.pdf") compares the performance of non-fluorinated polymer processing aids [illegible]uorinated processing aids and concludes that polymer processing aids based on fluoroplastics or on fluoroelastomers provide better process stability, higher outputs, and better film surface quality. The results are summarized in that selection guide as follows:

PPA TYPE	PROS	CONS
Waxes	• Very inexpensive	• Propensity to bloom and cause defects • Higher cost due to higher concentration dose • Organoleptic issues and deteriorates mechanical properties
Stearates	• Very inexpensive • Slightly more effective than waxes	• Propensity to bloom and cause defects • Higher cost due to higher concentration dose • Higher concentration can lead to die buildup • Organoleptic issues
Silicones	• Strong throughput, torque, and die pressure buildup benefits, especially in high-speed lines	• Limited thermal stability • Higher cost due to higher concentration dose
Pure Fluoroplastics	• High thermal stability (up to 340 °C)	• Very expensive in pure form

PPA TYPE	PROS	CONS
Fluoroplastic PEG blend *(PCL blend is not available for fluoroplastics)*	▪ Lower cost due to lower concentration dose ▪ Will work at higher shear rates, especially for wire and cable applications	▪ Slightly reduced thermal stability performance compared to pure fluoroplastics (to a maximum of 230 °C) ▪ High PEG dosing can sometimes negatively impact the printability of films and lead to screw slippage
Pure Fluoroelastomers	▪ Among the most efficient processing additives ▪ High thermal stability (up to 300 °C)	▪ Very expensive in pure form
Fluoroelastomer blends *(Combines fluoroelastomers with a synergistic interfacial agent (processing agent))*	▪ Lower cost due to lower concentration dose	▪ Limited thermal stability (except in the case of fluoroelastomer PCL blends)
Fluoroelastomer PEG blends *(A fluoroelastomers blend that uses polyethylene glycol (PEG))*	▪ Lower cost due to lower concentration dose ▪ Superior performance in low-shear-rate applications	▪ Slightly reduced thermal stability performance compared to pure fluoroelastomers (to a maximum of 230 °C) ▪ High PEG dosing can sometimes negatively impact the printability of films and lead to screw slippage
Fluoroelastomer PCL blends[1] *(A fluoroelastomers blend that uses polycaprolactone (PCL))*	▪ Lower cost due to lower concentration dose ▪ High thermal stability compared to pure fluoroelastomers (up to 300 °C) ▪ Lacks printability issues or potential screw slippage of PEG blends	▪ None

4. Which specific PFAS do you use (by application), and in what quantities? 'Quantity' is ideally expressed as tonnes or kg of PFAS, but if that is not available, quantities of product sold would be useful to provide us with an estimate of the quantity of PFAS used.

PFAS	**Quantity of each PFAS used and application (specify food or non-food)**
Please name each PFAS you use in this column	*Please enter quantity used with units and state application (e.g. inks in food packaging)*
[redacted] 5.1.1c	

5. If you use PFAS substitutes or are aware of them, what are they, what quantity are they used in and what do you use them for?

PFAS-substitute	**Quantity of each PFAS-substitute used and application**

Please name each PFAS-substitute you use in this column	*Please enter quantity used with units and state application (e e.g. inks in food packaging)*
Food and Non-Food Packaging	Chemours produces fluoropolymer resins, coatings formulations, and fluoroelastomers which are intended for sale to customers who produce the final Food Contact Materials and Articles for repeat-use food-contact applications. There are currently no viable alternatives to Fluoropolymers. While some chemistries might offer a similar performance to fluoropolymers for a particular parameter or property, it is the unique combination of properties that set fluoropolymers apart and make them vital to the sectors and industries they serve.

6. What are the advantages of using PFAS? Please provide quantitative information if possible. Factors may include cost, efficiency, safety, etc. Data on costs are particularly useful.

Function	**Advantages of using PFAS (specify food or non-food)**
Food and Non-Food Packaging	Blown films, also commonly known as tubular films, are created by extruding plastic through a tubular-shaped die and then stretched and blown with air to create a very thin-walled film. Polyethylenes such as LDPE, LLDPE and HDPE polymers are common resins that are used to create blown films. Common product created from blown films is consumer packaging. Other types of film include greenhouse films and shrink wrap films. Blown film machines are typically very tall vertical towers that stretch and blow the films into their final form. After the air exits and the film cools, it is rolled through a series of rollers that flatten it into layers. Extrusion line product quality and output can be maintained or increased by utilizing so called polymer processing aids. These aids are formulated with fluoroelastomers embedded into so called polyethylene master batch pellets that are blended with polyethylene pellets at various concentrations in the extrusion process. Examples of the economic benefit of formulating with polymer processing aid at concentrations of 500 ppm to 800 ppm, including further background information on the process, functionality of the polymer processing aid and the benefits have been summarized in an Educational White Paper that is attached as a reference to this submission (please see: "CHEMOURS_Section A - Specific Uses_Other_Chemical and Industrial Processes_Question 9_Polymer Processing Aids") and excerpts are highlighted in this text. In the blown film process the polyethylene pellets are melted and sent through an extruder. The fluoroelastomer in the melt reaches the extruder die wall surface and changes the surface dynamics by reducing the coefficient of friction. This enables the material to flow through without the sticking and stopping that causes melt fracture. In addition, the fluoroelastomer creates a slippery surface that reduces torque and back-pressure inside the extruder and the die itself. The benefits of adding fluoroelastomer containing polymer processing aids to polyethylene for blow film production are summarized in the Educational White Paper as: • Increased product quality • Prevent melt fracture • Improve surface appearance • Increase physical strength • Improve film gauge thickness control • Decreased Die Lip Buildup • Less time cleaning

	• Fewer surface imperfections • Less scrap • Increased Output • Lower back pressure • Minimize motor load drop • Increase extruder speed Furthermore, the key finding of an economic evaluation in that Educational White Paper are summarized as follows: **KEY FINDING** Adding 800 ppm of PPA only increased output to 1,680 lb/h (Case C) compared with 1,650 lb/h with 500 ppm PPA. The increase of 300 ppm decreased profitability by $24,263 (assuming a selling price of $1.10/lb of film and a resin price of $0.80/lb). **KEY FINDING** Adding 500 ppm of PPA and moving to a three-layer coextrusion product would increase profits by over $227,000 a year, or over $250,000 a year for a five-layer coextrusion product, compared with the base case. **KEY FINDING** When the value of the higher uptime that a PPA can provide (because of reduced die lip buildup) is factored in, in addition to the increased output provided by the PPA and moving to a five-layer coextrusion product, the model reveals that the operator can improve profitability by almost 3¢ a pound.

7. What are the advantages of using alternatives to PFAS compared to PFAS? Please provide quantitative information if possible. Factors may include cost, efficiency, safety, etc. Data on costs and availability for widespread use in the market are particularly useful. Please note that further detailed information on costs is requested in Question 11.

Function	**Advantages of using alternatives to PFAS (specify food or non-food)**
All Functions	Chemours produces fluoropolymer resins, coatings formulations, and fluoroelastomers which are intended for sale to customers who produce the final Food Contact Materials and Articles for repeat-use food-contact applications. There are currently no viable alternatives to Fluoropolymers. While some chemistries might offer a similar performance to fluoropolymers for a particular parameter or property, it is the unique combination of properties that set fluoropolymers apart and make them vital to the sectors and industries they serve.

8. How do you predict demand for PFAS on the **European** market to change over the next 10 years for the following applications in the absence of a Restriction? Please give reasons for your forecasts of change.

Function	**Probable future trend, and reasons (specify food or non-food)**
Food and Non-Food Packaging	[redacted] 5.1.1c

9. What is your or your members' most likely response to a REACH restriction on PFAS?
Please add additional rows if you wish to provide data on more than one concentration limit (e.g. if you wish to provide data on a concentration limit that is technically feasible and one that is sufficient to address intentional use).

	Ranking of likely responses to a restriction: **1** = most likely, **2** = likely, **3** = potentially, **4** = unlikely, **5** = non-viable			
Function	Chemical substitution	Alternative technique	Discontinue PFAS-dependent operations	Operations would not be affected, i.e. business as usual
Food and Non-Food Packaging	5	5	5	5
	Comments/clarifications: Restrictions on packaging would result in the total loss of Chemours fluoropolymer business in the sector, causing the loss of revenue but most importantly forcing a reduction of our workforce in Europe.			

10. Please provide a break-down of the necessary steps and indicative time to complete the necessary changes to your process, justifying the necessary transition period (e.g. time required for R&D, product testing, certification (legal, type testing.), and commercialisation). **Please specify food or non-food.**

Function	**Necessary transition period (months)**	**List the steps to be undertaken**	**Comments on how far advanced this process is, and likelihood of success**
Comments/clarifications: Chemours interprets these questions as best answered by downstream users of our products.			

11. Can you provide estimates of the costs that might be incurred by your company or members from a potential REACH restriction of PFAS for your business? **Please specify food or non-food.**

Function	**One-off costs (e.g. R&D and investments)**	**Annual recurring costs (e.g. production costs and testing costs)**	**Other (please specify)**
Please provide supporting information on the types of costs you would incur			

Chemours interprets these questions as best answered by downstream users of our products.

Overall, restrictions on kitchenware would result in the total loss of Chemours fluoropolymer business in the sector, causing the loss of revenue but most importantly forcing a reduction of our workforce in Europe.

12. Can you provide a brief explanation of other potential impacts to your company, members and/or your customers from a potential REACH restriction? For example: non-compliance with specific legislation; cleaning requirements, durability of equipment, changes in energy efficiency, etc.

Restrictions on packaging would result in the total loss of Chemours fluoropolymer business in the sector, causing the loss of revenue but most importantly forcing a reduction of our workforce in Europe.

13. Do you have any other relevant information related to a restriction on the use of these PFAS?

Fluoropolymers are critical to modern life

Fluoropolymers have a unique combination of properties that no other chemistry contains. Fluoropolymers are a critical chemistry for a number of sectors and industries in the EU and across the globe. Their unique combination of properties makes them durable, efficient, reliable, versatile, and ultimately fundamental to the products they enable. Their properties include fire resistance, weather resistance, temperature resistance, chemical resistance, non-wetting and non-sticking properties, and high-performance dielectric properties.

There are currently no viable alternatives to Fluoropolymers

While some chemistries might offer a similar performance to fluoropolymers for a particular parameter or property, it is the unique combination of properties that set fluoropolymers apart and make them vital to the sectors and industries they serve.

Further information on benefits and typical applications for fluoropolymers in the food processing industry are shown below (excerpted from Chemours Brochure: "An Introduction to Chemours™ Fluoropolymers". Please contact us if you would like to receive a copy):

Food Processing

Benefits

The non-stick performance, chemical inertness, and exceptional purity of fluoropolymers are the best ways to keep food processing equipment running smoothly and profitably.

Components and linings made with Teflon™ PTFE help to cut maintenance costs, increase uptime, increase throughput, safeguard product purity, and allow use of same equipment over a wide range of food products (multipurpose plant operation). The key properties of fluoropolymers in the food processing industry are:

- Corrosion resistance over a wide temperature range, more universal, and more economical than exotic metal alloys
- No chemical interaction or corrosion with foods to compromise taste or create contamination. No absorption of common food preservatives
- Extremely low extractables and reactivity plus high purity
- FDA/European Directive compliant
- Approved for potable drinking water applications
- Non-stick, easy release. Equipment surfaces are easy to clean and remain clean longer.
- Faster, easier cleaning (meets EHEDG Cleanability requirements), cuts downtime for cleaning
- Resists onset of biological film formation
- Reduces chemical usage for cleaning
- Excellent steam and chemical sterilization performance (CIP, SIP)
- The use of fluoropolymers in shatterproof coatings for fluorescent light tubes reduces the risk of glass contamination in food chain.

Typical Applications

- Conveyor belts
- Baking liners
- Industrial bakeware
- Non-stick metal coatings
- Seals, gaskets, packing, valve seats
- Valves, fittings, pumps
- Sight glasses, flow meters
- Pipes, columns, tanks, vessels
- Expansion joints, bellows
- Hose, tubing
- Filters, strainers
- Dispensers, containers
- Shatterproof lamps

Saint-Gobain CHEMFAB® PTFE-coated glass fabric conveyor belt for food processing

Shatterproof lamp with PFA coating

Teflon™ PTFE bellows for bottling of beverages

Teflon™ non-stick coatings system for bakeware and cookware

"Stringent EU regulations are in place to safeguard consumer safety and are updated on a regular basis to reflect the latest scientific evidence and meet changing marketing trends and consumer habits." For further information, please see: https://www.plasticseurope.org/en/focus-areas/health-and-safety/food-contact.

"Commission Regulation (EC) No 1935/2004 (https://eur-lex.europa.eu/legal content/EN/ALL/?uri=CELEX%3A32004R1935) provides a harmonized legal EU framework. It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs). The principles set out in Regulation (EC) No 1935/2004 require that materials do not:

- Release their constituents into food at levels harmful to human health
- Change food composition, taste and odor in an unacceptable way

Moreover, the framework provides:

- for special rules on active and intelligent materials (they are by their design not inert)
- powers to enact additional EU measures for specific materials (e.g. for plastics)
- the procedure to perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority
- rules on labelling including an indication for use (e.g. as a coffee machine, a wine bottle, or a soup spoon) or by reproducing the appropriate symbol. For more information, please refer to the following document on Symbols for labelling food contact materials.
- for compliance documentation and traceability

Commission Regulation on Good Manufacturing Practices, Commission Regulation (EC) No 2023/2006 (https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32006R2023) ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation:

- premises fit for purpose and staff awareness of critical production stages
- documented quality assurance and quality control systems maintained at the premises, and
- selection of suitable starting materials for the manufacturing process with a view to the safety and inertness of the final articles

Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

The most comprehensive specific EU measure is Commission Regulation (EU) No 10/2011 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0010&from=EN on plastic materials and articles also known as the Plastics Implementing Measure (PIM) sets out rules on the composition of plastic FCMs and establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. The Regulation also specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles.

An important mechanism to ensure the safety of plastic materials is the use of migration limits. These limits specify the maximum amount of substances allowed to migrate to food. For the substances on the Union list the Regulation sets out 'Specific Migration Limits' (SML). These are established by EFSA (European Food Safety Authority) on the basis of toxicity data of each specific substance. To ensure the overall quality of the plastic, the overall migration to a food of all substances together may not exceed the Overall Migration Limit (OML) of 60mg/kg food, or 10 mg/dm^2 of the contact material.

The Regulation sets out detailed migration testing rules. Although migration testing in the food prevails, migration is usually tested using 'simulants'. These simulants found in (EU) No 10/2011, Annex III, Table 1, are representative for a food category, e.g. Acetic acid 3 % (w/v) is assigned for acidic foods. The migration testing is done under standardized time/temperature conditions, representative for a certain food use, and covers the maximum shelf life of packed food.

To ensure the safety, quality and compliance of plastic materials, adequate data on the composition of (intermediate) materials has to be communicated via the manufacturing chain, up to but not including the retail stage. For this purpose, a 'Declaration of Compliance' (DoC) needs to be provided. The DoC is based on supporting documentation which documents the reasoning on the safety of a plastic food contact material, and which must be provided to enforcement Authorities on their request." (see: https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en). Please note, coating uses are not covered under the Plastics Implementing Measure (PIM), but are instead covered under the member state specific regulations in Germany BfR (https://bfr.ble.de/kse/faces/resources/pdf/510-english.pdf) and the Netherlands (VGB) (http://www.adfopack.nl/assets/dutch-packagings-and-consumer-articles-regulation-from-january-2017-(20122016).pdf) .

[redacted] 5.1.1c

It is our understanding that, according to Commission Regulation (EC) No 1935/2004 (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R1935), Food Contact Materials and Articles are defined as materials and articles, which, in their finished state a) are intended to be brought into contact with food; or b) are already in contact with food and were intended for that purpose; or c) can be reasonably expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

Chemours produces fluoropolymer resins, coatings formulations, and fluoroelastomers which are intended for sale to customers who produce the final Food Contact Materials and Articles for repeat-use food-contact applications. Possible end-uses include consumer cookware and industrial food processing equipment, polymer processing aids for polyolefin film manufacturing or blow-molded articles, and general articles such as flowmeters, tubing, gaskets, seals, pipes in fluid handling systems, conveyor belts and similar items for use in industrial food processing and industrial food manufacturing facilities.

-------END OF QUESTIONNAIRE-------