

Questionnaire PFAS used in industrial and domestic kitchenware

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 5.1.2e@exponent.com and 5.1.2e@emrc.co.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.

Possible restriction of PFAS: Food contact materials

1. Please fill in the following information.

Contact name	5.1.2e
Role in organisation	
Name of organisation	The Chemours Company
Preferred contact phone number	5.1.2e
Email address	5.1.2e@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
Non-stick coatings utensils and cookware	5.1.1c
Greaseproof paper, muffin cases, etc.	
Baking trays, sheets and food conveyor belts	

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 alternative to PFAS used
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.

Possible restriction of PFAS: Food contact materials

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
<i>Please name each PFAS you use in this column</i>	<i>Please enter quantity used with units and state application (e.g. non-stick cookware)</i>
Fluoropolymers	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
<i>Please name each PFAS-substitute you use in this column</i>	<i>Please enter quantity used with units and state application (e.g. non-stick cookware)</i>
All Fluoropolymer 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. As an example from our website [https://www.teflon.com/en/consumers/teflon-coatings-cookware-bakeware/safety/myths], side-by-side testing between fluoropolymer nonstick coatings and ceramic coatings shows that cookware made with fluoropolymer nonstick coatings offers superior food release and durability. More Durable, Hard Wearing For the past 50 years, fluoropolymer nonstick coatings have delivered improved nonstick performance. Based on a Chemours lifecycle assessment, it takes seven ceramic pans to deliver the same level of nonstick performance as one pan featuring fluoropolymer Teflon™ Platinum coating. No Gimmicks or Sticking Fluoropolymer nonstick coatings and "ceramic" coatings both start from minerals to create a synthetic coating. So, what's the difference between the two? We don't claim to be natural or pretend to be something we're not. Our coatings have been affirmed as safe for food contact by regulatory bodies such as the European Food Safety Authority (EFSA), French Food Safety Agency (ANSES) and the U.S. Food and Drug Administration (FDA). Longer Lasting Means Better Sustainability

Possible restriction of PFAS: Food contact materials

	Because cookware and bakeware made with fluoropolymer nonstick coatings last longer, they're more sustainable. So, products not only last longer, they also produce less waste, energy, and CO ₂ emissions.
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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
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. The characteristics and benefits have recently been summarized on page 21 in the "Socio-economic assessment of the US Fluoropolymer Industry" (attached to this submission as "CHEMOURS_Fluoropolymers SEA_USA_FluoroCouncil_2020.pdf") and quoted here: "Characteristics: • Low permeation but allows for semipermeable structure; • Chemical resistance; • Helps prevent corrosion; • Low surface energy, low friction; • Low and high temperature resistance (e.g. from -200 °C to +260 °C for PTFE and PFA); • UV resistance and transmittance (e.g. articles can be made translucent); • Flexibility; • No flame propagation and low smoke generation; • Non-stick; and • Durability. Benefits: A. Increased lifetime of the product (hence consumer savings from less frequent replacement). B. Non-stick cooking, avoiding marks/burns. C. Easier cleaning, including use in dishwasher. D. Reduction of fat/oil use in cooking. E. Savings on water, energy in cleaning/downtime F. Waterproof properties. G. Fireproof properties. H. Chemical resistance."

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
All Functions	Chemours produces fluoropolymer resins, coatings formulations, and fluoroelastomers which are intended for sale to customers who produce

Possible restriction of PFAS: Food contact materials

	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.
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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
All Functions	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
All Functions	5	5	5	5
	Comments/clarifications: 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.			

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).

Possible restriction of PFAS: Food contact materials

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?

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 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.

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

<u>Fluoropolymers are critical to modern life</u> 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. <u>There are currently no viable alternatives to Fluoropolymers</u> 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
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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/dm² 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](http://www.adfopack.nl/assets/dutch-packagings-and-consumer-articles-regulation-from-january-2017-(20122016).pdf)) .

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.

Fluoropolymers are subjected to high-temperature processing to fabricate final food-contact articles (for example, "Coatings that are used in food contact applications need to be cured at a minimum of 315 °C and in most cases 400 °C" (<http://www.ptfecoatings.com/what-we-do/faq.php>)).

Types of fluoropolymers used are of "high molecular weight, have narrow molecular weight distribution, and have negligible oligomer content and organic and inorganic leachables." See Henry et al, 2018 incl. the supplemental data attached as "CHEMOURS_Henry_et_al-2018-Integrated_Environmental_Assessment_and_Management.pdf" and "CHEMOURS_Henry_et_al-2018-IEAM_Supplemental_Data.pdf".

Regulatory agencies have published the following:

- Work on migration of PFAS substances into food simulants was contracted by the Netherlands Food and Consumer Product Safety Authority, to the National Institute for Public Health and the Environment to look at Per- and polyfluoroalkyl substances in food contact materials (see “Per- and polyfluoroalkyl substances (PFASs) in food contact material”, B.G.H. Bokkers et al., RIVM Letter report 2018-0181; <https://www.rivm.nl/bibliotheek/rapporten/2018-0181.pdf>): Chapter 1.2.1. “Technical functionality of different PFASs” explains “In coatings in kitchenware FCMs, PFASs are mainly used as monomers, forming the core chain of fluoropolymers at curing. For instance, the coating of frying pans is often a polytetrafluoroethylene (PTFE) produced by polymerization of the PFAS tetrafluoroethylene. The polymers formed have high molecular weights (>100,000 D) and contain negligible residual quantities of monomers and oligomers, and therefore migration of the monomer or related oligomers is very low (See Henry et al, 2018 incl. the supplemental data attached as “CHEMOURS_Henry_et_al-2018-Integrated_Environmental_Assessment_and_Management.pdf” and “CHEMOURS_Henry_et_al-2018-IEAM_Supplemental_Data.pdf”). Because PTFE is poorly water soluble, the polymerization is conducted in an emulsion in water...at the end of the polymerization reaction, the aqueous part of the mixture, including most of the surfactant, is removed. So, besides the use as monomers, some PFASs are used as ‘polymerization production aids’ in coatings. Production aids are substances that are added to the polymer, but not with the intention to be present or have a technological function in the final product. The surfactant does not become part of the polymer chain and does not convey specific properties to the polymer. As the fluoropolymers are applied (on metal surfaces) under high temperature (> 100°C), residual low molecular weight PFASs will further be removed by evaporation.” Chapter 10.4. “Migration of PFASs from FCMs vs PFASs on positive list” concludes “... Coatings are considered to be of lesser concern, because of the negligible release of PFASs from polymers.”
- On June 11, 2019, the U.S. FDA released a statement entitled “Statement on FDA’s scientific work to understand per- and polyfluoroalkyl substances (PFAS) in food, and findings from recent FDA surveys” June 11, 2019 (<https://www.fda.gov/news-events/press-announcements/statement-fdas-scientific-work-understand-and-polyfluoroalkyl-substances-pfas-food-and-findings>): “...Overall, our findings did not detect PFAS in the vast majority of the foods tested. In addition, based on the best available current science, the FDA does not have any indication that these substances are a human health concern, in other words a food safety risk in human food...”

In an independent test conducted by the Danish Consumer Council THINK Chemistry, it was evaluated whether fluorinated substances were released from frying pans to food. “16 commercial frying pans were tested from different manufacturers, filled with olive oil and placed in an oven at 200°C for 30 minutes. Olive oil extracts were analyzed for 22 specific fluorine substances and for total organic fluorine. No detectable fluorinated substances were released.” “Chemistry in frying” June 18, 2018 (utilizing Google Translate) <https://kemi.taenk.dk/test/test-kemi-i-stegepander>.

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