Questionnaire PFAS used in food and feed production and distribution equipment

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 5.1.2e @exponent.com) and 5.1.2e @emrc.co.u.uk) by November 13th 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.

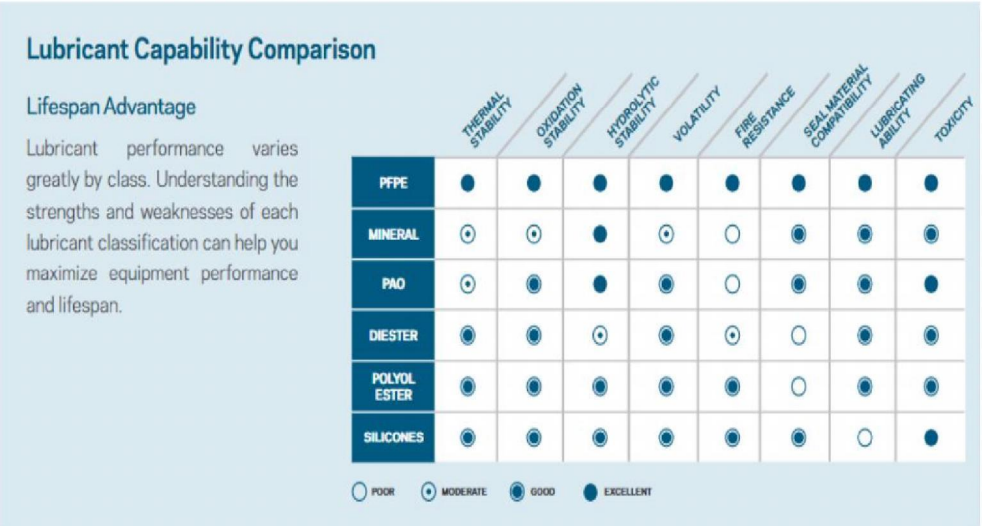
1. Please fill in the following information.

Contact name	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**
Seals, O-rings, gaskets	5.1.1c
Tubing and pipes	
Valves and fitments	
Conveyor belting	
Tank (etc.) linings	
Filter membranes	
Sensor covers	
Lubricants	
Equipment specific to food and feed transport	
Other applications of PFAS	*Please add more rows if necessary*

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
Seals, O-rings, gaskets Tubing and pipes Valves and fitments Conveyor belting Tank (etc.) linings Filter membranes Sensor covers Equipment specific to food and feed transport	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.
Lubricants	As a downstream user of PFPE Lubricants at our manufacturing sites, we know first-hand that there are no alternative substances that provide the same performance in critical applications where they are used. These are typically pumps involved in highly reactive material processing where equipment failure must be avoided for safety and no alternative lubricants can provide the same performance or lubricant lifetime. Please see the lubricant capability comparison chart below. 

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

Please name each PFAS you use in this column	*Please enter quantity used with units and state application (e.g. conveyor belting)*
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**
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.

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**
Seals, O-rings, gaskets Tubing and pipes Valves and fitments Conveyor belting Tank (etc.) linings Filter membranes Sensor covers Equipment specific to food and	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_EU_PlasticsEurope_2017.pdf") and quoted here: Fluoropolymers are useful for crucial components in food and pharmaceuticals production and packaging to enable quick and flexible processing, safe storage and meeting the highest purity and hygiene standards. Characteristics Fluoropolymers exhibit the following unique set of characteristics, which are particularly important in these applications: • High purity. • Almost universal resistance to chemicals and oil (relevant to hygiene standards, no flavour imparting). • Low and high temperature resistance (e.g. from -200 °C to +260 °C for PTFE and PFA). • Non-stick and low friction properties (allows flow of materials and prevents residual or bio-film build-up). • High corrosion and abrasion resistance. • Low vapour permeability. • Low leachables.

feed transport	Benefits Taken together these characteristics enable outstanding functionality as well as the highest purity and hygiene standards in the food and feed production sector, which delivers wider societal benefit, including: A. Increased lifetime of components. B. Lower cleaning and maintenance costs. C. Increased productivity by enabling production of multiple products with the same equipment, reducing failures and improving flow of process substances. D. Higher production yields and quality from improved purity of process substances. E. Health benefits from high purity and hygiene standards, lower health risks from cross contamination. F. Lower levels and risk of exposure of workforce and environment to chemicals, including avoiding leaks. G. Prolonged preservation of the product.

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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
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<td>Lubricants</td>
<td>Non-flammable

Thermal Stability (over broad temperature range)

Oxidative Stability

Hydrolytic Stability</td>
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	Chemical Stability Insolubility in Most Common Solvents Compatibility with Metal and Metal Compounds Compatibility with Elastomers Resistance to Radiation Shear Stability Biologically Inert

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 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, 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**

	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.

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 Food and Feed Equipment is a smaller subset but is still estimated to account for 3,000 metric tons of demand in 2015, according to the PlasticsEurope Socio-economic Analysis of the European Fluoropolymer Industry (2017). Applying the estimated rate of growth results in approximately 3,390-3,660 metric tons in 2030. Please also see the below excerpt from the Socio-economic Analysis: Fluoropolymers play an important role in food safety and cost-efficiency of food and beverage manufacturing. This sector, in turn, plays an important role in the European economy. As with other sectors, efficiency is important in global competitiveness, keeping costs to consumers low. Avoiding contamination in production is essential. FoodDrinkEurope estimated that the sector accounted for 15% of turnover and some 13% added value of the manufacturing industry in 2012. Around 289,000 companies were involved, employing some 4.2 million people and generating turnover of €1.2tr as of 201389. By Member State, the largest turnover in the food production sectors were registered in Germany (€173bn), France (€155bn) and Italy (€111bn) respectively. A large number of companies in the sector are small and medium enterprises (SMEs) – some 286,000 accounting for 99% of all companies, half of turnover and two thirds of employment. Annual R&D expenditure is around €2.8bn91. The EU is a major exporter of food: 21% of global food exports are from within the EU, with a sales value of almost €92bn in 2014. (Food Drink Europe, 2016).

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 food and feed equipment 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).

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 food and feed equipment 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.

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.

"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) .

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.

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