PFAS EDUCATION

PART 2: FLUOROPOLYMERS AND HUMAN HEALTH

PFAS Education Series

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Definition of Fluoropolymers:

Fluoropolymers are defined according to Buck et a.l[1] as a distinct subset of fluorinated polymers, based on a carbon-only polymer backbone with fluorine atoms directly attached to it, e.g., polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP) and perfluoroalkoxy polymer (PFA). Many fluoropolymers have been approved for food contact applications by regulators, including the US FDA (21 CFR 175.1550), the European Union through Regulation (EU) 10/2011 and also through specific national regulations such as German BfR recommendation LI.

Fluoropolymers do not present an unacceptable risk to human health.

The current OECD definition of PFAS includes thousands of substances with wide ranges of properties, including classes such as fluoropolymers which have traditionally been differentiated from legacy non-polymeric PFAS (PFOA or PFOS). In 2021, the OECD wrote, “The term “PFASs” is a broad, general, non-specific term, which does not inform whether a compound is harmful or not, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety”.[2]

A typical restriction on a substance or material requires the demonstration of “unacceptable risk”, and fluoropolymers do not meet this standard, as demonstrated by years of research:

- The OECD is a central source of definitions for global chemical regulation (including the definition of PFAS) and classifies polymers with “insignificant environmental and human health impacts” as polymers of low concern.[3]

- PTFE is not soluble in water (or any other common solvents) and is not mobile in the environment.[4]

- Fluoropolymers have been repeatedly found to meet all of the OECD characteristics of polymers of low concern,[5] based on their stability, lack of bioavailability, lack of bioaccumulation, and general absence of observed ill effects.

- In a scientific opinion published in 2016 relating to the risk analysis of chemical products in food, the scientific committee of the European Food Safety Authority (EFSA) specified that the risk analysis of polymers used in food additives must consider the molar mass of the polymer in question. For fluorinated polymers, EFSA proposed a threshold of 1,500 Daltons. Beyond this threshold, EFSA indicated that it is unlikely that the polymers will be absorbed through the gastrointestinal barrier and therefore considered that they do not present a health hazard.[6] By comparison, PTFE for food contact applications is characterized by sizes ranging from hundreds of thousands to several million Daltons. This recent opinion from EFSA shows that fluorinated polymers and in particular PTFE used for food contact materials like nonstick coated cookware do not pose a concern for health authorities.

Studies have consistently shown that fluoropolymers do not pose a risk to human health, largely due to their inertness, insolubility, and lack of reactive functional groups.

- A 2016 study by Naftalovich et al. shows that PTFE ingestion to increase satiety was both successful and safe. They also reviewed the biological safety of PTFE.[7]

- A 2022 study by Lee et al. shows that fluoropolymers such as PTFE are safe when ingested. For example, no toxic effects were observed from PTFE exposure in mice. No traces of PTFE were observed in the blood of mice even though they were exposed to very large amounts of PTFE.[8]

- The International Agency for Research on Cancer (IARC) has repeatedly investigated the carcinogenicity and toxicity of PTFE, finding it has no toxicological impact, and cannot be classified according to its carcinogenicity (IARC Group 3).[9]

Use of fluoropolymers in cookware and bakeware does not lead to negative health impacts.

The evidence does not indicate that use of fluoropolymer-coated cookware exposes users to non-polymeric PFAS.

- In a study on articles in the Korean market, Choi et al show that only a very limited number of articles (3 out of 139 fry pans) show migration of low molecular weight PFAS and only in the first migration experiment with no detection in later experiments. All detected quantities were significantly below the level of concern.[10]

- Studies of PTFE-coated cookware have detected no or for some products only traces of low molecular weight PFAS in the first migration experiment. The French consumer association 60 millions de consommateurs (n°579, April 2022), published a study on 9 non-stick coated articles. Despite detecting very low levels of low molecular weight PFAS, the author conceded that these substances “were probably not used in the manufacturing of the pans

but could have been introduced in an accidental manner during manufacturing, packaging or transport".[11]

- PTFE is known to start to deteriorate at an extremely slow rate above 260 °C (500°F). Above 360 °C (680°F), the degradation of PTFE starts to be measurable. However, according to the German Federal Office for Risk Assessment (BfR), the concentration of these emissions while normally using PTFE-coated cookware is so low that there is no health risk for the user.[12]

- It should be noted that degradation temperatures for fats and oils are typically lower than 200 °C (392°F), consequently at a much lower temperature than when fluoropolymers would begin to degrade. For instance, emission of volatiles, such as aldehydes, from coconut, safflower, canola, or extra virgin olive oil are measured by Katragada et al. from 180 °C (356°F).[13] This suggests that regular usage of fluoropolymer-coated cookware would not result in sufficient temperatures for fluoropolymer degradation.

Studies and expert reports consistently evaluate PTFE coated cookware as safe for users.

- The European Food Safety Authority (EFSA) published a 2020 report assessing the safety of PFAS in food contact materials, primarily focusing on non-polymeric legacy PFAS (PFOA and PFOS).[14] The study assessed the use of PTFE in cookware, saying it may contribute to human exposure on the scale of micrograms per kilogram, a level far below background exposure from eating fish, meat, eggs, and fruit (among the most common sources of exposure to PFAS).

- The American Cancer Society considers the use of fluoropolymer-coated cookware safe, saying "there are no proven risks to humans from using these products. While PFAS can be used in making some of these coatings, it is not present (or is present in extremely small amounts) in the final products".[15]

Fluoropolymers, including PTFE, are widely used in other applications with no evidence of negative health effects.

PTFE is widely used in medical devices, including implanted devices, which are highly regulated and thoroughly studied for any negative health impacts. Evidence demonstrates the use of PTFE in these devices is safe, suggesting it does not pose a health risk for humans in other uses such as in cookware.

- The US-based independent research and innovation organization ECRI (Emergency Care Research Institute) was tasked by the US Food and Drug Administration (FDA) to carry out a review of the scientific literature and produce a report on the state of knowledge of the biocompatibility of PTFE-based (medical devices in terms of local and systemic host

response. The analysis covered a total of 52 studies. The analysis found no local response to PTFE in implanted devices, and no exaggerated or fatal systemic responses.[16]

The general consensus of researchers is that PTFE and fluoropolymers do not present a health risk to humans.

- Their suitability for direct use in the human body is a central reason for their role in medical devices, and many researchers have argued that PTFE should be considered a polymer of low concern by meeting or exceeding all OECD criteria. This view is reinforced by regulatory agencies in the EU and the United States in multiple reviews and meta-analyses.

- The scientific literature on the health impacts of fluoropolymers, PTFE particularly as used in cookware, suggests that the use phase does not pose a risk to human health, as the fluoropolymers themselves are not absorbed by the body (not biologically available) and have no indicated harmful effects, and other non-polymeric PFAS are not present in meaningful quantities in the final products.

Beyond fluoropolymers, exposure to non-polymeric PFAS in other applications nonetheless presents a risk to health.

- According to the European Chemicals Agency (ECHA), the largest sources of PFAS contamination in the environment come from non-polymeric applications such as fluorinated refrigerants or waterproof coatings [e.g., treatments and finishes], which then raise concerns for exposure to humans through the food and water supply.[17] Regulatory solutions for PFAS exposure should be guided by the scientific consensus, while considering categories like fluoropolymers which have been consistently shown to be safe and result in minimal exposure.

Where or why does nonstick cookware come into all this?

PTFE, or polytetrafluoroethylene, is the PFAS material that makes nonstick coatings non-stick. As we discussed in Part 1 – PTFE is a fluoropolymer: it is non-water soluble, it is non-toxic, and it is not mobile or bio-accumulative. It has a certain level of persistence, but as with other fluoropolymers, it is this trait that makes it beneficial in so many applications.

Fluoropolymers do not fit any of the new classifications such as:

PBT : Persistent, Bioaccumulative, Toxic
vPvB : very Persistent, very Bioaccumulative
PMT : Persistent, Mobile, Toxic
vPvM : very Persistent, very Mobile

Looking at PTFE from a high level, it offers many benefits to the products that use it. It is an insulator, so it reduces heat transfer. It reduces friction, which is what allows it to aid products from cookware to cars. Also, we must remember this is one of the non-water soluble PFAS types, so water contamination is not possible.

Fluoropolymers, like PTFE, are stable under normal, foreseeable use conditions. Stability is resistance to physical, chemical, or biological breakdown. Fluoropolymers, in general, have very good chemical and thermal stability due to the strength of the Carbon to Fluorine bond. (Henry et al: 2018).[5]

PTFE is the most stable fluoropolymer and has a continuous use temperature of 500°F (260°C). (Plastics Safe Handling Guide 2018).[18] This temperature is well above temperatures realized during normal cooking and baking activities when a nonstick housewares article is used per the manufacturers' use and care instructions.

Consumer Nonstick Housewares Products

Fluoropolymers, mainly PTFE, are the principal ingredients in traditional nonstick coatings for housewares. In most cases, these coatings are water-based, liquid coatings. The PTFE has to be stable in this liquid mixture in order to be applied to a product like a piece of cookware. PTFE, as helpful as it is, is extremely stubborn when it comes to mixing with water. In order to get PTFE to be stable in a water mixture, a surfactant is needed as a dispersing aid. Historically, the surfactant used to make PTFE stable in water was a fluorinated surfactant (i.e. fluorochemical).

You don't need a lot of the fluorochemical to make this work. A good analogy is if you had an Olympic size swimming pool, you would need to add a thimble-sized amount of the fluorosurfactant to make the PTFE stable. To put this small amount into another perspective, it translates to just over a minute in a century, or 0.000000025%

Aqueous film forming foams (AFFF) used to fight petroleum-based fires can often contain as much as 3.0% of fluorochemicals which are PFAS of true concern. To contrast these amounts, it would require 2 million years of cookware production to equal the environmental exposure caused by 1 year's use of AFFF.[19]

There are PTFE manufacturers that are committed to the reduction of emissions from polymerization aid/surfactant technology used in the fluoropolymer manufacturing process, the adoption of state-of-the-art emission reduction technologies, and informing downstream users of fluoropolymers about their safe handling, use, and prevention of environmental release.[20]

Conclusion:

There is no scientific basis that PTFE-coated cookware and bakeware poses a hazard or risk to humans or the environment when used under normal conditions. Therefore, in our opinion it is safe to use and should not be restricted.

More from the PFAS Education Series

In the other parts in this series by CBA, we discussed several topics around PFAS and Cookware & Bakeware.

Part 1: Cookware, PFAS, and PTFE, the definition of PFAS involving a large family of substances with significantly varied properties and uses, was discussed. PFAS was divided into two distinct groups: non-polymeric and polymeric. The polymeric PFAS (fluoropolymers) are neither water soluble, nor mobile, nor bioavailable, nor bio accumulative.

Next in the series:

Part 3: A Closer Look at PFAS in Cookware & Bakeware: other contested issues with fluoropolymers were discussed such as, Environmental Emissions of PFAS, End of Life of Nonstick Cookware, Feasibility of Alternatives to PTFE.

Visit the Good Science webpage to explore.

The Cookware and Bakeware Alliance

The CBA is a not-for-profit trade association owned by its membership: manufacturers of cookware, bakeware and kitchenware with substantial operations and headquarters in the United States. The CBA began in the early 1920s as the Aluminum Wares Association, became the Metal Cookware Manufacturers Association in the 1960s, and in the 1970s changed its name to the Cookware Manufacturers Association in recognition of its representation of all types of cookware and bakeware materials. The CBA's mission is to inform and promote the industry to its members, their customers and to the general public.

The members of The Cookware & Bakeware Alliance (CBA) develop standards to promote the welfare of the cookware industry and improve its service to the public. The CBA Engineering Standards are continually updated to reflect changes in materials and technology and include test methods for nonstick finishes on cookware that when followed ensure coating performance and durability.

Nonstick cookware and bakeware manufactured according to CBA Standards use only US FDA food contact compliant materials for surfaces. CBA supports the responsible manufacturing and safe

uses of PTFE and other fluoropolymers, and a science-based approach to regulations that benefit human health and the environment. CBA supports labeling provisions to alert consumers to the presence of PFAS, but based on current science, considers it unnecessary to prohibit sales and eliminate consumer choice.

Your cookware and bakeware industry resource.

Knowledge is powerful. This is a key element in why The Cookware & Bakeware Alliance was formed back in 1922, to collect and share important information and create safe consumer products.

For years we have answered questions and shared resources on important topics facing our industry. Many times, only part of the answer is shared, or one viewpoint. The Good Science site has been created to help provide resources and access to more information on important topics. We now bring all of this information to our website to share and promote Good Science. Visit the Good Science webpage to explore.

For questions, please contact Fran Groesbeck, Managing Director (fran@cookware.org)

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