August 22, 2023

Non-confidential comments for Annex XV restriction report: Food contact materials

Dear Madame or Sir,

We welcome the opportunity to provide input on the restriction proposal regarding per- and polyfluoroalkyl substances (PFAS). This submission was prepared by Associate Professor Xenia Trier (University of Copenhagen) and Dr. Juliane Glüge (ETH Zürich) with input of other members of the Global PFAS Science Panel (GPSP). The GPSP is a collaborative partnership among academic researchers, regulatory scientists and policy analysts dedicated to enhancing understanding of PFAS and to protecting human and environmental health from potentially adverse effects associated with PFAS through better informed decision-making. The scientific work of the GPSP in the last five years has considerably advanced the understanding of PFAS and the GPSP would like to take the opportunity to also give input to the PFAS restriction proposal. Dr. Glüge and Dr. Trier have both been approved by the Risk Assessment Committee (RAC) of the European Chemicals Agency to follow the UPFAS RAC meetings on Food contact materials (FCMs).

We see the restriction proposal as a very important initiative and good way forward to counteract the ongoing emissions of PFAS in Europe (and in part even worldwide). Our submissions should therefore be seen as a support of the restriction proposal to make it even stronger and more fully complete. The current submission is on Food contact materials.

In the following we provide references to EU and national regulations in 1) REACH PFAS restriction proposal and to EU and national regulations on food contact materials, and to commercially available non-fluorinated alternatives of relevance to 2) Non-stick coatings in industrial and professional bakeware and 3) Food contact materials for the purpose of industrial and professional food and feed production.

1) REACH PFAS restriction proposal and EU and national regulations on food contact materials

The current food contact material regulation consists of a Framework Regulation (EP 2004, 2021), which covers all possible food contact materials, of which 17 different commonly used FCM are listed in its Annex 1. For five materials there is specific regulations, i.e. on plastics (EC 10/2011, with updates) - Plastic Materials, Active and Intelligent Materials, Recycled Plastic Materials, Ceramics and Regenerated Cellulose Film (EC 2023a). The remaining FCMs without specific EU regulations are referred to as 'non-harmonized FCMs'. Only for plastics there is a positive list, containing monomers and additives such as processing aids which EFSA has authorized for use to make polymers including some thermoplastic FP elastomers (e.g., Table 1 in Annex I of EC (2011)). The FCM regulation also requires that Non-Intentionally Added Substances (NIAS), which may stem from residuals, impurities and transformation products should not migrate in amounts that are harmful to human health and lays out test conditions. Currently there are 19 PFAS substances listed in this consolidated FCM Plastics Regulation (FCM substance No. 131, 132, 134, 148, 281, 282, 391, 423, 468, 854, 860, 861, 896, 903, 926, 973, 1045, 1061 and 1063).

However, the scope of the current EU Framework Regulation and the specific directives/regulations is only to address human health risks. It is not in their scope to assess or control environmental risks. REACH (and within REACH the PFAS restriction proposal) therefore acts as a gap-filler which will addresses the environmental risks.

The gap of the current FCM regulations in addressing environmental risks is also described and acknowledged in the Roadmap on the revision of the FCM regulation (EC 2020d) and described by the Directorate General For Health and Food Safety (DG Sante) in a recent presentation (EC 2023b). The roadmap also describes the need to align the hazards assessments (One Substance, One Assessment) and to address the most harmful substances as outlined in the Chemicals Strategy for Sustainability (i.e. PBT/vPvB and Equivalent levels of concern, such as PMT/vPvM) (EC 2020b, 2020c, 2020a).

For the 12 non-harmonized FCMs, the member states may refer to national legislations or recommendations on FCM. For the FCMs mentioned in 2) and 3) particularly the German BfR recommendations on food contact materials (BfR 2023b) are relevant, since they contain a variety of specific use-cases, for which non-fluorinated FCMs are listed. Examples include recommendations on XXI/1. C*ommodities based on natural and synthetic rubber in contact with food* (BfR 2023a), *XXXIX.* And *Commodities Based on Polyurethanes* (BfR 2012) . This shows that not only are a variety of non-fluorinated FCM alternatives commercially available, but that they have been assessed and recommended by national authorities for food contact.

In summary, we support the analysis of the dossier submitters that the REACH restriction proposal has legal grounds to cover food contact materials.

2) Non-stick coatings in industrial and professional bakeware

The potential derogations 'non-stick coatings in industrial and professional bakeware until 6.5 years after EiF' has been marked for reconsideration after the Annex XV report consultation.

It is stated in the restriction proposal that 'affected activities here include both the production of non-stick bakeware and the recoating of the bakeware and other applications where non-stick coatings provide benefit to industrial and professional food and feed production. There is sufficiently strong evidence that technically and economically feasible alternatives are available for some applications but not all.' It was concluded that there is a high substitution potential at EiF for the sector as a whole [sufficiently strong evidence] and low substitution potential at EiF for some products [weak evidence].

It is also indicated in the restriction proposal that some companies (particularly SMEs) at EiF may have difficulty transitioning to alternatives and need time for adaptation and testing for some product lines. On the other hand, it is also stated (in Annex E, page 169) that one provider supplying both silicone and fluoropolymer non-stick coatings coated until now one third of their trays with fluoropolymers and the remainder with silicone. The fluoropolymer coating has a 30% longer lifetime than the silicone equivalent but a higher price. Over the lifecycle, the cost of the silicone option is 30% cheaper. It was also noted that curing temperatures required for fluoropolymers lead to a rapid weakening of aluminum, leading in turn to reduced lifetime and higher costs.

This shows that alternatives to fluoropolymers in non-stick coatings in industrial and professional bakeware are available and not more expensive than fluoropolymer coatings. It may be true that some SMEs may have developed their businesses over several years and may find the reinvestment needed to switch to alternatives unaffordable on a short-medium timescale. However, these investments could be covered with loans whereas emissions of PFAS to the environment (e.g., from the production of the fluoropolymers or from the recoating) cannot be taken back.

Also, in the considerations of the costs of PFAS, externalities of the cost of pollutions now and in the future need to be factored in, such as:

- costs to human and environmental health due to PFAS exposure at the workplace (PFAS production/ product manufacturing/use/end of life); polluted drinking water, from soil and food around polluted production sites or from polluted wastewater and contaminated sludge as fertilizer)
- costs of cleaning drinking water
- remediation of polluted sites
- loss of resources (polluted soil, water, food, materials that cannot safely be recycled, use of energy to remediate resources and to mitigate (filter) pollution, loss of water in water treatment, use of chemicals and other materials to clean resources)
- costs from loss of property value in polluted areas, and loss of tax-income when the most resourceful people move away from PFAS-pollution impacted communities.

We argue therefore that a derogation should not be given when alternatives are available on the market.

On the point that the baked product can affect the choice of coating and that for some products a silicone coating may not be so well suited (Annex E, page 169). If a derogation is given, then it should be phrased very specifically to this particular use case and not cover the sector (non-stick coatings in industrial and professional bakeware) as a whole.

3) Food contact materials for the purpose of industrial and professional food and feed production

For food contact materials (FCM) used in the industrial production of food and feed, a time-limited derogation until 6.5 years after EiF is proposed. The following applications are *inter alia* covered by this derogation:

1) Piping and tubing for drinking water applications;
2) Filters to capture contaminants from, for example, steam filtration in food processing;
3) Seals, O-rings, gaskets, tubing and pipes, expansion joints;
4) Valves and fitments, conveyor belting, chutes, guiding rails, rollers, funnels and sliding plates, tanks, rollers, linings, blades of knives and scissors, springs, filter membranes and sensor covers, lubricants;

We question whether a derogation is required for all applications mentioned above, because there are many non-fluorinated alternatives for FCMs for the purpose of industrial and professional food and feed production already on the market. Many of these are also listed in the German BfR recommendations for materials and chemicals to be used in contact with food. The following subsection gives some examples of those alternatives.

Piping and tubing

Piping and tubing for drinking water applications used for the infrastructure and which are on the European market includes polyethylene (Ostendorf_Kunstoffe 2023), polypropylene (Polymelt 2023) and cement (Soukatchoff et al. 2001) and all of them have been widely applied.

Pipes in the food industry are often made out of stainless steel (Butting 2023). For corrosive substances (e.g., seawater in desalination plants), corrosion-resistant alloys can be used, either for the whole pipe or as pipe cladding materials (AMI 2020). The company Bal Seal Engineering has published a chemical compatibility chart that lists the compatibility of many different chemicals with nine corrosion-resistant alloys (BalSealEngineering 2019).

Tubing that transfer milk, beverages or other food ingredients during food processing can be made out of polyethylene or silicone rubber (DefendOurHealth 2021b).

Filters

Filters are used in various steps in the food and beverage production and therefore many different filters are available (K2TEC 2023). K2TEX offers e.g., stainless steel filters for the filtration of medium to high viscosity products. Filtering with filter bags using stainless steel bag filter housing is also offered (K2TEC

2023). The filter bags itself can be of different materials, including polyester and polypropylene (K2TEC 2023).

Filter membranes

Filter membranes are available based on high-molecular cellulose diacetate (Eastman 2023), natural membrane proteins (Aquaporin 2020), ceramic (Tetra_Pak 2023), non-fluorinated polymers (Euronews 2022; Tetra_Pak 2023), and silicone (Daken_Chemical 2023).

Seals, O-rings, and gaskets

Food grade seals, O-rings and gaskets for the food, dairy and water industries are available based on silicone (Amazon 2023; PPE 2023; TheRubberCompany 2019).

Conveyer belts, roller conveyer and roller

There are also conveyer belts and roller conveyer belts for the transfer of food and beverage products in the food and feed production made of stainless steel, plastic, cotton, polyolefins, polyester or silicone rubber that can be used as alternatives to conveyer belts that use PFAS (DefendOurHealth 2021a; Marvu 2023). Similarly, rollers can be made out of steel or polymers such as PVC (Ellegaard 2023). Rollers covered with food-grade polyurethane are also on the market (TruTrac 2023).

Funnels

Funnels are available from different materials, including food-grade nylon (TheCheeseMaker 2023), plastic, stainless steel (Webstaurantstore 2023) or glass (Food-men 2023).

Linings

Linings for food and beverage applications are offered with ethylene propylene diene rubber (EPDM), nitrile butadiene rubber (NBR) and silicone rubber (MVQ) and can be used for applications up to 90 °C and 16 bar (EPDM and NBR) or up to 180 °C and low pressure (MVQ) (InterApp 2022). Only applications for the most extreme chemicals, up to 200 °C and operating pressure up to 16 bar might need fluoroelastomer liner (FPM) (InterApp 2022). Tanks and pipes in food contact and for potable water can be coated with glassflake epoxy (Chemco 2023).

Expansion joints

Expansion joints suitable for contact with food, also oil and fat containing food, are available with EPDM and NBR (Gteek 2023).

Slip agents and lubricants

PFAS-free slip agents are authorized additives in the EU Plastics Regulation EC 10/2011 in EC(2011). PFAS-free lubricants are also available, including vegetable oils low in acids (e.g., sunflower oil (Honary 2001)), synthetic esters, polyalkylene glycols and water (USEPA 2011).

Valves

Valves are important elements of all food and beverage processing plants. The choice of the type of valve and of the material depends mainly on the nature of the food and beverage material (DBV 2021).

Generally, there are four types of valves in the food and beverage industry: direct contact valves, utility services valves, solenoid valves, and sanitary valves.

Direct contact valves are those which directly come in contact with food or beverage material (DBV 2021). Generally, stainless steel is ideal for manufacturing direct contact valves for the food and beverage industry (DBV 2021).

Solenoid valves are designed in a way that they are resistant to high humidity, extreme room temperatures, and corrosive environments. A food-grade solenoid valve is typically made from stainless steel to meet these requirements (SIO 2022).

Sanitary valves are used for those applications that require clean and sterile processing (SIO 2022). Sanitary ball valves that offer complete shut-off functions are preferred in the beverage processing industry since they provide more control as compared to a sanitary butterfly valve or globe valve. While most of them are made from stainless steel, they can also be made from brass or white plastic (SIO 2022).

Utility service valves regulate the supply of steam, water, and other non-food and non-beverage materials that are used in the preparation, packaging, or transportation of food and beverages (DBV 2021) . The choice of the material of the valve and whether or not it needs to be coated depends on the substances which need to be handled and the conditions (Tameson 2023).

An example of the many possible PFAS-free alternatives for valves is shown in Table 1, which has been taken from Tameson (2023). More specifically it illustrates the compatibility (according to Tameson (2023)) of common corrosive media with typical ball valve materials, and that it only for very few applications may be necessary to give specific derogations to use PFAS.

Table 1: Compatibility of common corrosive media with typical ball valve materials, where the non-fluorinated alternatives have been taken from Tameson (2023)

Media	Ball valve material information
Sulfuric acid	• Stainless steel (SS316): SS 316 is highly resistant to sulfuric acid at concentrations up to 20% and temperatures up to 150 °C. However, at higher concentrations and temperatures, it may corrode. • Hastelloy: Hastelloy is highly resistant to sulfuric acid at concentrations up to 70% and temperatures up to 100 °C. At higher concentrations and temperatures, it may corrode. • Polypropylene (PP): PP is resistant to sulfuric acid at concentrations up to 70% and temperatures up to 80 °C. However, it is not recommended for use with concentrated sulfuric acid or at higher temperatures. • The ceramic ball valve is a more expensive alternative at high pressures and temperatures
Hydrochloric acid	• Hastelloy C, and titanium

Nitric acid	• Concentrated nitric acid (above 70%): Ball valves made from materials such as Hastelloy C, titanium, or zirconium are recommended due to their excellent corrosion resistance in highly oxidizing environments. • Dilute nitric acid (below 70%): Materials such as stainless steel can be used for ball valves operating in dilute nitric acid solutions at low pressures and temperatures. • High temperature and pressure nitric acid: For ball valves operating in high temperature and pressure nitric acid solutions, materials such as Inconel or Monel may be suitable due to their high strength and corrosion resistance at elevated temperatures.
Chlorine	• Stainless steel 316
Alcohols, Ketones, Esters, Ethers	• Alcohols: Stainless steel • Ketones: Ketones can be highly reactive and may attack certain valve materials. For example, acetone can dissolve certain types of plastic valves. Stainless steel and brass valves may be suitable for some ketones, but it is important to consult with the valve manufacturer for specific recommendations. • Esters: Esters are generally compatible with stainless steel valves. However, some esters, such as ethyl acetate, can be aggressive and may require the use of coatings. • Ethers: Ethers can be highly reactive and may attack certain valve materials. Stainless steel and brass valves are suitable for use, but it is important to consult with the valve manufacturer for specific recommendations.

It is also stated that coatings can be used as barrier between the metal and the corrosive media, preventing direct contact and reducing the risk of corrosion (Tameson 2023). Examples of non-fluorinated coatings include epoxy and other polymer coatings.

Table 1 and the paragraphs above show that there are alternatives to fluoropolymer valves, even for harsh and corrosive materials.

Conclusion

The examples provided illustrate that there are alternatives for many uses for FCMs for the purpose of industrial and professional food and feed production. We request therefore that – in the case a derogation is needed at all – that the derogation is phrased so that it only and specifically makes reference to those uses for which there currently are no alternatives on the market instead of giving a general derogation to the whole sector. We would also recommend an extended online search for providers of alternatives, since such industries may not be aware of the restriction proposal and may not have submitted comments.

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