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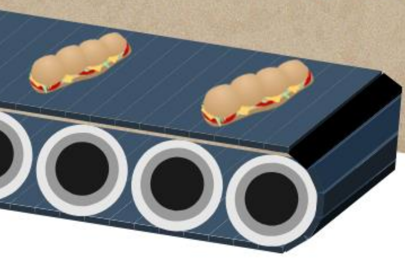
Regulating Regrettable Substitution of PFAS
in Food Contact Materials, Packaging and Cosmetics



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Ministerie van Volksgezondheid, Welzijn en Sport

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Disclaimer

Prologue

Before diving into the report, I want to thank everyone who made this internship possible. First, I want to express thanks to my daily supervisor, **Jurgen van Belle**, for treating me like a true colleague, being a good source of information and entertainment, dealing with me for an entirety of 6 months, and motivating me to stay to work for the Ministry for (hopefully) many years to come. Then I would like to give gratitude to my SBP supervisor, **Maarten van den Nieuwenhof-Schilstra**, for his enthusiasm regarding the project, and availability for questions with his always super-fast responses. I hope I have not scared him too much with my report, as I am afraid he will now be reluctant to touch anything which might be contaminated with PFAS. And the last, but certainly not least, individual person I would like to thank is my scientific supervisor **Dina Maniar** for her kind words, and willingness to think along every step of the way, even if it was not in her field of expertise.

My gratitude also goes out towards the **organisers of the Science, Business & Policy track**, as without this track I would not have been able to get to know the world of policy this well within my studies of Chemistry, and to the **Ministry of Health, Welfare and Sports** for giving students like me the opportunity to explore the working field of policy by offering these internships. Lastly, I would like to show appreciation for my **colleagues at the Department of Nutrition, Health Protection and Prevention** for welcoming me with open arms and the warm and fun atmosphere they have created throughout my entire internship.

Executive Summary

Per- and polyfluoroalkyl substances (**PFASs**) are a large chemical family of fluorinated substances. They are **chemically resistant**, **thermally stable**, **water- and oil-repellent**, **non-stick**, **versatile**, and more. These properties make it that they are used for many applications in, for example, the energy, chemical, pharma, food and cosmetic industries. However, many of these substances have a negative effect on the environment as they are **persistent** (due to their high resistance), **bioaccumulative**, **phytotoxic,** and contribute to **global warming**. Besides this, they also negatively influence our health as they cause **reduced immune function**, **insulin dysregulation**, **increased cholesterol**, **cancer**, **decreased reproductive health**, **adverse developmental effects for (unborn) children,** and more. Some PFASs are therefore restricted via various regulatory measures, such as the **Stockholm Convention**, **EU POPs Regulation, Cosmetic Products Regulation**, **plastic materials and articles Regulation**, **Drinking Water Directive**, the **Montreal Protocol**, and the **REACH Regulation**. However**,** seeing the limitations with the scopes of these regulations and the current scientific information on PFASs, a **restriction on the manufacturing, placing on the market and use of the PFAS family as a whole** has been proposed. Stakeholders involved with the problems surrounding PFAS and this restriction, identified with a **power-interest matrix,** were the **general public**, the **Netherlands Food and Consumer Product Safety Authority**, **Academic institutions**, **Non-Governmental Organisations**, the **industry**, the **EU Member States**, the **RIVM**, the **Ministry of Health, Welfare and Sports**, the **Ministry of Infrastructure & Water Management**, and **the European Chemicals Agency**.

If the use of PFASs becomes restricted, substitutes for them will be used. The Ministry of Health, Welfare and Sport therefore found it important to investigate the possible substitute substances and evaluate them to **identify which could cause substantial or a too high risk of unknown harm** to the environment and human health, especially when being compared to the corresponding PFASs. Substitutes determined to cause substantial or a too high risk of unknown harm were marked as possible **regrettable substitute**. Within this report we looked at PFASs and their substitute substances used within **food contact materials**, **packaging** and **cosmetics**. Within the **multi-criteria analysis** the substitute substances **nitrile rubber**, **polyvinyl chloride, poly(methyl methacrylate), polyvinylpyrrolidone**, but possibly also **mineral oils** were marked as possible regrettable substitutes. It was recommended to the Ministry to look further into these substances to determine whether they are truly a regrettable substitute.

To illustrate the stakeholders involved with the substitute substances and their possible regulation, another **stakeholder analysis** was done. This stakeholder analysis could be used to in the future made a policy roadmap. To determine whether the Ministry would be able to implement the given recommendation, an internal analysis was done in the form of a **McKinsey 7s framework**, from which no evident gaps were identified. It was recommended that as a **next step**, the multi-criteria analysis overviews should be used as **living and continuous tables**. Lastly, some points of discussion were given, in the form of questions that could still be asked, possible implications, and a point of attention addressing the principle of better regulation.

A translation of this executive summary in Dutch can be found in the Appendix, Chapter 9.1.

Table of Contents

Abbreviations

All abbreviations are underlined the first time they are used in the report.

Abbreviation	Written out
CMR	Carcinogenic, Mutagenic, or toxic for Reproduction
ECHA	European Chemicals Agency
ECTFE	Polyethylene-Chlorotrifluoroethylene
ELoC	Equivalent Level of Concern
ETFE	Ethylene Tetrafluoroethylene
EU	European Union
FCM	Food Contact Materials
FEP	Fluorinated Ethylene Propylene
FKM	(Per)fluoroelastomers
GWP	Global Warming Potential
HFPO-DA / GenX	2,3,3,3-tetrafluoro-2-(Heptafluoropropoxy)Propionic Acid
I&W	Infrastructuur & Waterstaat
NGO	Non-Governmental Organisation
NVWA	Netherlands Food and Consumer Product Safety Authority
OECD	Organisation for Economic Co-operation and Development
PAP	Polyfluoroalkyl Phosphate Ester
PBT	Persistent, Bioaccumulative and Toxic
PEEK	Polyether Ether Ketone
PFA	Perfluoroalkoxy Alkane
PFAS	Per- and Polyfluoroalkyl Substance
PFDA	Perfluorodecanoic Acid
PFHpA	Perfluoro-Heptanoic Acid
PFHxS	Perfluorohexane Sulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonate or Perfluorooctanesulfonic acid
PFPE	Perfluoropolyether
PLC	Polymer of Low Concern
POP	Persistent Organic Pollutant
PTFE	Polytetrafluoroethylene
PVDF	Polyvinylidene Fluoride
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIVM	Rijksinstituut voor Volksgezondheid en Milieu
SBP	Science, Business & Policy
SCFP	Side-Chain Fluorinated Polymer
SVHC	Substance of Very High Concern
TWI	Tolerable Weekly Intake
VGP	Voeding, Gezondheidsbescherming en Preventie
vPvB	very Persistent and very Bioaccumulative
VWS	Volksgezondheid, Welzijn en Sport

1 Introduction to the report

If you have been following the news, you will most likely have come across the term "PFAS".[1–5] This is because the world is becoming more aware of the rising presence and negative effects per- and polyfluoroalkyl substances (PFASs) have on the environment and our health. Seeing the current scientific information on PFASs, the Netherlands together with four other European Union (EU) Member States, have proposed a restriction on the manufacturing, placing on the market, and use of PFASs as a whole.[6] However, if all PFASs become restricted, substitutes for them will be introduced. To avoid an undesirable future scenario, it is necessary to take a look into which substitutes might be used beforehand and evaluate them to identify if they could also cause substantial harm to the environment or our health. Possible ways to limit the use of these regrettable substitutes, which are defined as substitute chemicals that have different or unknown hazards compared to the original unwanted substance, will be investigated.[7,8] To make the scope within the planned time achievable, only the substitution of PFASs within food contact materials (FCM), packaging and cosmetics will be investigated.

The main research question is therefore: **Is there any regrettable substitution of PFASs expected within FCM, packaging and cosmetics, which should be regulated within the EU?**

1.1 Formal Framework

This internship has the objective of formulating advice for the regulation of regrettable substitutes of PFASs within FCM, packaging and cosmetics, which can be shared with the Dutch parliament and possibly the European Chemicals Agency (ECHA, received the proposed EU PFASs restriction). This will be done for the Ministry of Health, Welfare and Sports (Dutch: Volksgezondheid, Welzijn en Sport (VWS)), within the Department of Nutrition, Health Protection and Prevention (Dutch: Voeding, Gezondheidsbescherming en Preventie (VGP)) for the product safety team, which is why the main aim is to create an overall better quality of life for the people. Additionally, since the organisation forms a part of the Dutch government, a Dutch translation of the executive summary is supplied at the end of this report in the Appendix, Chapter 9.1. The internship took place from the 8th of January till the 28th of June 2024, with a total duration of 25 weeks. The author of this report, Didi Ubels, has a background in Chemistry with a focus on material and polymer science. As the internship is executed within the Science, Business & Policy (SBP) track, an integration of the discipline's policy and science (mainly chemistry) will be made. The supervisors of Didi Ubels involved with the internship are stated in **Table 1**.

Table 1: Internship supervision division.

Name	Institute	Function	Role in supervision
Jurgen van Belle, MSc	Ministry of VWS, Department VGP	Senior Policy Officer	Daily supervisor
Dr. Dina Maniar	University of Groningen, Zernike Institute for Advanced Materials	Assistant Professor	Science supervisor
Maarten van den Nieuwenhof-Schilstra, MSc	University of Groningen, SBP Master's track	Lecturer	SBP supervisor

1.2 Approach

To find the answer to the main research question, a series of subchapters are given. A reading guide to these can be found in **Table 2**. The research question will be foremost answered by a literature review, including scientific papers, but also (governmental) reports and legislative resources. Apart from a literature review, meetings with relevant parties, webinars, conferences and workshops will be attended. To apply the attained knowledge, analysis methods will be used (e.g. multi-criteria analysis) to substantiate the proposal, forming a final advice and thereby answering the main research question.

Table 2: Reading guide.

#	Chapter title	Description
2	Introduction to PFASs	Gives a general introduction to PFASs (e.g. definition, properties) followed by the effects they have on the environment and our health.
3	Uses of PFASs	Includes an overview of uses for PFASs within FCM, packaging and cosmetics with a summation of the most used PFASs per category.
4	PFAS Related Legislation	Describes regulatory measures currently in place for PFASs, the proposed PFAS EU restriction and the dominant comments placed on this restriction.
5	Stakeholders PFAS Restriction	Contains a stakeholder analysis in which the role of stakeholders with the PFAS problem and restriction proposal will be illustrated to show their dynamics.
6	Comparison Overview	Gives an overview of the PFASs used within FCM, packaging and cosmetics, and their identified substitutes. These substances are compared to one another, with a set of substantiated criteria, via a multi-criteria analysis.
7	Regulation of Regrettable Substitutes	Advice will be given regarding the main research question by relating back to earlier chapters. The implementation of the final advice will be substantiated and possible implications will be identified.

2 Introduction to PFASs

PFASs are highly fluorinated substances that contain at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).[9] This definition is in line with the proposed EU PFASs restriction, which will be introduced later, and the newest definition of the Organisation for Economic Co-operation and Development (OECD) from 2021.[6,10] However, the definition of PFASs still varies in the literature, which should be kept in mind when reading other reports. PFASs are an exceptionally large chemical family, the Environmental Protection Agency PFASs master list shows that over 12.000 PFASs have been produced and the classification browser PubChem shows that over 6 million could be synthesized.[11–13] The vast amount of PFASs reveals that there are many differences among them and even when their chemical structures are of close resemblance, their physicochemical properties can vary.[14] This makes it tricky to make general statements about their mechanical and physical properties. However, a few conclusions can be drawn about PFASs in general.

The C-F bonds present in PFASs are extraordinarily strong and stable, resulting in high chemical and thermal resistance. When multiple fluorine atoms are attached to the same carbon, such as with fully a fluorinated methyl or methylene carbon atom present in PFASs, the stability increases even further. This is due to the resonance structures (same molecule structures with delocalization of electrons) which can then form.[15] As fluorine is the most electronegative element, its bond with carbon is highly polar, creating an attractive partial charge.[16,17] The high electronegativity and therefore low polarizability of fluorine also causes weak intermolecular forces and a low surface energy for PFASs.[18] This causes hydrophobicity (water-repellent), oleophobicity (oil-repellent) and low adhesive forces (non-stick).[19–21] The combination of these properties with their amphiphilic structure (hydrophobic tail and hydrophilic head) makes that PFASs are widely used as surfactants and coatings.[22]

PFASs are divided into two main classes, non-polymers and polymers, due to the great difference between them in physical, chemical, and biological properties.[23,24] Non-polymeric PFASs are further split into two subclasses: perfluoroalkyl substances, where all hydrogen substitutes (excluding those in functional groups) are replaced by fluorine, and polyfluoroalkyl substances, where some hydrogen substitutes are still present.[25] These (sub)classes are shown in **Figure 1.** Non-polymeric PFASs commonly consist of two structural components, namely a perfluorinated hydrophobic chain (tail), which has a length of between 4 and 17 carbon atoms, and a hydrophilic functional group (head), which is often a carboxylate or sulfonate group (**Figure 2**).[15,26] The most well-known non-polymeric PFASs are perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) (**Figure 3**).

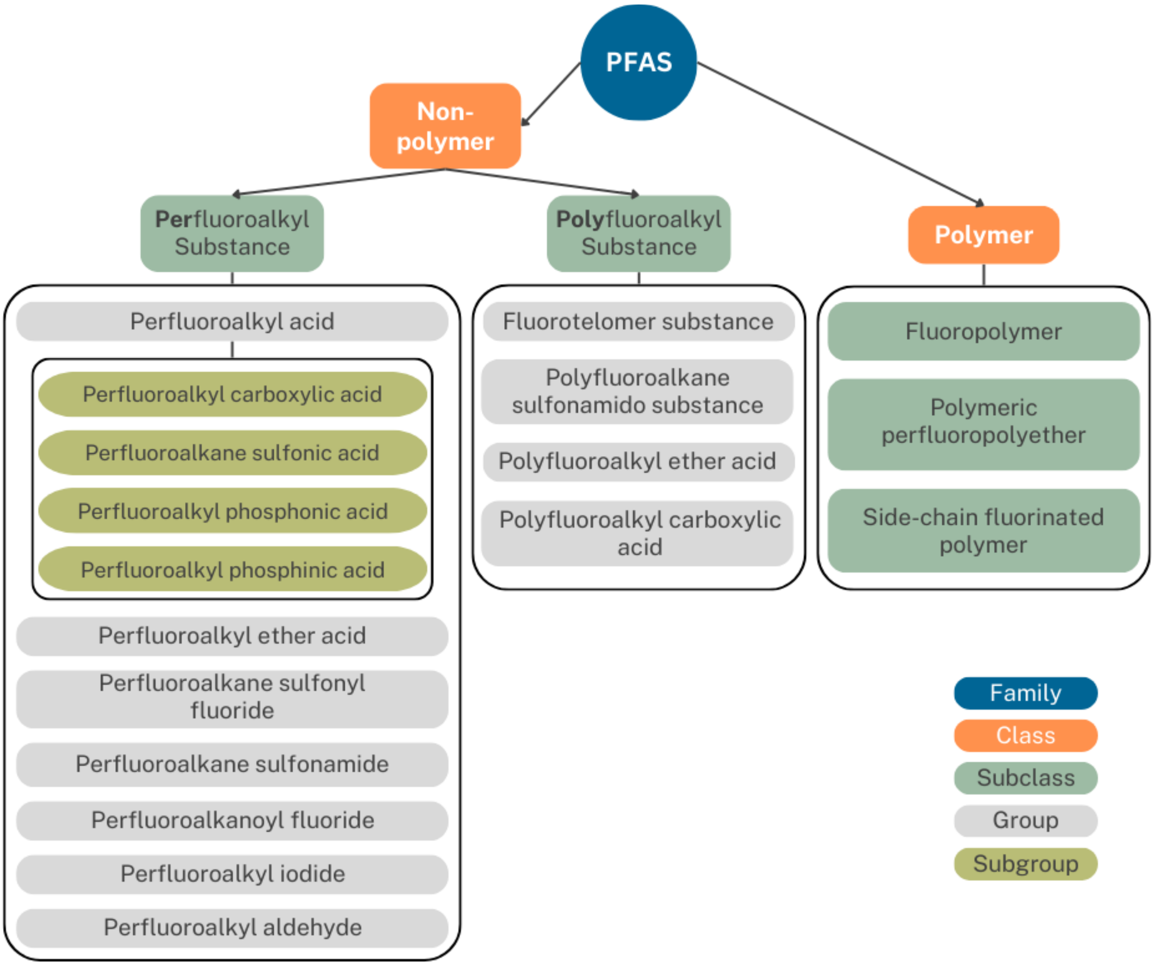

Figure 1: PFAS (sub)classes and (sub)groups. Created in Canva and adopted from the Interstate Technology and Regulatory Council.[27,28]

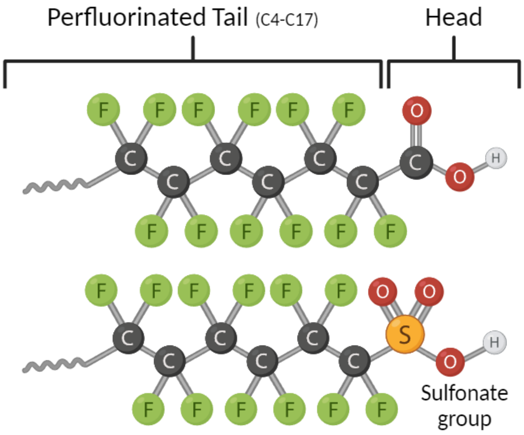

Figure 2: General chemical structures of common non-polymeric PFASs. Created in BioRender.[26,29]

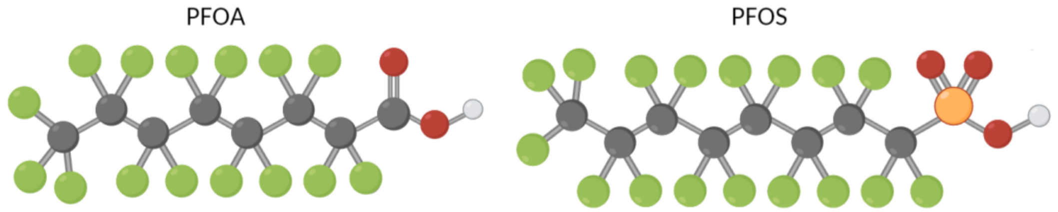

Figure 3: Chemical structures of PFOA (left) and PFOS (right). Atom colours correspond as depicted in Figure 2. Created in BioRender.[26,29]

Polymeric PFASs are placed in their own class and are often solid plastic-like materials. The class "polymer" is termed here as stated in the ECHA Guidance for monomers and polymers.[23] A polymer is then defined as a substance containing large molecules (polymer molecules) which consist of a sequence of at least three repeating smaller chemical units (monomers) and are distributed over a range of molecular weights. Their larger size and therefore higher molecular weight make their properties differ from smaller, low molecular weight non-polymers. The properties of the polymers themselves can vary greatly as well, depending on their molecular weight distribution, giving them great versatility.[23] Polymeric PFASs subclasses consist of side-chain fluorinated polymers (SCFPs), perfluoropolyethers (PFPEs) and fluoropolymers (**Figure 1**).[28] SCFPs have a non-fluorinated polymer backbone and fluorinated side-chains (**Figure 4**).[30] PFPEs have a fluorinated polymer backbone containing ether linkages (C-O-C) (**Figure 5**). Fluoropolymers are the most often used polymeric PFASs and have carbon backbones which have been fully fluorinated.[22] The most well-known and extensively used fluoropolymer is polytetrafluoroethylene (PTFE, a.k.a. Teflon) (**Figure 6**).

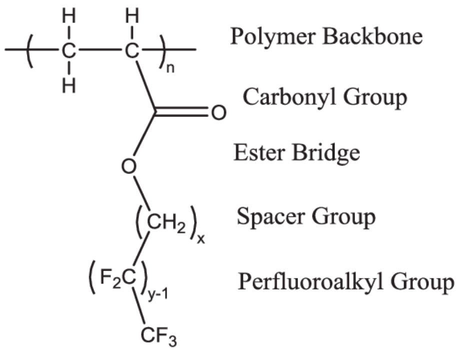

Figure 4: General chemical structure of SCFP.[31]

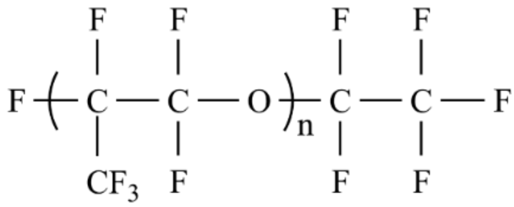

Figure 5: General chemical structure of PFPEs.[31]

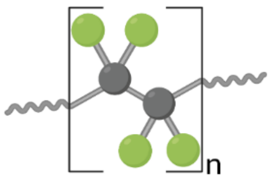

Figure 6: Chemical structure of PTFE, consisting of fluor (green) and carbon (grey) atoms. Created in BioRender.[26,29]

To conclude, the general physicochemical properties of PFASs can be summarised as follows: they are **extraordinarily strong and stable** causing **high chemical and thermal resistance**, they are **hydrophobic** and **oleophobic**, have **low adhesive forces** causing them to be **non-stick** and **great versatility** is possible with polymeric PFASs as their properties are tuneable by molecular weight. Thanks to these useful properties, PFASs are applied within a large variety of industries, such as the food and pharmaceutical industries, and have a vast amount of uses.[22] The use categories that will be examined in this report are FCM, packaging and cosmetics, which will be done in Chapter 3. Knowing that PFASs are used for a considerable sum of applications, meaning they are present almost everywhere, it is key to know their effects on the environment and our health to determine their impact.

2.1 Environmental Effects of PFASs

To determine their effect on the environment, PFAS presence, mobility, and toxicity are of value. PFASs are man-made chemicals, which do not occur naturally and were first manufactured in the 1950s.[32] However, research has shown that PFASs are now present everywhere in the environment, meaning excessive emission by humans must have occurred.[33–37] The release of PFASs into the environment occurs during their production, use and disposal (**Figure 7**), in varying degrees depending on the application and PFAS type.[38] Their spatial distribution depends on how they have been released (via air, water, or soil) and their physicochemical properties (e.g. water solubility, vapour pressure, critical micelle concentration), which determines whether adsorption or absorption takes place (e.g. in dust or sediments) versus transport in air or water.[38,39] The high mobility of certain PFASs causes long-range transport on a global scale, making it that they are even found in remote areas like the Artic.[40]

PFASs are known as the forever or eternity chemicals. This is because of the extraordinarily strong and stable C-F bond, which was introduced earlier. This strength and stability bring resistance against chemical and thermal degradation, making the PFASs themselves or their degradation products (a.k.a. arrowheads) extremely persistent.[41] The persistence is one of the reasons PFASs are proposed to be restricted, as it means the concentration of PFASs in the environment will only increase due to the continued emissions and limited degradation.[6] However, persistence on its own is often not seen as an intrinsic hazard, but in combination with other effects, it can cause catastrophic damage. The persistence and the fact that PFASs are amphiphilic and oleophobic causes many PFASs to be bioaccumulative.[15] Bioaccumulation is defined as the intake of a substance and its concentration in an organism, so a net result of uptake and release.[42] PFASs are predominantly absorbed via the roots of plants and bind to proteins, accumulating in protein-rich environments.[43,44] However, the data currently available on their bioaccumulation potential has been deemed insufficient to substantiate bioaccumulation for all PFASs.[6] The bioaccumulative nature of the PFAS depends on three physicochemical parameters, their water solubility, vapour pressure, and critical micelle concentration, which directly correlate to their functional group(s) and chain length.[15,45–47]

A separate comment addressing the bioaccumulation potential of polymeric PFASs should be made. They are thought to be less readily absorbed, as their high molecular weight could inhibit cell membrane crossing.[24] However, researchers like Lohmann et al. beg to differ.[48] Even if they cannot, they can still contain non-polymeric PFAS impurities, used as reagents or polymerisation aids, which have been proven to bioaccumulate.[30,48] The polymeric PFAS type matters as well. SCFPs can hydrolyse, severing their fluorinated side chains, therefore being a continuous source of non-polymeric PFAS, namely perfluoroalkyl acids.[49–52] The tendency for SCFPs to contain impurities has also been proven, therefore their ability to be a precursor for bioaccumulating toxic non-polymeric PFASs is evident.[30] PFPEs however do not seem to degrade under environmental conditions, as a study by Tsuda et al. found negligible amounts of low molecular weight species during degradability tests on DEMNUM, a typical PFPE polymer.[53] The research on the environmental effects of PFPEs is however limited and shows knowledge gaps.[54] More studies have been done on fluoropolymers, which are insoluble in water and have been shown not to degrade in the environment.[55,56] However, to fully assess and manage fluoropolymers, their entire life cycle should be taken into account. The emissions of harmful substances (e.g. unreacted monomers, oligomers, polymerization aids, degradation products, other unintended by-products) during manufacturing and incineration should be monitored more closely, as crucial data is lacking. For all these polymeric PFASs, it remains that they will end up in our environment in some fraction, in some way. Even if they show no degradation and seem safe now, their effect in the far future can be questioned.

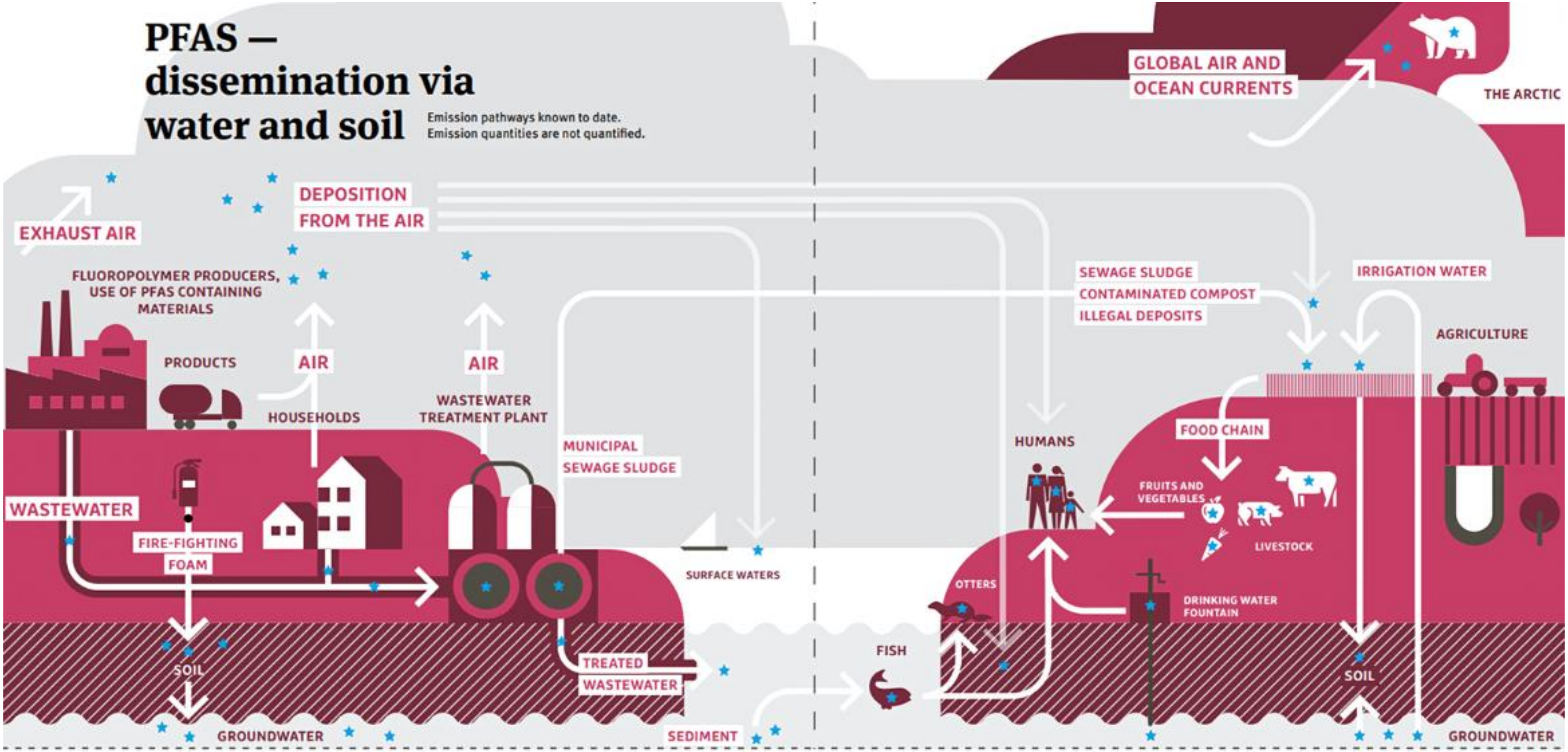

Figure 7: Known PFAS emission pathways showing how PFASs end up in the environment and our food chain. Image taken from the Federal Environment Agency.[57]

Besides their persistence, mobility, and bioaccumulation, some PFASs also contribute to global warming and are phytotoxic. The presence of pollutants like PFAS inhibits the ability of the ocean to act as a proper sink for CO_2, leading to an increase of atmospheric carbon which contributes to global warming.[58] This is due to the oceans being natural reservoirs for CO_2, playing an important role in the carbon cycle and regulating climate change. PFASs disrupt this by inhibiting the uptake of CO_2 by settling on the ocean floor and by perturbing biological activities in e.g. plankton. PFASs can bind to and activate PPARα (receptor protein), causing a conformational change.[59,60] PPARα modulates the expression of genes involved in fatty acid uptake, activation, and oxidation. PFAS exposure therefore induces an overgeneration of reactive oxygen species (a.k.a. oxidative stress), e.g. H_2O_2, $^{\bullet}O_2$ and $^{\bullet}OH$, which damages plant cell structure and organelle functions.[61] Biochemical activities, such as photosynthesis, protein synthesis, and carbon and nitrogen metabolisms, are then perturbed. This is why PFASs are considered phytotoxic and how they inhibit plankton to absorb CO_2. Apart from their influence on the carbon cycle, fluoride gases are also some of the strongest greenhouse gases as some have a Global Warming Potential (GWP) thousands of times higher than CO_2.[62,63]

Now that PFASs are everywhere, it is key to know how to remove them. Even though removal is an end-of-pipe solution and not a (more effective) source approach, it is still relevant as when PFASs are banned, they will still be in the environment due to their persistence. The removal of PFASs from water and soil is complex and costly.[64,65] This is because of the large sum of parameters (e.g. PFAS concentration, PFAS mixture, medium pH, presence of other contaminants) that need to be taken into account.[66] When treating groundwater contamination the "pump and treat" method where the contaminated groundwater is pumped up and treated with e.g. activated charcoal is often used. This method is however not effective in removing all PFASs and the regeneration of the sorbent is expensive. Current remediation methods for contaminated soils also have limitations. The simplest method, excavation and landfilling, is often impossible due to the lack of landfill space. Alternative treatment methods (e.g. large-scale soil washing, immobilization of PFASs, other in-situ remediation methods) are not technically ready. A relevant concern is therefore that PFAS contamination could be poorly reversible or even irreversible, and may reach levels that could render natural resources such as soil and water unusable in the future if emissions are not depressed.[67]

To conclude, if their release is not minimised, the presence of PFASs in the environment and our exposure to them will continue to increase, as they are very **persistent**, **mobile** and **difficult to remove** from contaminated soil and water. This is an unwanted situation, as their negative effects on the environment in the form of **bioaccumulation**, **phytotoxicity** and **global warming** will therefore increase as well. Their toxic effects on animals and humans are another large concern that becomes imminently more prominent thanks to this increased presence, which will be discussed in the next subchapter.

2.2 Health Effects of PFASs

Besides their negative effects on the environment, PFASs also influence the health of wildlife. To get a grasp on their ecotoxicological data, the ECOTOX Knowledgebase can be used.[68] An extensive collection of almost 300 studied PFASs can be found here, with most records being present for PFOA and PFOS. This database shows that PFASs have negative health effects on a variety of creatures, such as amphibians, birds, fish, reptiles, mammals, and more. These effects are present in the form of a reduced growth rate, reproductive toxicity, cholesterol accumulation, reduced egg hatching and more, therefore reducing the quality of life and overall survival rate of these animals.[69–71]

The relative toxicity of non-polymeric PFASs can to some extent be predicted, as it is influenced by the chain length and functional head group.[72,73] Multiple studies show a trend with long-chain PFASs being more toxic than PFASs with shorter chains, with a maximum residing around a chain length of 8 to 10 carbon atoms.[74–79] With regards to the head group, mixed messages were found about the relative toxicity of sulfonates versus carboxylates with similar chain lengths. The effect of the functional head group on toxicity seems to also heavily depend on the investigated species. This shows that although quite some research on the toxicity of PFASs has been done, comparison of the toxicity across PFAS species is difficult, due to differences in elimination half-lives, species, measurement of exposure levels and a lack of mechanistic data.[59]

Humans are also affected, as they get exposed to PFASs daily via ingestion, inhalation, hand-to-mouth contact, but also via dermal exposure.[38] Sources can arise from swallowing contaminated drinking water, foods, soil or dust, breathing contaminated air, using PFAS-containing consumer products such as pans and treated textiles, and packaging materials. Estimates of exposure media and routes collected by De Silva et al. are stated in **Table 8** in the Appendix, Chapter 0. From this study, it was concluded that the main exposure routes are dietary and water ingestion, which have been indicated to readily absorb perfluoroalkyl acids.[80] Less is known about their absorption after inhalation or dermal exposure.

The European Food Safety Authority published a scientific evaluation of the risks to human health related to PFASs in food.[81] They concluded that the main contributors to dietary exposure are 'Fish meat', 'Fruit and fruit products' and 'Eggs and egg products'. The European Food Safety Authority set a new safety threshold for the main accumulating PFASs, PFOS, PFOA, perfluorononanoic acid (PFNA) and perfluorohexane sulfonic acid (PFHxS), according to a Tolerable Weekly Intake (TWI). The TWI represents the amount of a substance that can be consumed during an entire life without having a significant negative effect on your health. The grouped TWI for these four PFASs was determined to be only 4.4 nanograms per kilogram of body weight per week. The National Institute for Public Health and the Environment of the Netherlands (Dutch: Rijksinstituut voor Volksgezondheid en Milieu, RIVM) concluded a risk assessment of exposure to PFASs through food and drinking water in the Netherlands. This study showed that the exposure the average Dutch consumer experiences is currently above the TWI (**Figure 8**, indicated by the bars surpassing the red line), meaning that for most of us, our health has already been negatively affected.[82]

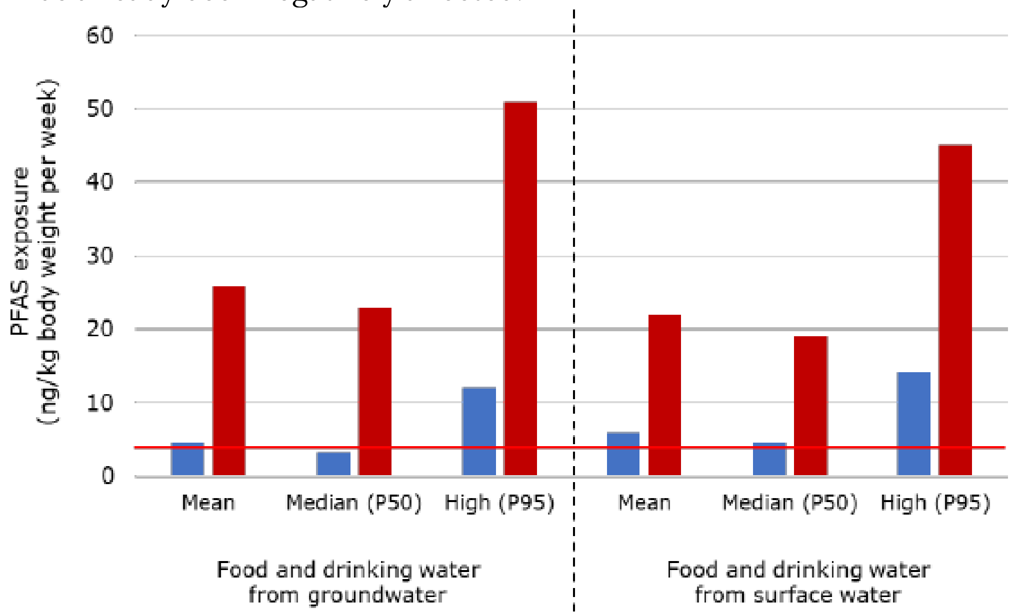

Figure 8: Mean, median (P50= 50th percentile), and high (P95= 95th percentile) lower bound (blue bars) and upper bound (red bars) long-term exposure to PFAS, through food and drinking water for the Dutch consumer aged 1-79 years. The TWI is indicated with the red line. Image taken from RIVM.[82]

Due to the constant exposure and therefore absorption, PFASs are omnipresent in humans, meaning that PFASs are present in (almost) every human's blood.[38] PFAS concentrations in humans depend on factors such as distance to contaminated sites, geography in general, sex and age. The concentrations vary from a few micrograms per litre to more than thousands of micrograms per litre for exposed occupational workers.[83,84] A recent review by Rosato et al. found that the estimated mean elimination half-lives in humans ranged from 1.48 to 5.1 years for PFOA, from 3.4 to 5.7 years for PFOS, and from 2.84 to 8.5 years for PFHxS.[85] Seeing the increasing exposure and long half-lives, PFAS concentrations in human blood will only increase, therefore creating a higher potential for long-term, intergenerational, adverse health effects.

When looking at the health effects on humans, multiple epidemiological studies have been done to prove adverse effects related to the exposure of (specific) PFASs, such as reduced immune function, insulin dysregulation, liver damage, increased cholesterol, different types of cancer, decreased reproductive health, and adverse developmental effects for unborn children (e.g. reduced response to vaccines and lower birth weight).[86–92] Even if PFASs are phased out completely at this moment, their effects will long linger, as exposure to offspring is unavoidable. In both humans and animals, PFASs are transferred to the foetus via the placenta and to the offspring via breast milk.[93–95] An overview of the adverse health effects PFASs have on humans is visually represented in **Figure 9**.

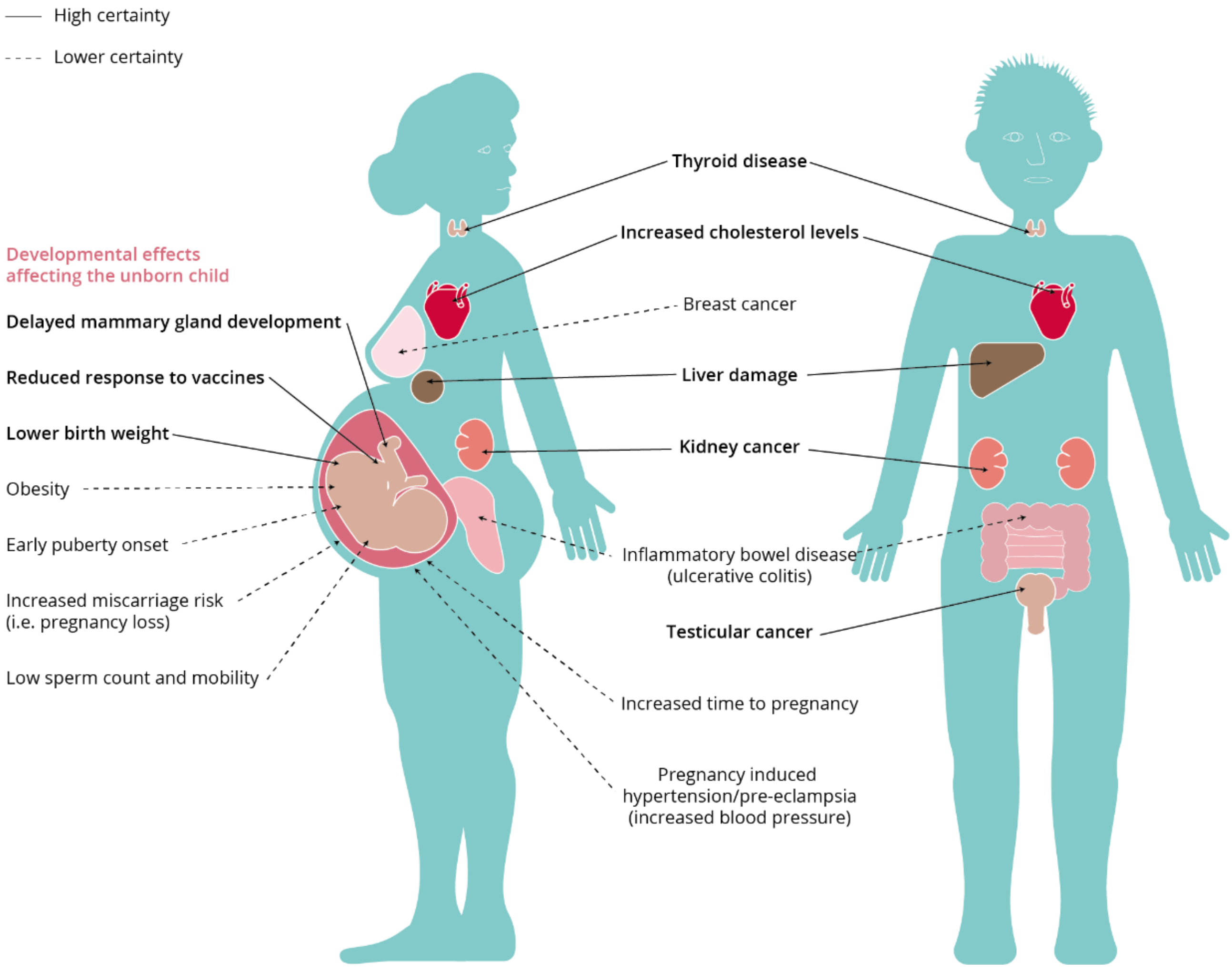

Figure 9: Adverse health effects of PFASs on humans. Image from the European Environment Agency.[96]

For the legacy PFASs, PFOA and PFOS, the adverse health effects are clear due to the fast amounts of studies, making it that they received official classifications. PFOA is classified as "carcinogenic to humans" based on "sufficient" evidence for cancer in experimental animals and "strong" mechanistic evidence in exposed humans.[97,98] PFOS is classified as "possibly carcinogenic to humans" based on "strong" mechanistic evidence. Although the data on other PFASs is lacking, studies that go beyond PFOS and PFOA have already reported similar adverse health effects.[99–102] Therefore there is a growing concern for the harmful effects of the complete PFAS family and why the substitution of one PFAS recognized as hazardous by another possibly equally hazardous PFAS with unknown toxicity is not a suitable solution.[49] A solution is found in the regulation of PFASs as a whole, with a switch to fluorine-free substitutes.

The health effects of polymeric PFASs are less clear. SCFPs are precursors of toxic non-polymeric PFASs, as stated earlier. PFPEs on the other hand seem like a safe material, but the carboxylic acid form has shown toxicity.[103,104] The research on the health effects of PFPEs is limited and shows clear knowledge gaps, so a clear conclusion cannot be drawn.[54] Toxicology studies on PTFE, a fluoropolymer, have shown an absence of systemic toxicity, irritation, sensitization, in vitro and in vivo genotoxicity and more, making it that it is even used in medical applications.[24] There is however no clear evidence that this holds for all fluoropolymers.

The **persistence**, **mobility**, and **bioaccumulation** of PFASs, combined with their related **high exposure levels** and **toxicity** show a **clear threat to our health and the environment**. Significant societal costs are expected from their continued use and emissions in the form of loss of natural resources, environmental quality and functioning, as well as health and remediation costs.[67] Even though studies relating to their negative health effects are far from done, as there are presumably additional currently unknown adverse health effects present and long-term effects are principally unknown, it is clear that they **need to be phased out as soon as possible**.

3 Uses of PFASs

Due to their various and desirable properties, PFASs are used for a variety of applications in thousands of tonnes per year globally in different industries (**Figure 10**).[6,22] However, to keep the scope of this report achievable within the set timeframe, only the use categories FCM, packaging and cosmetics will be examined. These categories, although not employing the most tonnes of PFAS annually, were chosen as they in some part all relate to consumer products. Consumer products come into close contact with our bodies creating explicit exposure and into the hands of the public where specialised waste management is often not an option. This means it that even in small quantities, PFASs can form a large risk in these applications. These subcategories also fit well with the organisation the internship is housed in, namely the product safety team within the Department VGP of the Ministry of VWS. This team is also mainly focused on consumer products, in the form of toys, fire safety of furniture, playground equipment, but also packaging and cosmetics.

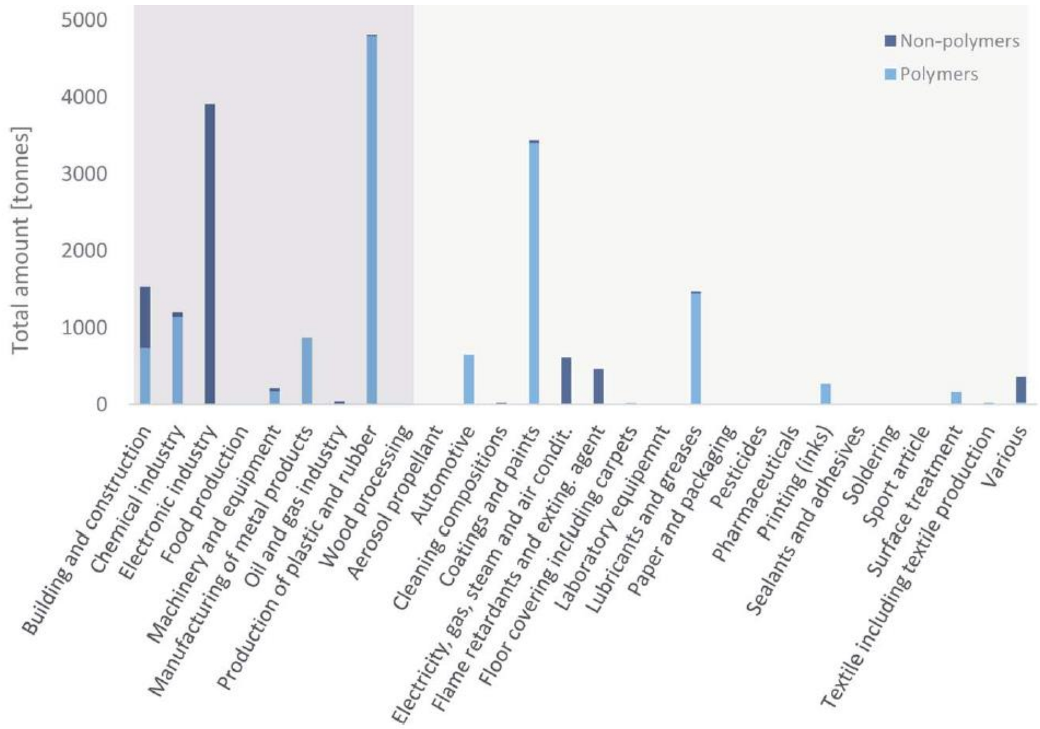

Figure 10: Amount of PFAS used per category in Sweden, Finland, Norway, and Denmark from 2000 to 2017. The grey background indicates industrial branches and the white background all other brances.[22]

3.1 Uses of PFAS in Food Contact Materials

PFASs are used within FCM applications due to their repellent properties, which makes them water and oil repellent, but also non-stick.[105] This makes them an ideal material to prevent water and oil leaks and food from sticking to the used equipment. FCM are materials meant to get into contact with food, however, the packaging of food is kept separate from this category in this report. The use category FCM is divided into two subcategories, consumer cookware and industrial applications. For consumer cookware, uses that the public has access to are represented. For industrial applications, the equipment to produce food and feed at an industrial scale is represented.

Fluoropolymers are often used for consumer cookware as a non-stick coating as they are also heat resistant and do not conduct electricity.[106,107] This makes it so that they can endure high heat during cooking and can be applied in electrical appliances. PFASs are used for pans, baking trays, cooking plates in appliances (e.g. toastie grills), consumer bakeware (e.g. cake tins, bread-loaf tins), filters to capture contaminants in food processing and seals, O-rings, gaskets, tubing, and pipes in electrical equipment (e.g. coffee machines).[6,105]

PFASs are used in industrial applications to enhance productivity, by preventing clotting, making clean-up easy or enabling hygienic conditions, thanks to their non-stick properties (giving them long-lasting oil and grease-free mould release) combined with their non-chemical reactivity, thermal resistance, and wear resistance.[105] They are often used to provide a non-stick coating to conveyor belts and to be processed into valves and fittings for commercial food and feed products. Other applications include release agents, piping, tubing, filters, seals, O-rings, gaskets, expansion joints, chutes, guiding rails, rollers, funnels, sliding plates, tanks, linings, blades of knives and scissors, springs, sensor covers, lubricants and re-coating of industrial bakeware.[22]

PFASs often used for FCM applications in consumer cookware and industrial applications are fluoropolymers (PTFE, fluorinated ethylene propylene (FEP), perfluoroalkoxy alkanes (PFA), polyethylene tetrafluoroethylene (ETFE), polyethylene-chlorotrifluoroethylene (ECTFE), polyvinylidene fluoride (PVDF) and (per)fluoroelastomers (FKMs)), and PFPEs.[22,105]

3.2 Uses of PFAS in Packaging

In packaging, PFASs are introduced in or on plastics, paper, and board to repel grease, stains, and water. This property is of importance in the food packaging industry, in which oil and water might leak from the food during preparation, transport and storage or for which temporary portable packaging is used. Certain feed packaging applications also require grease and water resistance to maintain the quality of dried pet food or agricultural feed. Generic packaging also benefits from the addition of PFASs, as the product will be protected from liquids or humidity entering the package. Below, a list of uses per subcategory is stated.

Food & feed packaging: Greaseproof paper (e.g. fast-food wrapping), baking paper, heat-resistant packaging, other food packaging (e.g. milk containers, stretch and shrink films, pouches, frozen food packaging), disposable foodware (e.g. paper plates, bowls, ice cream tubs), coating of food and beverage cans, pet food and agricultural feed packaging.[22,105]

Generic packaging (all non-food/feed applications): Paper (e.g. masking paper, pressure sensitive paper, wallpaper, tablecloths), paperboard (e.g. folding packaging cartons) and coated plastic glass or metal containers and plastic films.[22,105]

PFASs often used within food, feed or generic packaging applications are fluoropolymers (PTFE, FEP, PFA, FKMs), PFPEs, perfluoroalkyl phosphonic acids, perfluoroalkyl phosphinic acids, polychlorotrifluoroethylene and polyfluoroalkyl phosphate esters (PAPs).[112,105]

3.3 Uses of PFAS in Cosmetics

It might be unexpected, but PFASs are also present in cosmetics. They are added to condition and smooth hair and skin, create a shiny appearance or affect the consistency and texture of the mixture.[114] Cosmetic products are defined as any substance intended to be placed on the external parts of the human body or within the oral cavity, to clean them, perfume them, change their appearance, protect them, keep them in good condition or correct body odours.[115] PFASs are used intentionally in various categories of cosmetics as emulsifiers, antistatics, stabilisers, surfactants, film formers, solvents, skin conditioning, binding and viscosity regulators. Based on the analysis of three European cosmetic databases (CosIng, Kemiluppen, and CosmEthics) by the submitters of the PFAS restriction dossier, 42 PFASs were present in cosmetic products, among which PTFE and C9- 15 fluoroalcohol phosphate were most often found. The market share of PFAS-containing cosmetic products ranged from 1.1 to 1.3%. An analysis of this market share revealed that most occurred in decorative cosmetics (3.67%), followed by skincare (0.78%), hair care (0.65%), toiletries (0.27%) and lastly perfumes and fragrances (0.03%).[116,117]

The main PFASs identified within cosmetics were PTFE, C9-15 fluoroalcohol phosphate, perfluorodecalin, perfluorooctyl triethoxysilane, perfluorononyl dimethicone, polyperfluoromethylisopropyl ether, octafluoropentyl methacrylate, acetyl trifluoromethylphenyl valylglycine, methyl perfluorobutyl ether and PAPs.[22,105,110,111]

To summarize, PFASs are used within **FCM** in **consumer cookware** and **industrial applications** due to their water- and oil-repellent, non-stick, non-electricity conducting and high thermal resistance properties. They are used within **packaging** in **food**, **feed** and **generic packaging** for similar reasons. Mainly thanks to their water and oil repellency, to protect food during transport, from moisture and to be grease stains proof. Finally, for their use within **cosmetics**, they are used to improve the condition of hair and skin or to affect the product mixture consistency. Within all these categories **fluoropolymers**, most commonly PTFE, are often identified.

4 PFAS Related Legislation

The current irreversibility of the increasing concentration of PFASs in the environment, with the related exposure to humans and other organisms, makes it necessary to reduce emissions to a minimum to eliminate their presence and thereby their negative effects. PFAS emissions can be diminished via a regulatory way, by setting a restriction on the maximum concentrations or by a complete ban on the substances. In this chapter, the current regulatory measures, the EU restriction proposal, and the responses to this proposal relating to PFASs will be delved into.

4.1 Current Regulatory Measures

Several regulatory measures are already in place for PFASs. They are either in the form of a regulation, which is directly applicable in Member States after entry into force, or a directive, which must first be transposed before it is applicable in Member States.[112] A summation of these can be found below and a concluding note is stated at the end of this subchapter.

The **Stockholm Convention** is a global treaty to eliminate or restrict the production and use of Persistent Organic Pollutants (POPs) to protect human health and the environment.[113] POPs are persistent, widely distributed, bioaccumulative, and harmful to human health and/or the environment.[114] PFOS, PFOA and PFHxS are listed in the Stockholm Convention.[115] PFOA and PFHxS, their salts and related compounds (e.g. derivatives) are listed for elimination, meaning their production and use must be eliminated. PFOS, its salts and perfluorooctane sulfonyl fluoride are listed for restriction, meaning their production and use must be limited. Long-chain perfluorocarboxylic acids (C9-21), their salts and related compounds are being considered for inclusion. The Stockholm Convention is implemented in the EU via the **POPs Regulation** (Regulation (EU) 2019/1021).[116] PFOS, PFOA and PFHxS are therefore included, making their manufacturing, placing on the market and use in the EU prohibited.

The **Classification, Labelling, and Packaging Regulation** (Regulation (EC) No 1272/2008) ensures a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles.[117,118] It is the only EU legislation for the classification and labelling of substances and mixtures. When relevant information on a substance or mixture meets the classification criteria, the hazards are identified by assigning a hazard class (physical, health, environmental and additional hazards) and category. Once a substance or mixture is classified, the hazards must be communicated with labels (pictograms, signal words or standard statements) and safety data sheets. PFOS and its sodium salts; PFOA; ammonium pentadecafluorooctanoate; PFNA and its sodium and ammonium salts; perfluorodecanoic acid (PFDA) and its sodium and ammonium salts; perfluoro-heptanoic acid (PFHpA) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol are classified.[117]

The **Cosmetic Products Regulation** (Regulation (EC) No 1223/2009) establishes rules for cosmetic products made available on the market, to ensure internal market functioning and protection of human health.[124] PFOS and its salts (Ref. #1493); PFOA (Ref. #1561); PFNA and its salts (Ref. #1636); and PFHpA (Ref. #1705) are prohibited and therefore included.

Substances listed in the **plastics materials and articles intended to come into contact with food Regulation** (Commission Regulation (EU) No 10/2011) are allowed to be used as monomers or additives for FCM.[119] Migration limits or use restrictions are set for several PFASs, e.g. PFOA and 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid (HFPO-DA a.k.a. GenX).

The **maximum levels for certain contaminants in food Regulation** (Commission Regulation (EU) 2023/915) does not allow foods that exceed the maximum levels given to be placed on the market, used as raw material or mixed with others.[120] It limits the amount of PFOS, PFOA, PFNA, PFHxS and their sum allowed in several food items, including meat, fish and eggs.

The **Drinking Water Directive** (Directive (EU) 2020/2184) aims to protect citizens and the environment from the harmful effects of contaminated drinking water and to improve access to drinking water.[121] Due to the high solubility of some PFASs in water, high levels of them have been detected. Chemical parameters for a list of 20 PFASs are therefore included with a limit value of 0,50 µg/l for 'PFASs Total' and 0,10 µg/l for 'Sum of PFASs'.

Active substances in **plant protection** (Regulation (EC) No 1107/2009[122]), **biocidal** (Regulation (EU) No 528/2012[123]) and **human and veterinary medicinal products** (Directive 2001/83/EC[124] & Regulation (EC) 726/2004[125]) are regulated by an approval system. Meaning they can only be marketed with authorization, which some PFASs have. Plant protection products protect plants and crops against weeds, diseases, and pests. Biocidal products control fungi, pests, or organisms. Human and veterinary medicinal products are for the protection from diseases. Due to extensive evaluations and approval processes within the regulations and the importance of PFASs in these applications, the use as active substances in plant protection, biocidal and medicinal products are excluded from the EU PFAS restriction proposal.

The **Montreal Protocol on Substances that Deplete the Ozone Layer** (Regulation (EC) No 1005/2009) is an environmental agreement.[126,127] Ozone-depleting substances, when released into the atmosphere, damage the ozone layer, letting in harmful levels of UV radiation from the sun. The protocol regulates the production, import, export, placing on the market, use, recovery, recycling, reclamation, and destruction of these substances. The protocol predominantly covers chlorofluorocarbons, which are used in refrigeration, air-conditioning and foam applications, and powerful greenhouse gases. Hydrofluorocarbons were used to replace these substances as they do not impact the ozone layer.[128] However, hydrofluorocarbons are powerful greenhouse gases, so an amendment (the Kigali amendment) was added in 2019 to the Montreal Protocol to regulate the consumption and production of hydrofluorocarbons.[129,130]

The **Regulation for Fluorinated Greenhouse Gases** (Regulation (EU) No 517/2014) aims to reduce CO_2 emissions from industry by 70% in 2030 compared to 1990 by phase-down of quantities, prohibitions on use and placement on the market, continuation and expansion of leak test, certification, disposal and labelling regulations.[131] It lists several hydrofluorocarbons and perfluorocarbons.

The **Mobile Air-Conditioning Directive** (Directive 2006/40/EC) prohibits the use of F-gases with a GWP of more than 150 in new types of cars and vans introduced from 2011 onwards and in all new cars and vans produced from 2017.[132]

The **Registration, Evaluation, Authorisation and Restriction of Chemicals** (REACH) **Regulation** (Regulation (EC) No 1907/2006) is there to improve the protection of human health and the environment from the risks posed by chemicals while enhancing the competitiveness of the EU chemicals industry.[133],[134] It is guided by ECHA, which is an agency that carries out technical, scientific, and administrative tasks related to the implementation of EU chemical legislation and policy. When a manufacturer or importer brings a new substance to the market in quantities of one tonne or more per year, its risks must be identified and managed. This must be demonstrated in a registration dossier submitted to ECHA.[135] ECHA checks if the registration dossier complies with the regulations, supplies a proper testing proposal and provides adequate information. If the substance is found to be too hazardous, it is identified as a Substance of Very High Concern (SVHC) by meeting the criteria for classification as:

- carcinogenic, mutagenic or toxic for reproduction (CMR);
- persistence, bioaccumulative and toxic (PBT);
- very persistent and very bioaccumulative (vPvB);
- or on a case-by-case basis for those that cause an equivalent level of concern (ELoC) as CMR, PBT or vPvB substances.

If identified as SVHC, the substance will be included in the Candidate List of SVHC for Authorisation.[136,137] Substances subject to Authorisation are listed in Annex XIV to the REACH Regulation.[134] Once included, a substance cannot be placed on the market or used after a given date unless the companies are granted authorisation for their specific use. This is to ensure hazardous substances are progressively replaced by less dangerous substances or technologies where technically and economically feasible substitutes are available. The PFASs that are currently included in the Candidate List of SVHC for Authorisation can be seen in **Table 3.**[137]

Table 3: PFASs identified as SVHC for Authorisation under REACH.[137]

Year of inclusion	Substance	SVHC hazard properties
2012[138]	Perfluorododecanoic acid	vPvB
2012[139]	Perfluorotridecanoic acid	vPvB
2012[140]	Perfluorotetradecanoic acid	vPvB
2012[141]	Perfluoroundecanoic acid	vPvB
2013[142]	PFOA	CMR (toxic for reproduction) & PBT
2013[143]	Ammonium pentadecafluorooctanoate	CMR (toxic for reproduction) & PBT
2015[144]	PFNA and its sodium and ammonium salts	CMR (toxic for reproduction) & PBT
2017[145]	PFDA and its sodium and ammonium salts	CMR (toxic for reproduction) & PBT
2017[146]	PFHxS and its salts	vPvB
2019[147]	HFPO-DA (a.k.a. GenX), its salts and acyl halides	ELoC having probable serious effects to human health & the environment
2020[148]	Perfluorobutane Sulfonic Acid and its salts	ELoC having probable serious effects to human health & the environment & under assessment as PBT
2023[149]	Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine	PBT
2023[150]	PFHpA and its salts	CMR (toxic for reproduction), PBT, vPvB, ELoC serious effects to human health & the environment

The production and use of hazardous substances is also limited via REACH through a Restriction.[151] Member States or the European Commission may propose EU-wide restrictions on the manufacture, use or placing on the market of substances causing an unacceptable risk to human health or the environment. Restrictions are listed in Annex XVII to the REACH Regulation.[134] In the Appendix, Chapter 9.3, the REACH Restriction procedure is described.[152] Some PFASs are banned under this restriction, these are stated in **Table 4**. Some entries have been moved to avoid overregulation and administrative burdens, as the EU POPs regulation described earlier overrides the REACH restriction.[153]

Table 4: PFAS Restrictions handled under REACH so far.[134]

Year of submission	Scope	Location of the restriction
2006	PFOS ban.	Restriction moved to POPs Regulation. Digital registry not available.
2014	PFOA, its salts and PFOA-related substances shall not be manufactured, used, or placed on the market as substances on their own, as constituents of other substances, in a mixture or in articles.	Restriction moved to POPs Regulation.[154]
2015	A restriction on (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives in solvent-based spray applications for the general public.	Annex XVII, entry 73.[155]
2017	PFNA, PFDA, perfluoroundecanoic acid, perfluorododecanoic acid, perfluorotridecanoic acid, perfluorotetradecanoic acid; their salts and precursors shall not be manufactured, used, or placed on the market as substances on their own, as constituents of other substances, in a mixture or in articles.	Annex XVII, entry 68.[156]
2019	Restricting the use of intentionally added microplastic particles to consumer or professional use products of any kind (this includes particles of polymeric PFASs).	Annex XVII, entry 78.[157]
2019	Restrict the manufacture, use and placing on the market of PFHxS, its salts and related substances as substances, constituents of other substances, mixtures and articles or parts thereof.	Was not included as it was introduced in the POPs Regulation.[158]
2019	Perfluorohexanoic acid, its salts and related substances shall not be manufactured, or placed on the market as substances on their own, be used in the production of, or placed on the market in another substance, as a constituent; a mixture or an article, in from a certain concentration.	EU Member States voted in favour; regulation is being reviewed for final adoption.[159]
2022	Restricting the use of PFASs in fire-fighting foams.	Proposal waiting for decision making.[160]

To summarize, there are several regulations already in place restricting specific PFASs as POPs within the **Stockholm Convention** and **EU POPs Regulation**; with the **Classification, Labelling, and Packaging Regulation** to communicate hazards; within cosmetics via the **Cosmetic Products Regulation;** within the **plastic materials and articles Regulation** to limit them within FCM; within the **contaminants in food Regulation**; as contaminants within the **Drinking Water Directive**; within **plant protection**, **biocidal**, and **human and veterinary medicinal products**, going through extensive evaluations and approval processes via their corresponding Regulations; as ozone-depleting substances within the **Montreal Protocol**; as **fluorinated greenhouse gases** (within cars); and within the **REACH Regulation** which manages the risk of chemicals by identifying hazardous ones as **SVHC**, and setting in place **Authorisations** and **Restrictions**.

4.2 Proposed EU PFAS Restriction

As shown above, there is a lot of PFAS legislation already in place, however, there was a need for additional PFAS regulation in the form of an EU REACH Restriction on PFASs as a whole. This had multiple reasons. First, most of the regulations mentioned look at only one or a few uses/aspects, for example only at migration levels from plastic FCM to food (Plastic materials and articles intended to come into contact with food Regulation) or at health effects from cosmetics in direct contact with the human body (Cosmetic Products Regulation).[109,119] This means that even though PFASs do not cause direct harm in the relevant application (e.g. in cosmetics they might not cause direct harm when applied to the skin), they still end up in waste streams and eventually in our food chain where they can harm our environment and eventually our health. The full range of uses and effects can be included in a REACH Restriction, as is done in the EU PFAS restriction proposal. Secondly, most of the previously mentioned legislations follow a single-substance approach. Meaning that only one PFAS type fits within the scope. Via a group approach, as in the REACH PFAS Restriction proposal, a precautionary principle can be applied and the entire PFAS family can be included, making that regrettable substitution of one PFAS with another can be avoided (e.g. substitution of PFOA with GenX which has similar negative health effects). Lastly, it allows for the restriction to not just apply to the use stage, but also at the manufacturing stage, therefore tackling the problem at the source.

The proposed EU PFASs restriction has been submitted under a REACH Restriction regulation to ECHA by the Netherlands, Germany, Norway, Sweden and Denmark.[163] The scope contains all PFASs, defined as any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) group (without any H/Cl/Br/I attached to it). A few exceptions are made to this scope, namely substances that only contain some specific structural elements, as they are fully degradable and therefore do not form the same threat as other PFASs.[164] The conditions state that PFASs shall not be manufactured, used or placed on the market as substances on their own or in another substance, mixture or article. This shall apply 18 months after entry into force of the restriction. The following concentration limits are set:

1) 25 ppb for any individual PFAS (except polymeric PFASs), which will be compared with concentrations measured by targeted PFAS analysis. This currently covers about 40 PFASs, as it is limited by the availability of reference standards.
2) 250 ppb for the sum of PFASs, which applies to the sum measured with targeted PFAS analysis directly or after degradation of the sample. This is to address the risk of combined effects when several PFASs are present.
3) 50 ppm for PFASs, which applies if targeted analysis is not applicable, e.g. with polymeric PFASs. The total fluorine content is then analysed, which can include fluorine from non-PFAS sources. So, if the total exceeds 50 ppm, proof (supply chain information or analysis) for the fluorine measured being part of either PFASs or non-PFASs must be provided.

As a derogation, this shall not apply to fluoropolymers and PFPEs in FCM for industrial food and feed production until 6.5 years after entry into force. The non-stick coatings in industrial and professional bakeware are being reconsidered as potential derogations (until 6.5 years after entry into force), but the decision on this will be taken after the internship has been completed. Manufacturers, importers, and downstream users using these derogations must have a management plan. This plan must include information on the substances and products they are used in, a justification for their use, and details on the use and disposal conditions. The current timeline of the restriction proposal (**Figure 11**) and the derogations are relevant for further analysis and of special importance to the implementation as it indicates the time before the substitutions come into use. Please note that the timeline can still change due to uncertainties, as this is the first time such a large grouped scope is managed under REACH.

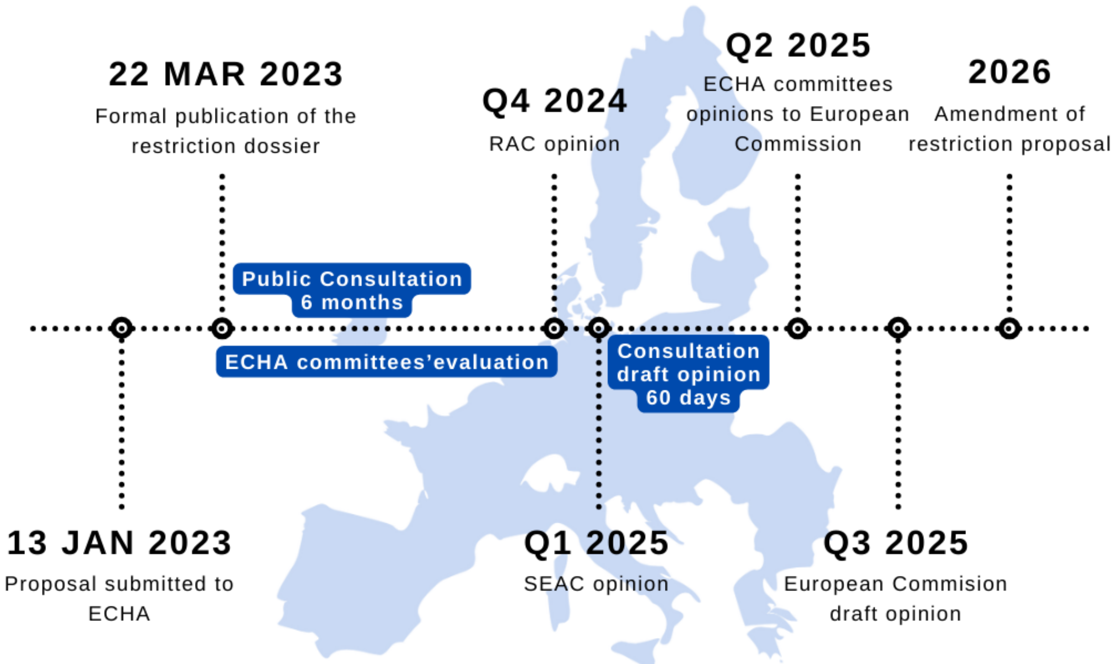

Figure 11: PFASs Restriction proposal dossier timeline.[161] Created in Canva.[29]

The restriction proposal contains numerous analyses of the PFAS market, uses, substitutes, and more. The dossier submitters in the end argument the proposed restriction is justified due to the extent of PFAS emissions (~4.5 million tonnes from the use stage alone in the next 30 years if no action is taken), the availability of suitable substitutes for many applications, the proportionality to the risk (societal costs associated with continued use will progressively increase and exceed the societal costs of a ban) and the transition period of 18 months (longer time-limited derogations for certain uses) allowing for selection, testing and implementation of appropriate substitutes. These conclusions are clear and rational but have been made with a focus on PFASs themselves. No extensive studies have been done on the possible hazardous effects of the available substitutes, particularly when compared to the relevant PFASs.

To conclude, a grouped **EU PFAS restriction** has been proposed with **clearly set conditions and concentration limits** to reduce the use of the entire PFAS family extensively and **avoid the regrettable substitution** of one hazardous PFAS with another. The **timeline** indicates that the amendment of the restriction proposal will happen in **2026**. However, as stated earlier, the REACH regulation is set to improve the protection of human health and the environment from the potential risks posed by chemicals. This means that if by banning all PFASs, regrettable substitutes become more regularly used, the broad objective of this policy is not achieved. Therefore, to avoid that in a few years' time we apprehend that a certain chemical is causing substantial harm, this knowledge gap should be filled.

4.3 Comments on the Proposed Restriction

By the end of the six-month consultation period (March 22nd till September 25th 2023), ECHA had received 5642 comments on the proposed restriction.[162] These comments ranged from a single word to hundreds of pages each. Comments could be handed in on behalf of an organisation (e.g. company, academic institution, non-governmental organisation (NGO), local authority), by an individual member of the public or Member State. Some provided detailed research data, others were confidential, and some were simply in favour of the restriction (e.g. reference numbers 3870, 3879, 3921, 3922). While many of these comments contain interesting views, and information (e.g. possible substitutes), only a portion of the comments could be analysed and those relevant to the scope of this report have been taken into account and are shown in the Appendix, Chapter 9.4. Conclusions and interesting ideas extracted from these comments are shared below or have been considered when drafting this report.

A substantial number of comments were given to request a derogation or exclusion of fluoropolymers. The reasoning came from the fact that the well-known fluoropolymers PTFE, ETFE, FEP and PFA have been shown to comply with the criteria for a Polymer of Low Concern (PLC) from the OECD, which "are those deemed to have insignificant environmental and human health impacts".[24,163] The PLC criteria vary, but the focus is on parameters that predict the ability of a polymer and its contaminants to cross cell membranes, bioaccumulate and be toxic (e.g. molecular weight, leachables, solubility, stability; **Figure 12**). That these fluoropolymers uphold these criteria is however argued by some to be predominantly due to the focus on the use stage, therefore not looking at the emissions or contaminants released during the manufacturing and their disposal, and not to be the case for all fluoropolymers as there can be a large variety in composition and grades on the market.[24,48,164] A second hesitation regarding these comments originates from the fact that the PLC criteria have not been officially accepted as a measure or tool that can be used for official legislation.

The contaminants in the form of unreacted reagents (e.g. monomers in the form of non-polymeric PFASs) or other PFASs used as processing aids are also frequently addressed in the comments. It is stated that unreacted monomers are most likely destroyed during the fluoropolymer use processing and that many fluoropolymers no longer require the use of fluorinated processing agents in manufacturing (e.g. by suspension polymerization of granular PTFE).[172] Therefore by restricting PFAS fluoropolymer processing aids, one of the key issues could be addressed, but it would not solve the problems regarding impurities present in fluoropolymers altogether.

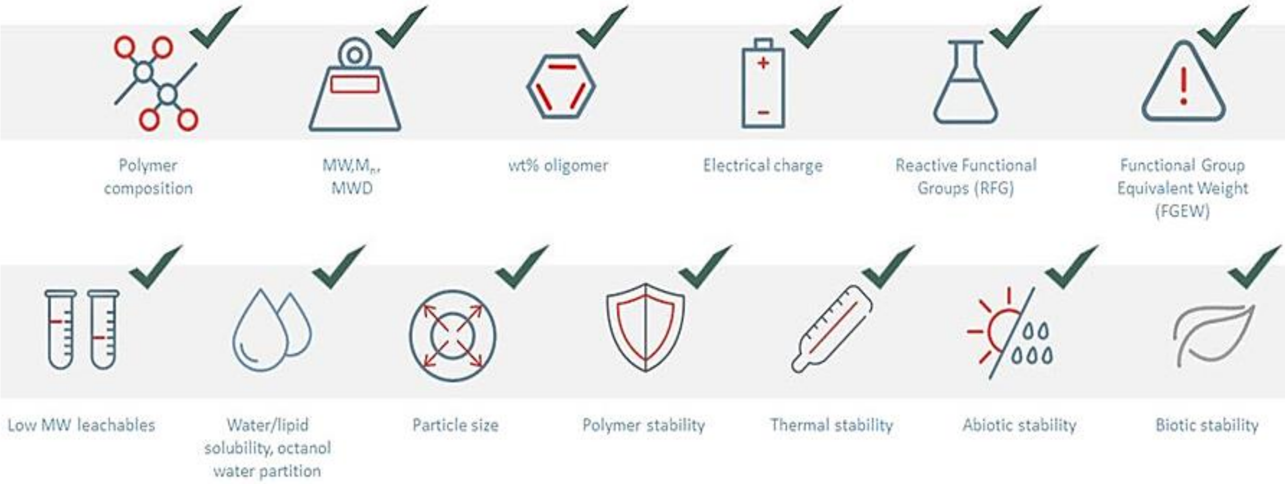

Figure 12: Visualization of often used PLC criteria.[164]

Finally, several comments address the disposal stage of fluoropolymers. Fluoropolymers may be disposed of via landfill, incineration, or recycling.[165] Landfill is not a sustainable disposal route, as this requires a lot of physical space, and recycling has been found to be difficult due to the PFASs often being present as a coating or as a small enclosed component. However, with incineration at high enough temperatures, fluoropolymers are often efficiently mineralized (i.e. all C–F bonds will break). The RIVM published a report in which it supposes that most PFASs, so also the possible contaminants and arrowheads, will largely degrade during the incineration process and be removed when the released gases are cleaned or when the carbon dioxide that was released is recovered.[166] For PTFE, the RIVM concluded that complete mineralization is achieved at temperatures above 800 °C after a couple of minutes.

To conclude, the **5642 comments** posted on the proposed restriction did bring about useful insights, primarily in the form of **arguments defending the use of fluoropolymers**, **addressing contaminants**, talking about **ways of disposal** (e.g. **incineration**), or **indicating possible substitutes**. However, most of these comments should be taken with a grain of salt, as these primarily originate from (fluoropolymer) industries themselves, which have a clear conflict of interest. To get an idea of the role industries sometimes play in the issue of PFASs, by lobbying of the chemical industry to influence the policy-making process, the American legal thriller film "Dark Waters" is an interesting movie to watch.[167] Therefore, these insights will be taken into account only if they are appropriately backed up further with scientific studies, such as with the incineration studies.

5 Stakeholders EU PFAS Restriction

If we look beyond the background information and at who is involved with the issues discussed within this report, starting with the problem of PFASs themselves and the corresponding EU PFAS restriction, several stakeholders can be identified and processed into a power-interest matrix (**Figure 13**).

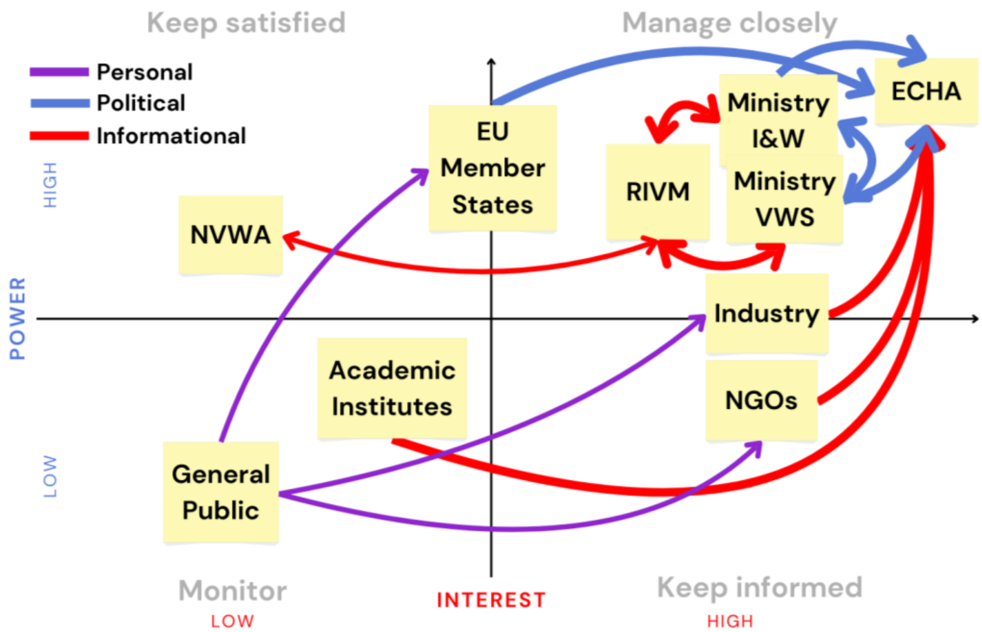

Figure 13: Power-interest matrix of the stakeholders involved with the PFAS problem and restriction, from the viewpoint of the Netherlands. The thickness of the arrows indicates the weight while the colours indicate the kind (top left legend) of input relationships between the stakeholders.

If we start at the bottom left of the power-interest matrix we can first see the **general public** as a stakeholder. All members of the general public are affected by the effects of PFAS, although the magnitude in which this occurs differs. Some are affected by direct exposure (e.g. living near a contaminated site), while others are affected by the downstream effects due to PFAS infiltrating and disturbing the food chain. Some members of the general public show an interest in the issues surrounding PFASs and the proposed EU restriction, as indicated by the number of comments posted on the restriction by individuals (~1500 comments), however, most are not aware or limited in knowledge on the issues. Therefore, being put at a **moderately low interest**. Although the general public has some power to influence political decisions, by for example voting for a specific party during elections, their influence is overall indirect and weak compared to other stakeholders. Therefore the general public was put at a **moderately low power**. Some members of the public do, for personal reasons, request NGOs, the industry and their Member State authorities to take action, as indicated by the arrows.

Moving up in the matrix, we find the **Netherlands Food and Consumer Product Safety Authority** (NVWA). The NVWA and other comparable parties from the other EU member states will have to enforce the restriction proposal, so they need to be kept informed and give their opinion on the enforceability of e.g. the concentration values to the relevant competent research institutes, such as the RIVM for the Netherlands. They therefore do have quite some say in the matter and are put at **moderately high power**, but are overall less invested as the restriction only becomes relevant for them in the final stage and after implementation, therefore being set at a **moderately low interest**.

Academic institutions, in the form of Universities and independent research institutes, are next. They conducted studies on the environmental and health impacts of PFAS contamination, thereby providing scientific information and evidence to ECHA to support the claims within the restriction proposal. There are also various researchers that specialise in PFAS or toxicity studies related to it, such as Dr Chuhui Zhang, Dr Martin van den Berg, and Dr Evangelia Ntzani.[168–170] So although they did not have a lot of direct influence, but did have critical input, they still have an **moderate power**. These institutions are often more interested in the result of their research and the academic value it has then how it influences policy-making, therefore having **moderate interest**.

When looking at parties with a higher interest, we find **NGOs**. Multiple NGOs, but most actively ChemSec and the European Environmental Bureau, are involved with the issues and restriction of PFAS.[171,172] They have actively lobbied against the use of PFAS and tried to supply information whenever possible for the proposed restriction to ECHA, therefore residing at a **high interest**. They have however less direct power on the matter, when for example being compared to a Ministry, as they are welcome at open discussions but are often less explicitly invited and can have less funds to lobby. They are therefore placed at **moderate power**.

Within the **industry,** different players can be identified among suppliers, manufacturers, downstream users, etc. The PFAS ban will have a direct effect on the industry, as it is a very common chemical family used within a multitude of industries, therefore they have an **high interest**. The industry therefore predominantly lobbied against the proposed restriction by also supplying informational studies defending the use of PFASs to ECHA. They however also do not have direct power, much like the NGOs, but overall have more specialised lobbyists and funds, therefore being placed above NGOs at **average power**.

All **EU Member States** deal with the PFAS-related problems and will have to positively vote on the final restriction proposal. They therefore have a relatively **high power** in the matter. The most actively involved Member States are Germany, Sweden, Norway, and Denmark, as they co-authored the restriction report. However, as this matrix was made from the viewpoint of the Netherlands and not all Member states are as actively involved in discussions, they are overall put at an **average interest**.

The **RIVM** is a key player involved with the PFAS restriction project within the Netherlands, mainly working on the needed research to back up the advice, processing the comments posted on the proposal and delivering expert informational input wherever necessary. They are therefore places at a **moderately high power**. The RIVM is also market as a competent authority for REACH and actively involved in all REACH related activities.[173] They are however not the main contact point in the Netherlands for this restriction proposal and therefore put at a **moderately high interest**.

The **Ministry of VWS** is one of the three key players within the Netherlands regarding the PFAS restriction proposal. The main focus of this Ministry is on human health, giving it a keen interest in the impact of PFAS on health, and it is actively involved with the PFAS restriction proposal with a focus on the relevant consumer products. It works integrally together with the other relevant ministry (next stakeholder) and the RIVM to supply politically heavy information to ECHA. The Ministry of VWS is a competent authority for ECHA, but not directly for REACH.[173] Therefore, the Ministry is put at a **high power** and at a **high interest**.

The **Ministry of Infrastructure & Water Management** (Dutch: Infrastructuur & Waterstaat, I&W) is the last key player within the Netherlands that is integrally involved with the PFAS restriction proposal, with its main focus being on the environment. It works integrally together with the Ministry of VWS and the RIVM to, again, supply politically heavy information to ECHA. This Ministry is another competent authority for ECHA and especially for REACH from the Netherlands and therefore placed slightly above the Ministry of VWS in terms of power.[173] The Ministry of I&W is overall put at a **high power** and **high interest**.

ECHA received the proposed PFAS ban.[174] They are responsible for creating advice within their specialised committees based on information from the Member States, but also from different players through stakeholder meetings and submitted comments from the industry, NGOs, academic institutions, etc. The advice the committees give is of the utmost importance as it will have to convince the Member States, EU Committee and EU Parliament to amend the restriction proposal. ECHA is the main player when it comes to the proposed EU PFAS restriction and therefore placed at the **highest power** and the **highest interest**.

To summarise, the identified stakeholders involved with the problems surrounding PFAS and the restriction proposal are the **general public**, the **NVWA**, **Academic institutions**, **NGOs**, the **industry**, the **EU Member States**, the **RIVM**, the **Ministry of VWS**, the **Ministry of I&W**, and **ECHA**. They all have a **varying power and interest**, as indicated in the **power-interest matrix**, therefore influencing the PFAS restriction proposal process each in their own way.

6 Comparison Overview

This chapter gives an overview of the PFASs that are used within FCM, packaging and cosmetics, and their found substitutes. These substances will be examined and compared to one another, to find out whether a substitute substance can be identified as regrettable by having different or unknown hazards compared to the original hazardous substance, in this case PFAS. This will be done in the form of an multi-criteria analysis with a set of substantiated criteria, which are first discussed. If after the multi-criteria analysis there are substitute substances that stand out due to their found negative effects, they will be marked and mentioned in the final advice. There they will be used to help answer the main research question, by being labelled as a possible regrettable substitute.

6.1 Criteria

Before starting the multi-criteria analysis, it is important to determine which criteria will be considered, why and with what magnitude. Below, the set criteria can be found in order of found importance. Ethics should always be kept in mind when making these kinds of differentiations. When looking at relevant ethical aspects, one can choose to differentiate by the type (e.g. young versus old) or size of the group of people affected, therefore taking a utilitarian approach.[175] This was however not done, as it was personally deemed unethical to differentiate between who is affected and who is not or in a lesser matter, while being unnecessary as most of the use categories analysed relate to consumer products, therefore having a similar use group.

Effects on Health

As this report is written for the Ministry of VWS, which is committed to improving the health and quality of life of all people, effects on human health are of the utmost importance. Properties and aspects that were kept in mind when looking at the effects on health are hazard classifications, special indications in the safety data sheets and toxicity. The values of these properties for the substance will be stated when determined and available. The overall effect on human health for the relevant applications is shown in the overview by one of the following colour indicators:

Proven negative health effects	Probable negative health effects	Neutral/unknown health effects	Probable no health effects	Proven no health effects

Effects on the Environment

The second area in which it is clear PFAS has a negative impact is the environment. The effects PFASs and other substances have on the environment also indirectly influence human health, as our food and water sources then become contaminated. Properties and aspects that were kept in mind when looking at the effects on the environment are persistence, (water) solubility, bioaccumulation potential, (phyto)toxicity and sustainability (e.g. life cycle). These will be stated when relevant and available. The overall effect on the environment for the relevant applications is shown in the overview by one of the following colour indicators:

Proven negative environmental effects	Probable negative environmental effects	Neutral/unknown environmental effects	Probable no environmental effects	Proven no environmental effects

Mechanical & Physical Properties

The main reason for PFASs being chosen as material over other substances is their unique strength and resistance against heat and other chemicals. Therefore the third most important criterion is the mechanical and physical properties of the substance. This will be relevant to determine whether a substance is a suitable substitute, but also for the environment and the costs (next criterium), as stronger substances are overall more sustainable due to their longer lifetime, needing to be replaced less frequently. Properties and aspects that were kept in mind when looking at the mechanical and physical properties are tensile strength (indicates general strength), flexural modulus (indicates bendability), melting point (M_p), maximum service temperature (M_S, indicates thermal resistance), but also physical properties relevant for the application (e.g. chemical resistance, water repellency). These will be stated when available. Due to the range of molecular weights present for the polymers, often a range or an average is given of these properties for the substances. The overall score is shown in the overview by one of the following colour indicators:

Weak	Relatively weak	Intermediate	Relatively strong	Strong

Effects on costs

The last criterion is the effects on costs. Properties and aspects that were kept in mind when looking at the costs are material costs, producer surplus (business closure versus substitute suppliers), consumer surplus losses (e.g. product price, costs from changes in characteristics), R&D costs (re-certification) and capital costs (e.g. new equipment). An indication of these costs will be given when available. Costs that will occur in the future with extended use, such as social and environmental costs relating to remediation and healthcare costs, are very hard to indicate and therefore not stated. Where possible, these costs were taken into account for the overall score and analysis. The overall effect on costs for the relevant applications is shown in the overview by one of the following colour indicators:

Very expensive	Relatively expensive	Moderate	Relatively cheap	Very cheap

6.2 Multi-Criteria Analysis

A multi-criteria analysis is a tool often used for policy analysis. It can consider multiple criteria in the planning or decision-making step of a policy cycle for a set problem.[176] It makes use of simple performance scores or colours to indicate the result on a certain criterion for a set of options. The criterion themselves are usually also weighted, making it that in the end certain options can be picked out easily, as they score the best or worst, for further implementation. For this analysis, the criteria described above were selected to be used. Within this specific multi-criteria analysis, the PFASs used within FCM, packaging and cosmetics will be analysed and compared to their substitutes for the use category as a whole. Hundreds of PFASs are used within some of these categories, however, evaluating all of them is not doable or proportionate for this report. Therefore only the most often used PFASs, as identified in Chapter 3, that are currently not restricted or on the SVHC list will be examined. It should be noted that contaminants in the form of, for example, processing aids are also not included. The possibility of contaminants being present will however be considered for the final advice. For the substitutes, it also holds that substances already restricted or identified as SVHC are excluded from this list, as well as their possible contaminants.

In **Table 5**, **Table 6** and **Table 7** overviews of the multi-criteria analysis can be found, in which just the coloured indicators are shown for each substance. The detailed multi-criteria analysis that includes concrete data per criterium and references for each substance can be found in the Appendix, Chapter 9.5. Various sources, including social media, articles and marketing ads, have been used to find these substitutes.[177–179] Even online shopping sites that are knows to be less trustworthy, like Temu, have been using the term “PFAS free” as a marketing strategy.[180,181] Although many PFAS substitutes have been found in this way for FCM and packaging, as suppliers are not obliged to state the materials that are used, their contents sometimes remained a mystery.[182,183] Lastly, please note that the substances found in these tables should not be viewed one-to-one within a single row, but as substances within a use category (FCM, packaging or cosmetics) compared generally to all the other substances in the entire use group.

6.2.1 Food Contact Materials

Table 5: Multi-criteria analysis overview of PFASs (left) and substitute substances (right) within FCM.

PFAS	Effects on human health	Effects on environment	Mechanical & physical properties	Effects on costs
PTFE				
FEP				
PFA				
ETFE				
ECTFE				
PVDF				
FKMs				
PFPEs				

Substitute substance	Effects on human health	Effects on environment	Mechanical & physical properties	Effects on costs
Borosilicate glass				
Polyphenylene sulfide				
Polyether ether ketone (PEEK)				
Polyurethanes				
Cast iron				
Ethylene Propylene Diene Monomer rubber				
(High-Density) Polyethylene				
Polypropylene				
Polyamide 66				
Polybutylene				
Silicone				
Polymer layer by plasma technology				
Stainless steel				
Polystyrene				
Polyether block amide				
Cross-linked polyethylene				
Nitrile rubber				
Polyvinyl chloride				

6.2.2 Packaging

Table 6: Multi-criteria analysis overview of PFASs (left) and substitute substances (right) within packaging applications.

PFAS	Effects on human health	Effects on the environment	Mechanical & physical properties	Effects on costs
PTFE				
FEP				
PFA				
PFPEs				
Polychlorotrifluoroethylene				
FKMs				
Perfluoroalkyl phosphinic acids				
Perfluoroalkyl phosphonic acids				
PAPs				

Substitute substance	Effects on human health	Effects on environment	Mechanical & physical properties	Effects on costs
Chitosan				
Polyphenylene sulfide				
Polylactic acid				
(High-Density) Polyethylene				
Polypropylene				
Polyamide 66				
Natural waxes				
Polybutylene				
Silicone				
Polystyrene				
Polyurethanes				
Polyether block amide				
Cross-linked polyethylene				
Poly(methyl methacrylate)				

6.2.3 Cosmetics

Table 7: Multi-criteria analysis overview of PFASs (left) and substitute substances (right) within cosmetic applications.

PFASs	Effects on human health	Effects on environment	Mechanical & physical properties	Effects on costs
PTFE				
Polyperfluoromethylisopropyl ether				
Perfluorononyl dimethicone				
Perfluoro-decalin				
PAPs				
Octafluoro-pentyl methacrylate				
C9-15 fluoroalcohol phosphate				

Substitute substance	Effects on human health	Effects on environment	Mechanical & physical properties	Effects on costs
Polylactic acid				
Natural waxes				
Silicone				
Synthetic waxes				
Mineral oils				
Polyvinylpyrrolidone				

6.3 General Remarks & Observations

Within the multi-criteria analysis overviews the substances have been evaluated individually, but some general remarks should also be made. To start, from the overviews it might seem that overall the analysed PFASs are not exceptionally hazardous. However, as discussed before, many of their negative effects can and most likely will occur at a later stage after their use and disposal. For example, within cosmetics the substances are easily released into the environment due to them being washed off while bathing and with fluoropolymers used as FCM specialised incineration at high temperatures is needed to fully break down the persistent molecules. Even while with this incineration full degradation can be achieved, a lot is still unclear about possible emissions of hazardous degradation substances. With regard to producer and consumer surplus losses, in a general sense with any substitute substance additional costs will occur. As many industries have now build their equipment to work with PFAS, so most likely new set-ups need to be developed and/or purchased. However, as explained earlier, the criteria cost is seen as least important as for this report the focus is on (human) health and the environmental effects.

To conclude, within the **multi-criteria analysis** a few substitute substances can be marked for attention. Within the FCM applications, the substitute substances **nitrile rubber** and **polyvinyl chloride** seem to have the lowest score with regards to the criteria, even when being compared to the corresponding PFASs. Within the packaging applications, the substitute substance **poly(methyl methacrylate)** was the only substance that stood out. Within the cosmetic applications, the substitute substance **polyvinylpyrrolidone**, but possibly also **mineral oils** could be interesting ones to look further into.

7 Regulation of Regrettable Substitutes

The time has come to answer the main research question: Is there any regrettable substitution of PFASs expected within FCM, packaging and cosmetics, which should be regulated within the EU? To do so, we look back at the summaries and conclusions drawn from previous chapters.

We found PFASs to commonly be **extraordinarily strong and stable** causing **high chemical and thermal resistance**; **hydrophobic**, **oleophobic**, have **low adhesive forces** causing them to be **non-stick** and have **great versatility**. However, thanks to these properties we also found them to be **very persistent**, **mobile** and **difficult to remove** from the environment, making their presence rise and their negative effects on the environment in the form of **bioaccumulation**, **phytotoxicity** and **global warming** more prominent. Combined with their related **high exposure levels** and **toxicity**, they show a **clear threat to our health and the environment**, and that they **need to be phased out as soon as possible**. Within this report we looked at PFASs used within **FCM** in **consumer cookware** and **industrial applications**, within **packaging** in **food**, **feed** and **generic packaging** and within **cosmetics**. Within all these categories **fluoropolymers** are often identified. There are several regulations already in place restricting specific PFASs, such as the **Stockholm Convention**, **EU POPs Regulation, Cosmetic Products Regulation**, **plastic materials and articles Regulation**, **Drinking Water Directive**, the **Montreal Protocol**, and the **REACH Regulation**. However, as these legislations are limited in scope, a grouped **EU PFAS restriction** has been proposed to reduce the use of the entire PFAS family extensively and **avoid the regrettable substitution** of one hazardous PFAS with another. **5642 comments** were posted on this proposed restriction and did bring about useful insights, in the form of **arguments defending the use of fluoropolymers**, **addressing contaminants**, talking about **ways of disposal** (e.g. **incineration**), or **indicating possible substitutes**. Stakeholders identified in the **power-interest matrix** involved with the problems surrounding PFAS are the **general public**, the **NVWA**, **Academic institutions**, **NGOs**, the **industry**, the **EU Member States**, the **RIVM**, the **Ministry of VWS**, the **Ministry of I&W**, and **ECHA**. They all have a **varying power and interest**, therefore influencing the PFAS restriction proposal process each in their own way. Within the **multi-criteria analysis** the substitute substances **nitrile rubber**, **polyvinyl chloride, poly(methyl methacrylate), polyvinylpyrrolidone**, but possibly also **mineral oils** were marked as possible regrettable substitutes.

From the identification of the possible regrettable substitute we can possibly conclude that some fluoropolymers seem like a better alternative and maybe should be considered for exclusion from the proposed EU PFAS restriction. However, as stated before, special care should be taken with the production and disposal of fluoropolymers. Even though some fluoropolymers could be safe to use in industrial applications with the right waste management, it is also of importance not to forget about the value of hope or image. If a message is send out to the world where additional exceptions are made for the use of PFASs, this can be seen as a betrayal as the knowledge on PFAS among the general public is limited, therefore they might see all PFASs as the same. Therefore, it is recommended not to alter the scope of the proposed EU PFAS ban, as there are enough suitable alternatives within FCM, packaging and cosmetics and to send out a clear message to the industry and general public.

With regards to the earmarked substitute substances, namely nitrile rubber, polyvinyl chloride, poly(methyl methacrylate), polyvinylpyrrolidone, but possibly also mineral oils, it is recommended for the Ministry of VWS to look further into these substances to truly determine whether they are indeed a regrettable substitute. From just the literature research done in this report with limited prior consisting knowledge, it is hard and most likely unwanted to draw hard conclusions. As a consultant or policy officer it is not always to goal to make the final decisions, but rather to shine a light on where issues might arise and what opportunities there are.

7.1 Implementation: Stakeholders

To help the Ministry of VWS with the next step, a look at the possible implementation is taken. This will help to illustrate how the Ministry can implement the advice and whether it will be able to implement the advice with regards to competencies and capabilities. To start off, another stakeholder analysis is made. This time the parties involved with the possible regrettable substitutes will be examined. These are the stakeholder that will either be able to have an influence on the given recommendation, by for example being able to vote it down, or that will be influenced by the advice itself. The power-interest matrix for this analysis can be seen in **Figure 14**.

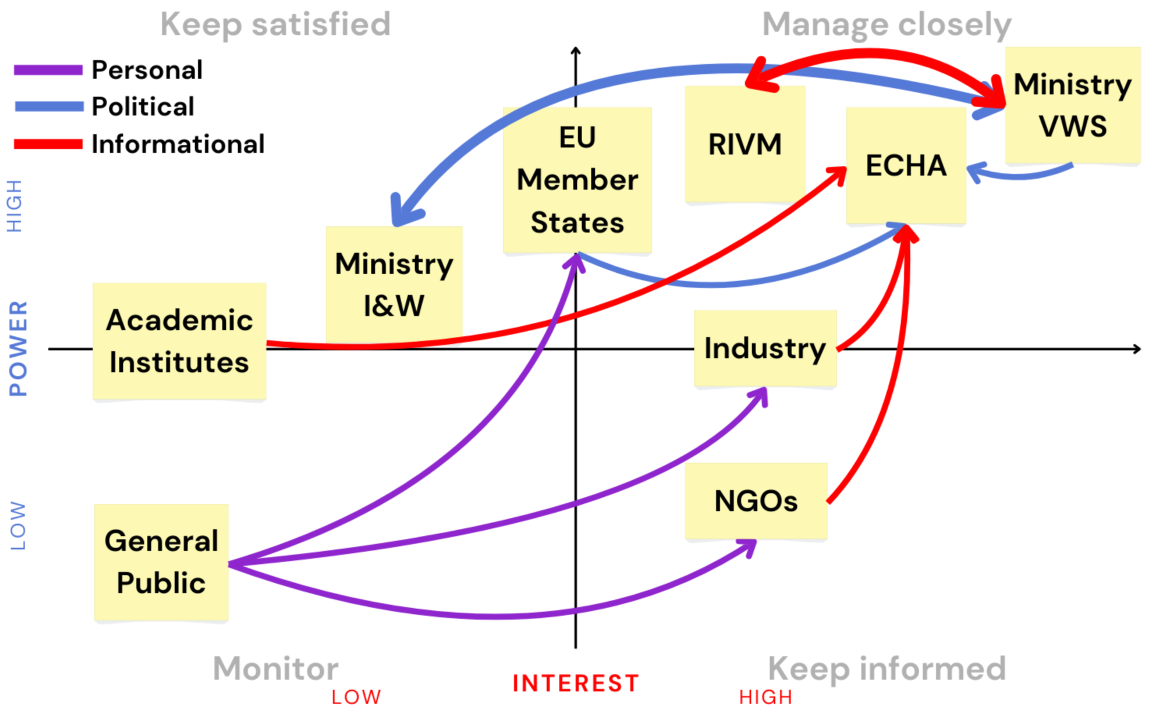

Figure 14: Power-interest matrix of the stakeholders involved with the possible regrettable substitutes, from the Netherlands as viewpoint. The thickness of the arrows indicate the weight while the colours indicate the kind (top left legend) of input relationships between the stakeholders.

If we start at the bottom left of the power-interest matrix we can first see the **general public** as a stakeholder. Most members of the general public would be affected by the substitute substances, although this would vary based on which products they use and the frequency of use. Some members of the general public show an interest in what chemicals are present in their products, however, most do not care too much. Therefore, being put at a **moderately low interest**. Although the general public has some power to influence political decisions, by for example voting for a specific party during elections, their influence is overall indirect and weak compared to other stakeholders. Therefore the general public was put at a **moderately low power** to influence possible regulations on the substitute substances. Some members of the public do, for personal reasons, request NGOs, the industry and their Member State authorities to look into questionable chemicals or products, as indicated by the arrows.

Academic institutions, in the form of Universities and independent research institutes, are located above the general public in the matrix. They will be able to conduct studies on the environmental and health impacts of the earmarked substitute substances, thereby providing scientific information which could be used for a possible restriction report. So although they do not have a lot of direct influence in politics, but can supply critical input, therefore having **average power**. These institutions are often more interested in the result of their research and the academic value it has then how it influences policy-making, therefore having **low interest**.

The **Ministry of I&W** will have to agree with any proposed additional regulations on substitute substances to bring it forward to the Dutch parliament. It has a main focus on the environment, while the analysis in this report where done with a main focus on human health and on consumer products, which are less relevant to them. The Ministry of I&W is therefore overall put at a **moderately high power** and **moderately low interest**.

When looking at parties with a higher interest, we find **NGOs**. **NGOs** such as ChemSec are actively involved with the substitution of PFAS. They even have a PFAS alternatives market place. They therefore reside at a **moderately high interest**. They have however less direct power on the matter, when for example being compared to a Ministry, as they are welcome at open discussions but are often less explicitly invited and can have less funds to lobby. They are therefore placed at **moderate power**.

Within the **industry,** different players can be identified among suppliers, manufacturers, downstream users, etc. Additional restrictions on substitute substances will have a direct effect on the industry, however, it could help their case to continue working with fluoropolymer. Therefore they were put at a **moderately high interest**. They however also do not have direct power, much like the NGOs, but overall have more specialised lobbyists and funds, therefore being placed above NGOs at **average power**.

All **EU Member States** will have to positively vote on any additionally proposed restrictions, for example on the substitute substances. They therefore have a relatively **high power** in the matter. However, as this matrix was made from the viewpoint of the Netherlands and not all Member states are as actively involved in discussions, they are overall put at an **average interest**.

The **RIVM** is a key player as they would need to do research to back up the advice, if it is decided that the substitute substances should be looked into further, and delivering expert informational input wherever necessary. They are therefore places at a **high power**. They are however already understaffed and almost at research capacity and therefore put at **moderately high interest**.

ECHA is for handling all REACH Restrictions. They are responsible for creating advice within their specialised committees based on information from the Member States, but also from different players through stakeholder meetings and submitted comments from the industry, NGOs, academic institutions, etc. Therefore ECHA is an important player when it comes to additional restriction for substitute substances with a **high power** and **high interest**.

The **Ministry of VWS** is the Ministry in which the internship is housed, they therefore have the most important say in determining whether the analysis on the earmarked substances should be taken further. The main focus of this Ministry is on human health, giving it a keen interest in the impact of the substitute substances on health, with a focus on consumer products. Therefore, the Ministry is put at a **high power** and at a **high interest**.

To conclude this stakeholder analysis, there are a lot of players involved with the (regulation) of substitute substances earmarked as possible regrettable substitutes. When looking at the stakeholders involved, a decision-making roadmap regarding the path the additional regulations need to take could be made. This would answer questions like which stakeholders have to agree with the given proposals and who would be able to bring a stop to it? However, due to time constraints, this was not done for this report. If the Ministry of VWS decides to look further into the earmarked substitute substances, it is recommended that they create such a roadmap ahead of time.

7.2 Implementation: McKinsey 7s

To be able to determine whether the hosting organisation, the ministry VWS, is able to implement the given advice, it is key to know their internal structure to determine the available competencies and resources. This will be done using the **McKinsey 7s framework**, in which hard and soft elements of an organisation are identified.[184] The hard elements are clear-cut, influenced by management, and consist of strategy, structure and systems. The soft elements are fuzzier, influenced by corporate culture and consist of shared values, skills, staff and style. Each of these elements are elaborated on below, linking them to the project where possible.

Strategy, reinforced by the mission and values, allows the organisation to formulate a plan of action to achieve their goals.[184] The Ministry of VWS states it is committed to improving the health and quality of life of all people in the Netherlands.[185] One of the ways in which it tries to achieve this is by promoting prevention, healthy nutrition and safe consumer products. These are the main strategies executed in the Department VGP, where people develop policies surrounding smoking, alcohol, drugs, healthy nutrition, food safety, but also product safety, within which the internship took place. The Ministry always tries to respond to (political) changes in the world and other forms of policy windows, such as the recent published Dutch parliament coalition agreement, to adopt these strategies to fit within the new political climate or to initiate new ones when the opportunity is there.

Structure is the way in which an organisation is organized, such as the chain of command and accountability relationships which form the organizational chart.[184] The Netherlands is organised as a decentralised constitutional monarchy with the Ministry of VWS being one of the 12 ministries, together forming the Dutch government.[186] Each ministry is structurally and hierarchically organized, headed by ministers who are supported by state secretaries. Conny Helder is the Minister of VWS, Pia Dijkstra the Minister for Healthcare and Maarten van Ooijen the State Secretary of VWS. For the product safety team within the Department VGP, Pia Dijkstra is the responsible Minister. When taking a step down in the hierarchical ladder, the Director-General for Health, Marjolijn Sonnema, is responsible for the Department VGP, which is in turn headed by managing Director Victor Sannes. If it is decided that the marked substitute substances should be regulated, a report should be drafted up and send to the Dutch parliament, but it will first have to go by these responsible people.

Systems entail the infrastructure of the organisation which establishes workflows and the chain of decision-making.[184] The Ministry uses many systems which streamline the internal communication and hierarchy, the most essential information system being Marjolein. This is a secured document managing system, which makes sure that documents pass by all relevant internal stakeholders for approval, before moving on to the next step, while archiving it. If the organisation decides to pass on the given advice, this system will be used for the internal VWS approvals. Marjolein is however known to have its drawbacks in the form of its rigidity, as only one correspondent can be assigned to a secured document. So if the wrong person is assigned as corresponded, the correct person will not have access to the document, and this is quite hard to correct. The organisation is currently setting up a working group to find and evaluate a new system to replace Marjolein with, showing their ability to self-improve and be self-critical.

Shared Values are the mission, vision, objectives, and values.[184] As mentioned earlier, the Ministry states it is committed to improving the health and quality of life of all people in the Netherlands; it aims for good quality, affordable and sustainable healthcare, proper sporting facilities and promotes prevention and healthy nutrition. This is relevant for the report and the advice, as they are there to protect Dutch citizens from harmful chemicals, such as PFASs and their possible regrettable substitutes.

Skills form the capabilities and competencies of an organisations that enables its employees to achieve its objectives.[184] The Ministry is known for the policies its develops to reach goals, set by for example the Dutch parliament, on healthcare, sports and wellbeing. It is capable to formulate policy recommendations in such a way that they are realistic and understandable by the general public. To make sure a developed policy is scientifically correct, executable, and achievable, the Ministry often seeks contact with the executing organisations (e.g. the RIVM or the NVWA). The Ministry is also known to supply feedback and opinions on European policies, which are often taken seriously by other Member States and EU organisations as the Netherlands is seen as an active and experienced Member State.

Staff involves talent management and the human resources.[184] Within the Ministry, diverse backgrounds can be found among its employees. From varying ages, genders, cultural backgrounds, but also educational backgrounds. Within the product safety team alone there are people with vastly different master's degrees, from law, philosophy, and public administration to chemistry. This makes it that the employees can give political input and advice on a large variety of topics and with varying points of views. It should be mentioned that in recent times the Ministry VWS has been in a negative media spotlight regarding employee satisfaction. Multiple employee surveys were taken within the Ministry during the internship. These showed that indeed the Ministry must make improvements regarding social safety and mental wellbeing, but it luckily also showed that within the Department VGP the problems are less prominent.

Style of an organisation is formed by the attitude of management employees, establishing a code of conduct by their way of working, through interactions and decision-making.[184] The management style of the Department VGP can be described as supporting, encouraging and open-armed. The managers act in a coaching manner, where the responsibilities are predominantly left up to the employees, showing a lot of trust and appreciation for the executed work. The projects are therefore largely created and executed with a bottom-up approach. The management employees furthermore show they open-armed demeaner by repeatedly clearly stating you can come to them anytime with any problems, worries or ideas.

From the elaboration of the elements in the McKinsey 7s framework it can be concluded that the Ministry of VWS should be able to take the substitute substances marked as possible regrettable substitutes for further analysis and eventually to the Dutch Parliament, if they decide to do so. The strategy and shared values of the Ministry match well with the project and the structure in the form of a hierarchical ladder which the advice must climb, via the system Marjolein, is clear. The Ministry has the relevant expertise and skills within its staff members to process and explain the scientific background information properly to the Dutch parliament and beyond, while being supported by the coaching managers.

Finally, a recommendation on a next step. The multi-criteria analysis tables should be viewed as continuous living tables. Substitute substances will continue to arise and will need to be continuously monitored. The created tables could be used as a tool to build up on for the next steps. It could be interesting to see whether they can be used together with the digital product passports that might be coming up within the EU for industries.

7.3 Discussion

To end the report, a few discussion points will be addressed. A lot of question can still be asked about the marked substances and their further analysis, such as what is considered safe enough? What are the combined effects of the different substances? Should these be taken into account as well and if yes, how? How do you outweigh the negatives against the positives? Especially when comparing within the same group of affected people (e.g. people working for Chemours, who could lose their job but become less exposed) or opposite groups (e.g. people who almost only experience positive effects vs almost only negative effects of the hazardous substances). Implications can also still occur and the proposed EU PFAS restriction can still change. The industry is still actively lobbying at ECHA and other institutions to try and get their way by, for example, getting additional exemptions for the use of fluoropolymers. So possibly, the substitute substances will be used less than expected, when the use of fluoropolymers will still be allowed. Lastly, to keep in line with the principle of better regulation, which aims to design and prepare EU policies and laws in the most efficient way to achieve their objectives, over or double regulation should be removed. This means that when the PFAS restriction or any other additional restrictions come into play, older regulations with overlapping scopes should be annulled.

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9 Appendix

9.1 Dutch Translation Executive Summary

Per- en polyfluoralkylstoffen (PFAS) maken deel uit van een grote chemische familie van gefluoreerde stoffen. Ze zijn chemisch resistent, thermisch stabiel, water en olie afstotend, kunnen een anti-aanbak laag creëren, veelzijdig en meer. Deze eigenschappen zorgen ervoor dat ze voor veel toepassingen worden gebruikt, bijvoorbeeld in de energie-, chemische, farmaceutische, voedsel- en cosmetische industrieën. Echter, hebben veel van deze stoffen een negatief effect op het milieu, omdat ze persistent zijn (vanwege hun hoge resistentie), bioaccumulatief, fytotoxisch en omdat ze bijdragen aan de opwarming van de aarde. Daarnaast beïnvloeden ze ook onze gezondheid negatief, omdat ze zorgen voor een verminderde immuunfunctie, insulinedysregulatie, verhoogd cholesterol, kanker, verminderde reproductieve gezondheid, ontwikkeling remming effecten hebben voor (ongeboren) kinderen en nog meer. Sommige PFAS worden daarom regeguleerd via verschillende regelgevingen, zoals het Verdrag van Stockholm, de EU POP's Verordening, de Verordening voor cosmetische producten, de Verordening voor plastic materialen, de Drinkwater Richtlijn, het Montreal Protocol en de REACH Verordening. Echter, gezien de beperkte reikwijdtes van deze regelgevingen en de huidige wetenschappelijke informatie over PFAS, is er een restrictie voorgesteld op de productie, op de markt brengen en het gebruik van de PFAS-familie als geheel. Betrokken stakeholders bij de PFAS problemen en de voorgestelde restrictie, geïdentificeerd met een power-interest matrix, waren het algemene publiek, de Nederlandse Voedsel en Waren Autoriteit, academische instellingen, Non-Governmental organisaties, de industrie, de EU-lidstaten, het Rijksinstituut voor Volksgezondheid en Milieu, het Ministerie van Volksgezondheid, Welzijn en Sport, het Ministerie van Infrastructuur en Waterstaat, en de European Chemicals Agency.

Als het gebruik van PFAS wordt beperkt, zullen er alternatieven voor in de plaats worden gebruikt. Het Ministerie van Volksgezondheid, Welzijn en Sport vond het daarom belangrijk om mogelijke alternatieve stoffen op te zoeken en te evalueren om te identificeren welke een substantieel of te hoog risico van schade voor het milieu en de menselijke gezondheid zouden kunnen veroorzaken. Alternatieven die met een substantieel of te hoog risico van onbekende schade werden geïdentificeerd, werden gemarkeerd als mogelijke “regrettable substitute”. In dit rapport is gekeken naar PFAS en hun alternatieve stoffen die worden gebruikt in voedselcontactmaterialen, verpakkingen en cosmetica. Binnen de multi-criteria analyse werden de alternatieve stoffen nitrilrubber, polyvinylchloride, poly(methylmethacrylaat), polyvinylpyrrolidon, maar mogelijk ook minerale oliën, gemarkeerd als mogelijke “regrettable substitute”. Het werd aanbevolen aan het Ministerie om verder onderzoek te doen naar deze stoffen om te bepalen of ze echte “regrettable substitutes” zijn.

Om de stakeholders die betrokken zijn bij de alternatieve stoffen en hun mogelijke regulering te illustreren, werd nog een stakeholder analyse uitgevoerd. Deze analyse kan in de toekomst worden gebruikt om een beleidsroutekaart op te stellen. Om te bepalen of het Ministerie in staat zou zijn om de gegeven aanbeveling uit te voeren, werd een interne analyse gedaan in de vorm van een McKinsey 7s-framework, waaruit geen duidelijke hiaten werden geïdentificeerd. Het werd aanbevolen dat de multi-criteria analyse overzichten als levende en doorlopende tabellen zouden worden gebruikt. Ten slotte werden enkele discussiepunten gegeven, in de vorm van vragen die nog gesteld kunnen worden, mogelijke implicaties en een aandachtspunt waarin het principe van betere regelgeving werd behandeld.

9.2 PFAS Exposure Sources

Table 8: Estimates of source contributions in percentages to adult exposures to PFASs.[196,197]

PFAS	Carbon length	Exposure medium				Exposure route			Study location
		Diet	Dust	Water	Consumer goods	Inhalation	Dermal	Indirect	
Perfluorobutanoic acid	4	-	4	96	-	-	-	-	North America
Perfluorohexanoic acid	6	38	4	38	-	8	-	12	North America
		87	4	-	-	2	-	-	Norway
PFHxS	6	57	38	-	-	5	-	-	Finland
		94	1	-	-	-	-	-	Norway
PFHpA	7	93	1	-	-	-	-	-	Norway
Perfluoroheptane sulfonic acid	7	-	-	-	100	-	-	-	Norway
PFOA	8	16	11	-	58	14	-	-	North America, Europe
		85	6	1	3	-	-	4	Germany, Japan
		77	8	11	-	4	-	-	Norway
		66	9	24	-	<1	<1	-	USA
		41	-	37	-	-	-	22	Korea
		99	-	<1	-	-	-	-	China
		47	8	12	-	6	-	27	North America
		95	<2.5	-	-	<2.5	-	-	Finland
		89	3	-	-	2	-	-	Norway
		91	-	3	-	5	-	-	Ireland
PFOS	8	66	10	7	-	2	-	16	North America
		72	6	22	-	<1	<1	-	USA
		96	1	1	-	2	-	-	Norway
		81	15	-	4	-	-	-	North America, Europe
		93	-	4	-	-	-	3	Korea
		100	-	<1	-	-	-	-	China
		95	<2.5	-		<2.5	-	-	Finland
		75	-	-		3	-	-	Norway
		100	-	-	-	-	-	-	Ireland
Perfluorooctylphosphonic acid	8	-	100	-	-	-	-	-	Norway
PFNA	9	79	5	-	-	1	-	-	Norway
PFDA	10	51	2	4	-	15	-	28	North America
		78	1	-	-	2	-	-	Norway
Perfluorodecane sulfonic acid	10	-	89	-	4	-	-	-	Norway
Perfluoroundecanoic acid	11	61	4	-	-	1	-	-	Norway
Perfluorododecanoic acid	12	86	2	2	-	4	-	5	North America
		48	15	-	-	-	-	-	Norway
Perfluorotridecanoic acid	13	89	1	-	-	-	-	-	Norway

9.3 REACH Restriction Procedure

Dossier: The restriction proposal dossier contains background information, including the identified risks, information on alternatives and the costs, environmental and human health benefits, resulting from the restriction. The dossier must be submitted within 12 months of when ECHA was notified by the submitters about their intention to prepare the proposal.

Committees' opinions: After it has been checked whether the proposal conforms to the set requirements, the dossier will be made publicly available for consultation, allowing interested parties to comment on the restriction within six months. Within nine months of the same publication date, ECHA's Committee for Risk Assessment will give its opinion on whether the suggested restriction is appropriate in reducing the risk to human health or the environment. At the same time, the Committee for Socio-economic Analysis prepares an opinion about the socio-economic impacts of the suggested restriction. Comments can be submitted on the Committee for Socio-economic Analysis draft opinion within 60 days of its publication. Committee for Socio-economic Analysis will then give its final opinion, within 12 months of the publication date of the restriction dossier.

Decision: The opinions of the Committee for Risk Assessment and Committee for Socio-economic Analysis will be taken into account by the European Commission, which will then take a balanced view of the identified risks and of the benefits and costs of the proposed restriction. Within three months of receiving the opinions, the Commission will provide a draft amendment to the list of restrictions in REACH (Annex XVII). The final decision is then taken via a set of procedures through which the Member States oversee how the Commission adopts the implementation, with scrutiny involving special Member States committees and the European Parliament.

Enforcement: Once the restriction has been adopted, the industry (manufacturers, importers, distributors, downstream users and retailers) must comply to it. The Member States are responsible for enforcing the restriction.

9.4 Comments on the Proposed EU Restriction

In Chapter 4.3, a summary was given on the relevant comments given on the EU PFASs restriction. A more detailed overview of relevant comments are stated below in **Table 9**.

Table 9: Overview of comments relevant to the scope, including the comment itself, a paraphrased version or a summary of it.[162]

Reference Number	Type	Org. type	Org. country
(Summary of the relevant part of the) comment			
3843	Individual	-	Austria
Asks for general exemption of fluoropolymers.			
3851	Behalf Of An Organisation	Company	Austria
Explains additional use of fluoropolymers for seals in FCM for industrial food and feed production.			
3853	Behalf Of An Organisation	Company	Germany
Asks for fluoropolymers exemption (+ additional irrelevant use).			
3855	Individual	-	Germany
Asks for an exemption of fluoropolymers with the reasoning that they are OECD PLC recognised. Fluoropolymers are non-toxic, non-bioavailable, non-water soluble and non-mobile molecules and are judged to have no significant impact on the environment and humans.			
3862	Individual	-	France
Use of Teflon pans causes daily exposure to PFASs due to damaged elements. Migration of PFASs into the cooked food: A study is needed, but this can easily be observed in any European family.			
3864	Behalf Of An Organisation	Company	Germany

PFAS used as coating in pumps with mechanical and chemical function cannot be substituted, due to the given boundary conditions. Necessary pumping tasks in the food and other industries could no longer be fulfilled. The PFAS used in are in an inert state.			
3865	Behalf Of An Organisation	Company	Austria
Exempt Fluoropolymers, especially PTFE. Alternatives will lead to shorter lifetimes and higher leakage due to lower chemical and thermal resistance.			
3866	Behalf Of An Organisation	Company	Finland
Exclude fluoropolymers. Low carbon foot print pipelines, seals, valves, vessels for food, etc. industry. H Have a 5-10 times longer lifetime and several times lower carbon footprint than any other material.			
3869	Individual	-	Germany
Differentiate PFASs further, only persistence is not enough to assume it is harmful or dangerous.			
3873	Behalf Of An Organisation	Company	Italy
Exclude fluoropolymers or fluoroelastomers (PTFE, FKMs, FEP), many of which are qualified as compatible for food and other uses. Currently no valid alternatives.			
3875	Behalf Of An Organisation	Company	Turkey
PFAS regulation should not affect the industrial bakeware market as there is no alternative to fluoropolymer coatings in terms of release performance. Closest alternative is three times worse.			
3876	Behalf Of An Organisation	Company	United Kingdom
Inclusion of fluoropolymers is unnecessary. These materials are used in sealing products with no alternatives. Many are approved for use in food and other applications, so classed and approved safe.			
3877	Individual	-	Japan
Request that the restriction is abolished. The European PFAS restriction would hinder their stable supply to customers because there is no alternative.			
3878	Behalf Of An Organisation	Company	Turkey
Teflon used in the production of industrial cakes as they are long-lasting and risk of food contamination is much less. To reduce emission and pollution, switched from liquid Teflon to electrostatic powder Teflon. When using silicone or ceramic coatings, the coating life is shorter (1/4 of Teflon or less).			
3883	Behalf Of An Organisation	Company	Norway
Including fluoropolymers in the scope does not respect the principle of proportionality and the aim of the proposal. A limitation of fluoropolymers will increase risk and negative impact related to safety for humans and the environment in the EU. There are non-fluorinated polymerization aids for PTFE.			
3886	Individual	-	Germany
Fluoropolymers are classified as non-hazardous. There are many technical processes in which these coatings are without alternative. A ban would lead to the outsourcing of production to third countries.			
3887	Behalf Of An Organisation	Company	Ireland
Fluoropolymers play an important role due to their chemical resistance, thermal resistance, mechanical properties, low permeability, low leachable and extractable content, low surface energy, low flammability, low friction and high levels of cleanliness. FKMs are more than €1000/kg, so used as last resort. The derogations are contradictory as they immediately ban the monomers but leave derogations for the polymers. The Health and Safety Executive has worked with the Environment Agency to produce an analysis of the most appropriate regulatory management options for PFAS. Of particular note: PFAS may be divided into two primary categories, non-polymeric and polymeric. Instead of registering polymers, the monomers and other reactants are registered in their place. However, polymer substances are not exempted from other parts of REACH, e.g. restriction. Possible differences in functionality for alternatives include: shorter service life, increased risk of failure, reduced service intervals and associated costs due to loss of production time, increased servicing costs, increased waste, increased emissions, increased risk of contamination of product.			
3890	Individual	-	Austria
Fluoropolymers represent a very selective group of substances that combine corrosion and temperature resistance in many chemical production processes and environment/alternative energy relevant processes where there are no alternatives.			
3892	Behalf Of An Organisation	Company	China
Consider a derogation for fluoropolymers and refrigerant gas due to lack of alternatives.			
3895	Behalf Of An Organisation	Company	Germany

Nearly all fluoropolymers are incinerated at the end of life. There is no practical measuring equipment to measure the REACH restricted PFAS emissions (ppb) in production areas such as ovens and ventilation systems. There are no global standards for measuring REACH-restricted PFAS in primary and finished materials such as PFA granules and liners. Alternatives for pump and valves (Polypropylene, Polyvinyl chloride, Glass, Ceramics, Mica, polyether sulphone, polyimide, EPDM rubber, Nitrile rubber, Acrylic rubber and Ethylene-acrylic rubber, but these are less corrosion resistance or still need fluoropolymer sealing.			
3897	Behalf Of An Organisation	Company	Netherlands
Produces PTFE coated glass and aramid conveyor belts, tapes and sheets and have undertaken many risk assessments. No specific risks for the use of PTFE ever came out. Because of the conveyor belts demands (temperature resistance and non-stick), there is no alternative. PTFE and PFA are not hazardous in use or in waste streams. Safety data supplied is mainly on food contact, there are hazards when the material comes above 400 °C, but overall is identified as harmless. With banning PTFE and PFA the EU will give a major advance to the rest of the world in production and distribution of necessary tools and products for innovations. Steel conveyor belts can replace PTFE in several applications, but will have serious disadvantages for efficiency, costs, environment and energy use: very high investment, heavy oven construction, higher energy use because it takes more heat out of the oven, higher energy use in propulsion, no non-stick possible, one-time use of release materials, high use of fats and oils for release, vibration leads to falling over of tin cans, resulting in extra waste and lower efficiency. Food industry alternatives: Silicone or polyvinyl chloride belts -> Thicker belts leading to lower heat conductivity through the belt resulting in lower output. Less easy to clean, increased hygiene risks. Packaging industry alternatives: Silicone covers -> lower lifetime & higher costs.			
3899	Behalf Of An Organisation	Company	Italy
Produces PTFE compounds, micropowders for additivities and post-treat PTFE suspension. PTFE cannot be considered and regulated in the same way as short chain PFAS, because it is not dangerous and cannot be replaced in majority of the applications. The properties of chemical inertia, thermal resistance and friction, are both the advantage and the problem because it is not toxic or dangerous for health, resistant to hard environment and working conditions, but also persistent in the environment. Support the fact that a good end of life management is the most efficient compromise.			
3900	Behalf Of An Organisation	Company	Germany
Used material: PFA. Classification, Labelling and Packaging Regulation No. 1272/2008: Not classified as hazardous substance. No hazard or exposure. No environmental emissions. No equivalent alternatives for (food) pumps, as they must be chemically sterilizable and with a resistance to sterilization agents.			
3902	Behalf Of An Organisation	Company	Germany
Used material: PVDF. No hazard or exposure. No environmental emissions. No alternatives for pumps in food precursors. Classification, Labelling and Packaging Regulation No. 1272/2008. Not classified as a hazardous substance.			
3906	Behalf Of An Organisation	Company	Germany
Manufacturer of rubberised roller covers with PFA or FEP coating, primarily supplies companies in the liquid packaging industry. The covers are required for the production of food packaging materials and cannot be substituted. When used as intended, no hazards are to be assumed. FEP, PFA and ETFE are PLC as defined by OECD. They are not high risk materials as they are not water soluble, not bioaccumulative, inert, stable and non-toxic and do not contain harmful PFAS materials. No substitute has been found in the entire rubber coating industry for about 25 years.			
3911	Behalf Of An Organisation	Company	Germany
Apply for a derogation of measuring and process devices, which cannot be substituted within a short time frame. A limitation to special applications or industries is not feasible, due to numerous uses. Measurement devices are used in various applications of process industries (e.g. food & beverage) and follow standards which require tests and approvals of instruments. To substitute PFAS, a redesign of an instrument including a requalification of the usability is necessary.			
3912	Behalf Of An Organisation	Company	Germany
Manufacturer of elastomer seals with expertise in fluorine-containing polymers. These polymers are used worldwide in demanding applications, e.g. in the food industry. Many fluoroelastomers have been approved for food applications. Safe alternative materials for sealing applications do not exist. Alternatives cause an endangerment of the safety (resistance against acids assuring they do not escape)			

and corresponding temperature resistance ranges do not exist. Differentiating between polymers and non-polymers is essential and meaningful: Fluoroelastomers are considered non-toxic, not bioavailable, not water-soluble and non-mobile. They meet the OECD definition of PLC. This results in unique and lasting performance in many uses and applications. Furthermore, the unique durability makes them ideal materials to enable innovations. Fluoropolymers should be exempted.			
3915	Behalf Of An Organisation	Company	Germany
Asks to make sure the restriction focusses on the correct group of PFAS, considering the molecular composition. FKMs should not be considered an equally dangerous material compared to other PFAS.			
3917	Individual	-	Finland
Highlights the hazard of PFASs to birds with multiple sources. It has been known for decades (1970's) that having birds in the same space as PFAS fumes can be fatal, 'Teflon toxicosis'. This has been seen in pets (e.g. canaries in kitchen area) and fowl (e.g. chickens exposed to PTFE-coated heat sources). The substances may also be harmful to avian reproduction.			
3918	Behalf Of An Organisation	Company	United Kingdom
Exclude PFA, FEP and ETFE. The restriction is based on persistence whereas the scope of REACH is to protect humans and the environment from harm. Persistence is not an indication of harm and thus out of scope. The environmental and toxicological profiles of fluoropolymers are distinctly different from other PFAS. The assumption that chemical properties are transferred is unfounded and as such the restriction is invalid. Fluoropolymers do not break down to form harmful chemicals, as proven by the Danish EPA. They have been classified as PLC. Technically and economically feasible alternatives are not available and cannot be made ready by the implementation date, nor could they be qualified, certified or approved.			
3920	Behalf Of An Organisation	Company	Germany
The definition is too broad, it includes substances that do not have hazardous properties or pose unacceptable risks (fluoropolymers), violates the principle of proportionality. Exempt fluoropolymers. Substitution, transition periods of several years are necessary to establish alternative products.			
3923	Behalf Of An Organisation	Company	Germany
There are long-chain PFAS that are very persistent and do not dissolve, therefore they do not represent an immediate risk to the environment. These compounds are non-toxic, non-mobile and do not accumulate. Particular attention does need to be paid to the production and to the end-of-life management. These are a small number of fluoropolymers: PTFE, PFA, ETFE and FEP. They should be excluded. There is not a realistic alternative to fluoropolymers, as the key function „persistence" can only be replaced by other „persistent" product			
3929	Behalf Of An Organisation	Company	Italy
Including fluoropolymers does not meet the goal of protecting human health and the environment. They are used in many applications where dangerous, hazardous, corrosive or pure fluids are handled and where metallic or "traditional" plastic materials fail to meet the corrosion resistance, liquid adsorption or contamination of pure substance. Pumps with lubricated shafts: PTFE does not require processing aids, which are generally used to protect against thermal degradation, or plasticizers used to improve overall elasticity. This means there is no leaching of foreign substance into the fluid flowing through the bearing. For these reasons PTFE is chosen for applications in food and drink processing plants, where other materials will progressively break down and leach potentially harmful substances.			
3931	Behalf Of An Organisation	Company	Germany
Asking for an exemption of certain fluoropolymers, for the use of lubrication in pumps for industrial food and feed production. There are no alternatives available which can adequately replace fluoroelastomers (especially not the FKMs) and only few alternative high-performance materials which can be used in seal applications (e.g. gaskets) like PEEK are available. Looking for alternatives since 2016, with recently a 10-month research project costing about €10,000 focusing on thermoplastic elastomers. The materials were unable to achieve sufficient resistance against chemicals while providing the required mechanical properties. The achievement of these two requirements are the major challenges in finding alternatives, especially for the fluoroelastomers.			
3942	Behalf Of An Organisation	Company	Japan
We would like to exempt fluoropolymers, a material for hollow fibre filtration membranes used in the production process of food products. Membrane filtration is economical because it does not require large amounts of waste, techniques, or energy, and it can be used to filter food without compromising			

its flavour. To maintain the economic viability, long-term physical strength and durability against cleaning chemicals are required, fluoropolymers are the only ones that can meet both requirements. In addition, fluoropolymers have a stable structure and are free of decomposition products during use, making them an essential material for safe food production. The products after use can easily be managed as industrial waste under the policy.			
3968	Behalf Of An Organisation	Company	Japan
Fluoroelastomer (fluorine rubber), fluoroplastic (fluorine resin), fluorinated grease/oil should be exempted because there is no evidence of harm. Most fluoroelastomers also contain bisphenol AF, a type of PFAS. The draft regulations for bisphenol AF are published in "ANNEX XV RESTRICTION REPORT - BPA and bisphenols of similar concern for the environment", these values should be followed. A realistic approach would be to create a list of PFAS substances or groups of PFAS substances with unacceptable risks, and then set conditions for adding them to the list.			
3974	Behalf Of An Organisation	Company	Switzerland
There are various applications of PFAS in FCM in consumer cookware. However, the impact assessment in Annex E focuses exclusively on non-stick coatings. The requirements for tubing and seals with food contact in electrical household appliances regarding temperature stability, pressure stability, chemical resistance (to cleaning and descaling agents) and food compliances are the same as in professional appliances and very similar to the ones for industrial food and feed production. Accordingly, there are no alternatives. Therefore request that proposed derogation for fluoropolymers and PFPEs for the use in industrial and professional food and feed production is extended to electrical household appliances. Additional emissions of the proposed derogation have been considered to be small.			
3977	Behalf Of An Organisation	Company	United Kingdom
Positive displacement pumps and associated fluid path technologies in industries including the food and beverage industry. Fluoropolymers are not bioavailable, bioaccumulative or toxic and should be exempted. PTFE does not oxidise, hydrolyse, photolyze, degrade by microorganism attack, is not mobile in water, is non-volatile and can be effectively incinerated above 800°C. Fluoropolymers processed by suspension polymerisation (granular PTFE and PVDF) do not require PFAS-based processing aids. Materials covered: PTFE (hose liners, seals, gaskets, diaphragms, pump components), PVDF (tubing, tubing elements, tubing assemblies, pump components, pump connectors, pump cartridges, pump heads), FKMs (gaskets, seals, O-rings, pump heads, pump drives, nozzles, diaphragms, pump components) & fluoropolymer oils and greases (PTFE, PFPE).			
3981	Behalf Of An Organisation	Company	Netherlands
Request a 12-year derogation for PTFE used in internally lubricated engineering thermoplastic, which are also used as FCM. The Society of Environmental Toxicology and Chemistry published an Environmental Toxicology and Chemistry and Integrated Environmental Assessment on fluoropolymers, which states that emissions during the use stage are negligible, because PTFE is bound within the polymer. Data shows that fluoropolymers are stable and not expected to transform to dispersive nonpolymeric PFAS.			
3989	Behalf Of An Organisation	Company	Germany
Products (compressed air systems) are used in many areas. PFAS are present in many components, e.g. lubricants and coatings of filter media. An example is greases for high-temperature applications in oil-free compressed air production in the food & beverage industry. PFAS are high-tech polymers that have no equivalent alternatives. The PFAS is used only in the inert state, exposure to humans and the environment is therefore excluded.			
3997	Behalf Of An Organisation	Company	Germany
A ban on PTFE is not appropriate as it is not hazardous in bonded form, a solid particle, does not dissolve in liquids, no evaporation of fluids, cannot be absorbed into the human body and does not accumulate in the environment. PTFE gaskets are an inherent part in industries such as the food industry and prevent the leakage of hazardous substances. PFASs must be considered individually: Polymeric/Non-Polymeric, Long/Short chain, etc. Possible alternative materials for gaskets: Silicone, EPDM, thermoplastic elastomers & NBR. Silicone gaskets do not have complete chemical resistance and are not resistant to aggressive acids.			
4022	Behalf Of An Organisation	Company	Turkey
Industrial non-stick coatings containing PFAS are very useful in industrial bakeware, because less oil can be used. If banned, customer' product surface will be carbonized oil.			

4024	Member State	-	Belgium
The Belgium government supplied studies on emission and contamination of PFASs. The results from one of these studies indicates the high uncertainty that still remains on the effectiveness of incineration. In this report it is insinuated that not only the incineration stage can be an emission point, but also the prewashing stages can generate PFAS emissions. The Federal Public Services of Economy and Health and Environment have recently launched a call that focusses on substituting substances of concern. PFAS have been identified as a priority group.			
4037	Behalf Of An Organisation	Company	Denmark
Fluoropolymers should be excluded as they have high molecular structures, are not volatile and will not dissolve in the human body or in water at normal use. Restrictions on emissions of volatile PFAS fluoropolymer processing aids and disposal, could be a solution. Use coatings containing different polymers (PFA, ECTFE, PTFE, FEP and ETFE). Normally do not recommend an expensive fluoropolymer if it is not necessary. Provides coating solutions to the food industry amongst others. For some of the applications there are alternative coating solutions within for example ceramic coatings. However for many, other properties from the fluoropolymers are needed. Do not see a long lasting non-stick alternative. The shelf life for these alternatives are also much shorter, which can lead to larger scrap.			
4039	Behalf Of An Organisation	Company	Switzerland
Fluoropolymer piping systems are essential for conveying critical media and require fluoroelastomer gaskets and diaphragms for valves. Currently, no technical alternatives match the performance of fluoropolymers for these applications, ensuring worker and environmental safety. Although fluoropolymers belong to the PFAS group, they have distinct properties and are considered to pose no risk to human health and the environment. The industry is also making strides in producing fluoropolymers without PFAS aids, improving abatement techniques, and ensuring complete mineralization at end of life. Therefore, a broad exemption for fluoropolymers in the PFAS restriction proposal is recommended.			
4097	Behalf Of An Organisation	Company	Italy
The alternatives in coatings are high molecular weight polyesters, however their potential life is lower than PFAS based coatings.			
4099	Behalf Of An Organisation	Company	United States of America
Believe that there should be an exemption for fluoropolymers, specifically: fluorocarbon, fluorosilicone and FKMs. These polymers are not mobile, not bio-available, not soluble in water and do not break down into other PFAS substances. They do not fit the toxicology and environmental effects associated with other PFASs. While these polymers are persistent, they fill a unique role in just about every industry that is not achievable through other materials. Their persistent nature is what allows them to fill these gaps in product applications. Decisions to list these polymers should be science based and not based on a generalization of the chemical makeup of the compounds.			
4104	Behalf Of An Organisation	Company	Japan
We reject this undifferentiated approach of group regulations and request that fluoropolymers materials required for production be exempted. Fluoropolymers can be classified as PFAS based on their molecular structure. However, their toxicological and ecotoxicological profile is essentially different from the majority of PFASs. Fluoropolymers that meet OECD standards for PLCs are non-toxic, biologically viable, water-soluble and non-mobilizing molecules, and are judged to have no significant impact on the environment or humans. The stability of fluoropolymers can be directly translated into unique and durable performance characteristics in many applications.			
4109	Behalf Of An Organisation	Company	Belgium
In following this grouping approach, the proposed PFAS Restriction would restrict PFAS that have not been risk-assessed and for which an unacceptable risk has not been demonstrated, in breach of Article 68(1) REACH. More specifically, the scope of the proposed PFAS Restriction is based on the OECD definition of PFAS which is based on chemical structure and does not take into account hazardous properties or risks. For example, fluoropolymers are thermally, biologically, and chemically stable, barely soluble in water, immobile, insoluble (Water, Octanol, etc.), and too large to migrate to cell membranes, so they are not incorporated into the body and are considered low concern from a human and environmental health perspective. Fluoropolymers are the only materials that simultaneously possess heat resistance, weather resistance, chemical resistance, water repellency, lubricity, and unique optical/electrical properties, and they have become indispensable materials in many fields.			

41111	Behalf Of An Organisation	Company	United Kingdom
Our company supplies safety-critical transfer devices typically used in the transfer of potentially explosive, potent, and sterile powder ingredients - requiring high containment or sealing. These markets include food, etc. transfer. A key requirement of the device is utilising effective sealing materials such as PTFE and FKMs seals. The device seals are in direct contact with the products within a safety and process critical device, meaning that any change in product or manufacturing process requires our customers to follow a rigorous change control process including re-validation.			
4118	Behalf Of An Organisation	Company	Japan
The concern about some fluorine compounds, such as bioaccumulation and toxicological effects, is not appropriate to be considered for all PFASs in general. The risks of each substance should be quantitatively evaluated and discussed.			
4125	Behalf Of An Organisation	Company	Netherlands
Fluortubing flexible hoses are used in Tuder Technica rubber hoses with PTFE liners, used for cosmetic, food, etc. applications. The Fluortubing liners are in the rubber hoses because of the combination of chemical resistance, heat resistance, cleanability, no leachable components and fully inertness. No other liner material has the same physical and chemical characteristics Potential alternatives could be steel & other metals, Polypropylene, Polyvinyl chloride, Glass/Ceramics/Mica Polyether sulphone or Polyimide but they have absolutely the same not same chemical resistance, heat resistance, cleanability and inertness.			
4130	Behalf Of An Organisation	European institution	Belgium
25 ppb for any PFAS as measured with targeted PFAS analysis does not appear useful. The unit µg/kg would be much clearer and will not be subject to any discussions on how to interpret ppb. A limit of 25 ppb (= 25 µg/kg) requires a test method with an appropriate Limit of Quantification. Using analytical instrumentation available in market surveillance and third-party laboratories will not be sufficient to test for a number of PFAS because the Limit of Quantification for these substances is too high. If it is the intention of the EU that "the measurement of PFASs with an available analytical method for a specific set of substances" shall be performed it is required to state this very clearly, e.g. with the order to use applicable EN standards, in the restriction text and not as a comment in a proposal or later in a guidance document. It is not defined in the restriction whether only fluoropolymers count as polymeric PFASs or whether SCFPs with hydrocarbon backbones also count as polymeric PFASs. It appears only meaningful that polymers with a backbone that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom count as polymeric PFASs since they cannot be analysed by targeted PFAS analysis whereas SCFPs such as side-chain fluorinated polyacrylic polymers can often be degenerated and the released fluorinated side-chains.			
4131	Behalf Of An Organisation	Company	United Kingdom
The generalisation of PFAS to include Fluoropolymers causes great concern. Our believe is that the use of PTFE components actual provides a reduction in risk to the environment, due to the properties it provides: almost totally chemically inert, wide temperature range -250°C To + 250°C, lowest Coefficient Of Any Solid Lubricant, Non-Stick, Self-Lubricating, easily machinable, moisture does not cause it to swell, does not degrade after exposure to long term direct sunlight and possesses excellent electrical properties.			
4137	Individual	-	United Kingdom
According to OECD criteria, fluoropolymers are PLC. Most of them are also suited and qualified for medical and food contact applications. They are: Non-toxic, Non-bioaccumulative, Non-mobile, Insoluble in water and organic fluids, Stable thermally, chemically and biologically & Durable. PTFE gives more to humankind that the negatives it takes away.			
4200	Individual	-	Japan
PTFE coated frying pans are now widely used around the world. Before Teflon-coated frying pans, we used iron frying pans with oil. If we imagine a standard family of four, we consume 60cc of oil in the morning, the same 60cc in the afternoon, and 120cc in the evening, which means we consume 87kg of oil per year. The health hazards of using 87kg of oil per year are much more serious. Oil intake causes obesity, heart disease, and high blood pressure, making it difficult to maintain a healthy social life.			
4201	Individual	-	Japan
In Japan, rice cookers are Teflon-coated. In the past, we used gas rice cookers without Teflon, but there was always a phenomenon that the rice was burnt. Japan consumes 10 million tons of rice every year. If			

the burnt portion is 3%, 300,000 tons of rice will be burnt and inedible. This will be a great loss for the nation. It is said that the burnt part is carcinogenic, so there are immeasurable health problems.			
4244	Behalf Of An Organisation	Company	Japan
We believe that the proposed restriction of PFAS is an excessive measure because it restricts more than 10,000 of organofluorine compounds on the grouping basis that they are persistent. Even if a substance that is clearly exempt from regulation is used, because it poses no danger to the human body or the environment, it is impossible to distinguish from substances that should be regulated because analysis methods have not been established. In order to avoid this, substances that have been confirmed to pose unacceptable hazards should be regulated individually. We determine that it is virtually impossible to set the concentration limits (25ppb, 250ppb,50ppm) in the second paragraph of the proposed limits. Even with full use of LC/MS/MS, the limit is to identify dozens of PFASs, and it is thought that it will take several years to several decades to develop the method.			
4245	Behalf Of An Organisation	Industry or trade association	Belgium
A total ban on fluoropolymers is not proportionate. The concerns of persistence raised in the restriction proposal can be appropriately managed through the implementation of responsible manufacturing and ELoC risk-management practices. There is not enough scientific data and evidence which would justify the complete ban of PFAS. The excellent chemical resistance and durability of fluoropolymers make them essential for many pump applications in: 5. Food and beverage processing applications, because of their non-sticking properties and chemically inertness, which is relevant for the regular cleaning and disinfection processes, and that the quality of the contacting food and beverage is not negatively changed. In case PTFE, PFA or polychlorotrifluoroethylene is used due to its sliding properties, an alternative could, from practical aspects be lead, but it is, due to its hazardous properties, no alternative. If metals are used instead of fluorinated polymers for sealing functions, the design needs to be re-worked, higher forces need to be applied to achieve the same tightness level, the machining tolerances must be more precise, and the chance that looseness appears in a shorter time increases. After dismantling, re-use of such metallic seals is impossible. In case polymer alternatives are identified, production process adaptions are required.			
4248	Behalf Of An Organisation	Company	United States of America
The Proposal is unclear in its scope as it does not specify the identity of PFAS substances in sufficient detail, arbitrarily relies on a non-legally binding accepted definition, presents methodological flaws in the assessment of hazard and risks of PFAS substances, presents insufficient information to allow an independent assessment of the hazard, presents insufficient information on the uses of the specific PFAS substance(s) and resulting emissions or exposure, does not properly assess the information on alternatives, does not properly assess the interplay with other EU legislation and does not sufficiently state reasons to support an action on an EU wide basis, does not allow an evaluation of the assessment of the proposed restriction and other identified RMOs in relation to their effectiveness, practicality and monitorability, presents inaccuracies on the conditions of the proposed restriction, in particular as regards proposed derogations, does not appropriately estimate on the "overall annual health costs following from exposure to PFAS in Europe" and of the costs to the society, opposes the outlined principles of ‘Better Regulation’ and will render agreed upon policies such as the EU Green Deal and the EU Green Deal Industrial Plan obsolete and will create illegal barriers to trade, causing the offshoring of companies from the EU and having a major socio-economic impact on the EU market.			
4260	Behalf Of An Organisation	Industry or trade association	Belgium
Fluoropolymers should be excluded as they do not pose any risk to the environment or human health, are non-mobile, non-bioaccumulative, non-toxic and flame retardant. We do not consider the current approach of undifferentiated group regulation to be suitable. Fluoropolymers are important enablers for numerous key industrial and future topics and for achieving the goals of the EU Green Deal.			
4262	Behalf Of An Organisation	Company	France
Repack-s is a downstream user of fluoropolymer compound billets (PTFE, PVDF, polychlorotrifluoroethylene, FEP and PFA) as well as billets and finished parts in FEPM and FKMs. Sealing components for machines and associated equipment’s as used in food & beverage, etc. As the fluoropolymer parts of are following the steel recycling loop, the condition for steel recycling guaranty the complete mineralisation of the fluoropolymers. No special measures have to be undertaken by the recycling industry.			
4264	Behalf Of An Organisation	Company	Italy

Although fluoropolymers fit the PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS. Fluoropolymers have documented safety profiles; are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic and they satisfy, themselves and in-use, the widely accepted polymer hazard assessment criteria to be considered PLC. At the end of industrial or consumer use, fluoropolymers may be disposed via the following routes: landfill, incineration, or reuse/recycling. There is considerable data demonstrating that fluoropolymers do not degrade in the environment or release substances of toxicological or environmental concern. A recent study demonstrates that PTFE is stable and does not degrade under environmentally relevant conditions. Further, fluoropolymers have negligible leachables, unreacted monomers, and oligomers most likely destroyed in fluoropolymer use processing and would therefore not be expected to significantly contribute to landfill leachate. Available data reveal that fluoropolymers are mineralized under commercial incineration operating conditions. In recent pilot scale studies representative of full-scale facilities, the most common form of end-of-life destruction conducted on PTFE found that combustion converted the fluorine into controllable hydrogen fluoride gas and that, of the 31 PFAS studied, no fluorine-containing products of incomplete combustion were produced above background levels. Food & Beverage sector: The EU food contact regulation requires that monomers, other starting substances, and additives used to produce food contact polymers should be risk assessed and authorized (EU 10/2011): the regulation lists authorized substances which are permitted to have food contact. The monomers, other starting substances, and additives used to produce fluoropolymers for food contact (e.g. PTFE, FEP, and PFA) have been authorized for food contact uses.			
4265	Behalf Of An Organisation	Company	Germany
The PTFE media filter use sectors to which our comment applies are the following: Sector: FCM and packaging, Use: Industrial food and feed production. PTFE media filters ensure low boron, low outgassing, chemical resistance and low pressure drop. The fibre diameter of the PTFE media ranges from 30 nm - 200 nm, which is extremely thin compared to other types of media, so that the filter pressure drop can be very low. As a result, significant energy savings are achieved, which contributes greatly to the reduction of CO2 emissions. They are mainly used in high performance filtration applications in professional or industrial settings (including semiconductors, pharmaceuticals, food, etc.) which present high volumes of air flow and where PTFE media filters allow to maintain a high level of air cleanliness. PTFE media filters are collected by professional waste contractors and subject to high-temperature incineration in accordance with the European Waste Code 150202 established under the Waste Framework Directive (2008/98/EC).			
4274	Behalf Of An Organisation	Industry or trade association	United States of America
The main concerns are the following: Overall, substances that are already restricted, banned or have been assessed as part of parallel restriction processes should not be part of the risk assessment of this restriction proposal. There is no scientific basis to refer to the potential irreversible adverse effects on the environment and on human health over time. Such vague assumptions do not constitute a demonstration of unacceptable risk as required by REACH. Persistence is not an intrinsic hazard, as it does not imply an adverse effect, and it should, therefore, not be used to justify the restriction of substances without having to prove unacceptable risk. Contrary to the assumption made in the Restriction Dossier, C6 is not used in consumer applications, especially due to the reduced use of C6 that will derive from the implementation of the Perfluorohexanoic acid restriction proposal. ATCS members welcome the development of emission minimisation techniques and have been implementing them as part of their commitment to sustainable production. It should be underlined that remediation technologies to remediate water and soil contamination are currently available. Current analytical methods do not ensure product compliance and enforceability of the proposed thresholds. We believe that the availability of harmonised analytical methods is a prerequisite to any regulatory action.			
4328	Behalf Of An Organisation	Company	Japan
Fryer hose for professional use: Fluororubber hose is used for the return piping of filtration edible oil (high temperature edible oil and silicone oil). Considering high temperature use environment, it is necessary to have heat resistance and edible oil resistance features.			
4333	Individual	-	Germany
The benefits of PFAS far exceed the risks. A blanket ban is stupid and harms the people of Europe. It sets back the standard of living by years. You are welcome to ban coated coffee cups; coated frying pans for			

all I care. But please do not ban technical materials that we can use everywhere in a meaningful and beneficial way.			
4345	Behalf Of An Organisation	Company	Germany
Manufacturer of industrial valves and pumps. Applications in the food and beverage industry, as they are non-stick and chemically inert, which is important for regular cleaning and disinfection processes, and the quality of food and beverages in contact with them is not negatively altered. Due to the requirements arising from WEEE, many pumps and valves are already returned to their manufacturers or other central collection points. The scope of collection should be further improved. In addition, procedures should be established for the separate collection of PFAS-containing materials from these collected products and their recycling or, if necessary, disposal under appropriate conditions should be improved. Concrete examples: PTFE, PFA or polychlorotrifluoroethylene are used for their tightening properties at high and cryo temperatures. Alternatives from a practical point of view could be metallic seals, but they are not as efficient as the PFAs ones ; the leakage rate is significantly less performant, which means leakages to environment and users. PTFE, PFA or polychlorotrifluoroethylene is also used for their sliding properties. The lead (Pb) could be an alternative if we do not take into account its hazardous properties, which cannot be considered. PTFE, PFA or polychlorotrifluoroethylene has been implemented for lead substitution, a step back is not conceivable. → this substitution would be a regrettable substitution in any case. For example, when metals are used instead of fluorinated polymers for sealing functions, the design must be revised, higher forces must be applied to achieve the same level of sealing, machining tolerances must be more precise, and the likelihood of seals loosening in a shorter time increases. After disassembly, reuse of such metal seals is impossible. In case polymer alternatives are identified, production process adaptions are required. New moulding processes need to be established, including new tools (which might require PFAS in the process, if no alternatives in such processes are found).			
4354	Behalf Of An Organisation	Industry or trade association	Japan
Japan Cosmetic Industry Association is representing interest of more than one thousand Japanese cosmetic companies. Inconsistences in the Proposed Restriction: (1) Persistence is not a recognized hazard. (2) Exposure assessment of individual PFAS compounds is missing. (3) The proposal does not follow the requirements imposed to ECHA regarding risk identification. (4) Restriction only by persistency is not consistent with existing regulatory flamework. Exhaustive Grouping of PFAS may Unnecessarily Restrict Chemicals, short-chain PFASs should be out of scope of the restriction because they have lower bioaccumulation. The following statements can be found in the report on perfluoroalkyl substances by The Agency for Toxic Substances and Disease Registry (ATSDR) and UNEP: 1) short-chain species have relatively good solubility in water and alcohol. 2) The bioaccumulation potential of perfluoroalkyls is reported to increase with increasing chain length. 3) The short-chain substances are not as bioaccumulative as the longer-chain substances such as PFOA and PFOS. PFASs are used in various industrial sectors. It is essential to design exposure scenarios for each PFAS used in different applications and to conduct exposure assessments according to their properties.			
4408	Behalf Of An Organisation	Company	Germany
Objective of this contribution to the PFAS consultation is not to defend PFAS in general but to support the selection process regarding potential exemptions, addressing especially fluoropolymers. Sector production equipment including machines (including food & pharma), etc. Request for exemptions of fluoropolymers in all kinds of sealings, gaskets, tubes, bellows, piston rings, semi-finished parts, tip seals, spring energized seals for the above mentioned sectors in demanding applications regarding (combinations of) high temperatures (>130°C), broad resistance against harsh media, electrical isolation properties, and/or low friction and low wear, good sealing behaviour, etc.			
4425	Behalf Of An Organisation	Company	Japan
Industrial pumps carry a wide variety of fluids such as foods with different features and conditions. Thus materials for the pump's liquid-contact parts need to tolerate these features and conditions for which PFASs (especially PTFE, FET, ETFE and FKMs) are compatible. In addition, PFASs (especially PTFE) in the pump industry are used in lubricants to reduce frictional wear and melting. Without them, lubricity is inhibited and resulting in a significant decrease in pump durability. PTFE, FEP, ETFE, and FKMs are			

essential for industrial pumps and cannot be substituted. Therefore, an exemption for industrial pumps from the restriction is necessary.			
4437	Behalf Of An Organisation	Company	Italy
We represent an international player in the production of fluoropolymer hoses, thermoplastic tubing, and gaskets. The proposed restriction does not differentiate between fluoropolymers and other families of PFAS. Fluoropolymers have unique properties that distinguish them from other PFAS and they do not have the environmental and toxicological profiles associated with some substances in this class of chemicals that are of concern. Fluoropolymers are durable, stable, and mechanically strong in harsh conditions in a variety of sectors. They are also stable in air, water, sunlight, chemicals, and microbes, and chemically inert, meeting the requirements for low levels of contaminants and particulates in manufacturing environments critical for the food and beverage, etc. industries. Finally, fluoropolymers are biocompatible; non-wetting, non-stick, and highly resistant to temperature, fire, and weather. We have identified the absence of specific uses: Food sector (consumer use): ▪ FCM (e.g., pipes and gaskets for coffee machines) for the purpose of consumer food preparation. The pipes are tasteless and odourless, free of phthalates, resistant to the liquids transported and to the products intended for cleaning, and able to comply with the hygiene standards. ▪ Special gaskets, used in the production of big and little household appliances, are non-toxic, conductive, food compliant, and have a good performance at very high and very low temperatures. We would like to express our appreciation for the consideration of the following proposed derogations: FCM for the purpose of industrial and professional food and feed production.			
4441	Behalf Of An Organisation	Company	United Kingdom
Relates to consumer and professional cookware and various sealing applications. The purpose of this submission is to provide an analysis of alternatives demonstrating that PEEK is a an existing and viable alternative to PTFE (and other fluoropolymers such as polychlorotrifluoroethylene, PVDF) in some critical applications and in particular, in cookware and sealing applications. PEEK has better mechanical properties than PTFE and it is also economically viable. This is demonstrated by the fact that there is an increasing number of cookware and sealing applications using PEEK on the EU market. PEEK is not hazardous, it is not a PBT/vPvB and it has additional environmental benefits compared to PTFE, such as recyclability and a better life cycle performance. However, PEEK has be shown to also be persistent and it could be bioaccumulative.			
4452	Behalf Of An Organisation	Company	Japan
Various functions are imparted to printing inks and overprint varnishes, and various additives are blended in order to exhibit these functions. Various waxes are known for the purpose of surface protection, but PTFE in particular has high heat resistance and is extremely difficult to substitute with other waxes. End uses include packages and labels: Paper & board packaging, Plastic packaging, Metal packaging for foods or beverage & Metal cap for bottle of beverage.			
4453	Behalf Of An Organisation	Industry or trade association	Japan
The proposal affects products relevant to the Green Deal. Therefore, PFAS should be restricted depending on their application. The proposal considers all PFASs as one group and restricts them uniformly, believed not to be appropriate in the view of risk assessment. Risk addressed by the restriction must be in the form of a Chemical Safety Report based on the relevant hazard and risk assessment, now on persistence alone, which is not considered a hazard endpoint. An 18-month transition period is unrealistic. Concern for large amount of PFAS-containing waste from what used to be sales stock, is there any effective plan for their disposal? The concentration thresholds are set at extremely low, but specific analytical methods are not specified. The thresholds for PFOA and PFOS are based on hazard, but this restriction set at a threshold of 25 ppb without any evidence.			
4463	Behalf Of An Organisation	Company	Germany
The Element 9 GmbH&CoKG (E9) is a newly launched German enterprise. The mission of E9 is to bring circular economy for Fluoropolymers into reality (large scale). It can be concluded that the activities of E9 are in good accordance with the goal of ECHA to close material cycles and protect environment from hazardous compounds. On the other hand forward looking industries like health care, green hydrogen, photovoltaics and computer technology can develop based in an environmental aware framework. A ban would be detrimental to cope with the collected waste streams coming back in future. Fluoropolymers are indispensable materials for key applications and almost impossible to be			

substituted. Based on this and due to the fact that sustainable recycling technology exists, E9 propose an exemption for all fluoropolymers.			
4474	Behalf Of An Organisation	Company	Italy
ATP is a company and manufacturer of customized PTFE matrix compounds and semifinished products from which seals are made. Sealing systems for Food & Beverage, etc. In the world of gaskets and sealing systems in general, it is impossible to find an alternative material to PTFE. Clean-in-Place and Sterilization-in-Place are the most common sterilization methods used in the food, beverage, etc. industries. These aggressive processes can quickly cause severe damage to elastomeric seals for the high temperatures reached, high loads and high pressure, meaning sealing systems made of PTFE are required. Other application examples are membranes and bellows made with modified PTFE which are mainly used in the Food and Beverage sector to keep an aseptic chamber separated from a normal one. Replacing a membrane with an alternative material, means that we need 150 spare parts of any other alternative material. Thus, could lead to an increasing of the maintenance costs for the customer, of the waste material and of the impact environment. In general, replacing a seal in PTFE matrix composite with an alternative material, means that we could have a drastic reduction of the tribological behaviour in terms of wear rate and friction coefficient up to 1000 times less.			
4477	Behalf Of An Organisation	Company	Germany
The PFAS group includes more than 10.000 different substances, including the group of fluoropolymers and fluoroelastomers which are extremely important and irreplaceable for the plant safety and service life of our customers. Fluoropolymers are PLC. We reject the generalized approach and demand to exempt fluoropolymers classified as safe materials as well as the materials necessary for their manufacturing from the regulation. PTFE and fluoropolymers are very expensive and difficult to process. Therefore, they are only used when no other alternatives are available. PTFE components for linings and coatings: Long-term stability and excellent corrosion resistance combined with flexibility and specific surface properties (low friction) are unique; substitution would lead to a deterioration of plant safety in chemical plants and safe food production.			
4501	Behalf Of An Organisation	Company	United Kingdom
The manufacturer of elastomeric seals using polymeric PFAS, such as FKM, and fluorosilicones, highlights the unique properties of fluoropolymers, including high fluid and temperature resistance, low permeability, and chemical stability, which are unmatched by other materials. They argue that the proposed PFAS restrictions fail to differentiate between harmful non-polymeric PFAS and the non-toxic, non-bioavailable, and environmentally immobile polymeric PFAS. Emphasizing the critical industrial applications of fluoropolymers in sectors like transportation, energy, and semiconductors, the manufacturer advocates for an unlimited exemption for fluoropolymers, aligning with the UK's regulatory approach that recognizes their low hazard profile. They stress that the restriction could hinder EU technological and environmental initiatives, lead to reliance on foreign technologies, and open the door to inferior substitutes. The manufacturer also points out legal and practical issues with the proposal, urging for realistic derogation periods considering the time needed to develop and qualify alternatives. Looks suspiciously like comment 4502.			
4502	Behalf of an Organisation	Company	Italy
Manufacturer of elastomeric seals using polymeric PFAS, such as FKM and fluorosilicones, emphasizes their unique properties, including high resistance to fluids and temperatures, low permeability, and high purity. These materials are essential in various industries due to their durability and safety features. The proposed PFAS restrictions fail to differentiate between polymeric and non-polymeric PFAS, despite the former's benign hazard profile and essential industrial applications. Argues for a derogation of fluoropolymers, highlighting their critical role in EU initiatives and the lack of viable alternatives. Stress that a ban would undermine EU competitiveness, innovation, and various critical sectors, leading to greater environmental and economic harm. Looks suspiciously like comment 4501.			
4518 & 4519	Behalf of an Organisation	Company	Japan
Manufactures products in Japan that contain PFAS. Request an exemption, based studies of the low environmental and health risk, as well as the unprecedented socio-economic impact. The REACH restriction is supposed to regulate “unacceptable risks to human health or the environment”, however, the proposed restriction lists more than 10,000 compounds based on the assumption that they are persistent and bioaccumulative. Other concerns, such as bioconcentration, transferability, and toxicological effects, are assessed for a few compounds. Fluoropolymers are identified by OECD as PLC.			

Therefore believe that fluoropolymers should be exempt. Agree to and support the statement made by Conference of Fluoro-Chemical Product Japan. Uses mentioned are not relevant.			
4521	Behalf of an Organisation	Company	Japan
Fluoropolymer (PTFE, PFA, FEP) processing manufacturer. Fluoropolymers are socio-economically essential and not hazardous under appropriate conditions. Believe that the restriction is extremely excessive by regulating all PFAS as one category. Support the statements made by JFIA and FCJ. Uses mentioned are not relevant			
4523	Behalf of an Organisation	Company	Germany
Produces PFAS polymers for diverse applications, including tubing, profiles, and shrink tubing, and is active in green deal initiatives and semiconductor manufacturing. Express concerns that a ban on PFAS polymers would have severe economic and socio-economic impacts due to the lack of alternatives, affecting Europe's competitiveness and socio-economic future. Process polymers like PTFE, FEP, PFA, ETFE and PVDF. Their operations involve using recyclable melt-processable grades, regranulation scrap internally, and maintaining a minimal waste footprint while complying with emission regulations. Resin waste re-channelled is between 5-12%, with incineration waste at less than 2%. Annually producing 160 tons, their key product properties include wide temperature range, chemical inertness, food contact approval, anti-adhesive qualities, UV resistance, pressure resistance, dielectric properties, low friction, and being non-toxic and non-flammable. They service 180 direct customers and approximately 300 indirect customers, with no known alternatives matching the comprehensive properties of fluoropolymers. Close collaboration with raw material suppliers aims to reduce emissions and develop alternatives, though none are expected for decades. Banning PFAS would necessitate significant investment in new equipment (€1.5 million) and redesign of components, resulting in lower sustainability and higher environmental footprints due to shorter lifecycles and increased waste. Major sectors impacted include green hydrogen production, semiconductor manufacturing, and food-related applications. Consequently, the manufacturer argues that a derogation is needed to continue essential developments and maintain a circular economy in the fluoropolymer industry.			
4524	Behalf of an Organisation	Company	United Kingdom
Document on exemption fluoropolymers with applications in various sectors including cookware and packaging. A derogation is also requested for Professional Cookware: Reusable bake and protect liners, trays, and bags, for bakery and (fast food) restaurant use			

9.5 Detailed Multi-Criteria Analysis

Please note that the references for the entire row, so also for effects on human health, the environment, etc., can be found in the most left cell.

9.5.1 Food Contact Materials

Below for all PFASs the issue of toxic fumes being emitted when used at high temperatures is addressed, as this is relevant for a lot of FCM applications. This phenomenon is known as polymer fume fever and relevant for almost all fluoropolymers.[187]

Table 10: Detailed multi-criteria analysis of PFASs and substitute substances in FCM.

Substance Chemical formula CAS Reference	Common applications	Effects on health	Effects on the environment	Mechanical & physical properties	Effects on costs
PFASs					
PTFE $(C_2F_4)_n$ 9002-84-0 [188–190]	Consumer cookware: e.g. pans, bakeware, seals. Industrial applications: e.g. liners, seals,	Decomposes and releases toxic fumes when heated above 400 °C. Considered safe under normal conditions.	Solubility in common solvents: none. Very persistent. Full mineralization at 800 °C.	Tensile str: ~30 MPa Flex Mod: 500-700 MPa M_p: ~330 °C M_S: 260-290 °C	PTFE powder: ~€20/kg Producer surplus losses are present due to concerns for the use of PTFE

	gaskets & conveyer belts.			Water/oil repellent and non-stick.	in cookware by consumers.
FEP $(C_3F_6.C_2F_4)_n$ 25067-11-2 [191,192]	Consumer cookware: e.g. pans, grill plates, cake tin. Industrial applications: e.g. tanks, liners, seals, gaskets, belts & tubing.	Degrades and releases toxic fumes when heated above 400 °C. Considered safe under normal conditions.	Water solubility: very low. Highly persistent. Full mineralization possible with incineration.	Tensile str: 20-30 MPa Flex mod: ~500 MPa M_P: ~260 °C M_S: ~200 °C Water/oil repellent and non-stick.	FEP pellets: ~€20/kg Producer surplus losses are expected due to concerns for the use of PFASs in FCM by consumers.
PFA $(C_2F_4)_n$-$(C_2F_3OCF_3)_m$ 26655-00-5 [193–195]	Consumer cookware: e.g. pans, toastie grills, cake tins. Industrial applications: e.g. mixing/storage tanks, liners, seals & tubing.	Releases toxic fumes when heated above 300 °C. Considered safe under normal conditions.	Water solubility: very low. Highly persistent. Full mineralization possible with incineration.	Tensile str: ~30 MPa Flex mod: 690 MPa M_P: ~300 °C M_S: ~205 °C Water/oil repellent and non-stick.	PFA pellets: ~€40/kg Producer surplus losses are expected due to concerns for the use of PFASs in FCM by consumers.
ETFE $(C_2H_4C_2F_4)_n$ 25038-71-5 [196]	Greenhouse films/roofing membranes, valves, tanks, linings and cookware coatings (within electronic appliances).	Releases toxic fumes when heated above 400 °C. Considered safe under normal conditions.	Water solubility: very low. Highly persistent. Full mineralization at 600 °C.	Tensile str: ~45 MPa Flex mod: 600-1200 MPa M_P: ~260 °C M_S: ~175 °C Non-stick, low flammability and good electrical insulation.	ETFE pellets: ~€30/kg Producer surplus losses are expected due to concerns for the use of PFASs in FCM by consumers.
ECTFE $(CF_2CFClCH_4)_n$ 25101-45-5 [197,198]	Conveyor belts, tanks, seals, gaskets, linings and cookware coatings (within electronic appliances).	Releases toxic fumes when heated above 300 °C. Considered safe under normal conditions.	Water solubility: very low. Highly persistent. Full mineralization by incineration may not be possible.	Tensile str: ~45 MPa Flex mod: ~1500 MPa M_P: ~220 °C M_S: ~150 °C Water/oil repellent, non-stick and low flammability.	ECTFE pellets: ~€30/kg Producer surplus losses are expected due to concerns for the use of PFASs in FCM by consumers.
PVDF $(CH_2CF_2)_n$ 24937-79-9 [199]	Conveyor belts, tanks, seals, gaskets, linings and cookware coatings.	Releases toxic fumes when heated above 300 °C. Considered safe under normal conditions.	Water solubility: very low. Highly persistent. Full mineralization by incineration may not be possible.	Tensile str: ~50 MPa Flex mod: ~1500 MPa M_P: ~180 °C M_S: ~150 °C Water/oil repellent, non-stick and excellent UV stability.	PVDF pellets: ~€10/kg Producer surplus losses are expected due to concerns for the use of PFASs in FCM by consumers.

FKMs Various (per)fluoroelastomers made up of (CH_2CF_2) and ($CF_3CF{=}CF_2$), ($CF_2{=}CF_2$) and/or ($CF_3OCF{=}CF_2$) [200,201]	Only industrial applications: seals, gaskets, O-rings, diaphragms and pump components.	Releases toxic fumes when heated above 350-400 °C. Generally not intended for FCM, as there is a concern for migration of contaminants.	Water solubility: very low. Persistent. Full mineralization possible using superheated water and a strong base.	Tensile str: 10–30 MPa Flex mod: 100–500 MPa M_p: 150-300 °C M_S: 175-280 °C Excellent chemical resistance and high temperature stability.	FKMs: ~€10–100/kg Producer surplus losses are expected due to concerns for the use of PFASs in FCM by consumers.
PFPEs $F(CF(CF_3)CF_2O)_n$-C_2F_5 60164-51-4 [202,203]	Industrial applications: lubricants, release agent, gaskets, seals and conveyor belts. Bakeware/oven coatings.	Releases toxic fumes when heated above 350 °C. Considered safe under normal conditions.	Water solubility: very low. Highly persistent. Low bioaccumulation potential. Low toxicity to aquatic life.	Tensile str: 1-10 MPa Flex mod: - M_p: - M_S: ~240 °C Water repellent and great chemical resistance.	PFPE oils: €200–1000/kg Producer surplus losses are expected due to concerns for the use of PFASs in FCM by consumers.
Substitutes					
Borosilicate glass Silica sand (59.5%), B_2O_3 (21.5%), K_2O (14.4%), ZnO (2.3%), and trace amounts of CaO and Al_2O_3 [204,205]	Kitchenware (e.g. baking dishes and glass cooking pots) and measuring cups.	Overall considered very safe, as there is a very low risk of contaminants and migration. Can still break and form sharp edges like regular glass.	Persistent. Requires the mining of raw minerals. Long lifespan and durable, so overall sustainable.	Tensile str: ~280 MPa Flex mod: 70–80 GPa M_p: ~1600 °C M_S: 360 °C High chemical durability, thermal resistance and transparent.	~€10/kg Very high energy costs, but a long lifespan. No foreseeable consumer surplus losses. Very different operations needed for production.
Polyphenylene sulfide $(C_6H_4S)_n$ 26125-40-6 [206]	Liners, tubing, waveguides, and seals.	Generally considered to be safe and non-toxic.	Not solvable in common solvents.	Tensile str: 50-80 MPa Flex mod: 3800-4200 MPa M_p: ~280 °C M_S: ~220 °C	~€5/kg
PEEK $(C_{19}H_{12}O_3)_n$ 29658-26-2 [207]	Seals, gaskets, liners, tubing and coatings for wires or blades.	Releases toxic fumes when used above 500 °C. Some allergic reactions have also been reported. Overall, considered safe under normal conditions.	Water solubility: very low. Generally considered biocompatible.	Tensile str: ~100 MPa Flex mod: 3800-4200 MPa M_p: ~345 °C M_S: ~260 °C Good insulator and excellent heat and chemical resistance. Low UV resistance.	PEEK pellets: ~€200/kg Should be usable with current PTFE equipment. Does require a higher processing temperature.
Polyurethanes $(ORCO_2NHR'NHCO)_n$	Conveyor belts, seals, gaskets, rollers, scrapers	Highly flammable, monomer used	Usage of volatile organic compounds in	Tensile str: 25-50 MPa	Polyurethane elastomers: ~€5/kg

R = alkyl or aryl group from the polyol. *R'* = alkyl or aryl group from the diisocyanate. 9009-54-5, 51852-81-4 [208,209]	and cutting boards.	(diisocyanates) is known to be hazardous (respiratory issues, skin irritation and sensitization) and is therefore restricted.	production, persistent (microplastic formation), incineration releases harmful substances and recycling is difficult. Biobased enzymatically synthesized versions are on the rise.	Flex mod: 30-1800 MPa M_P: 170-230 °C or none if a crosslinked thermoset M_S: ~80 °C Water repellent, chemical resistance, easy to clean, flexible and versatile.	Manufacturing of polyurethanes is expensive due to high energy use.
Cast iron Alloy consisting of mainly iron and carbon [210–212]	Pans, grills, bakeware and servicing ware (e.g. dish tray)	No evidence for toxicity. It can leach iron into food, possibly reducing an iron deficiency or causing an iron overload.	Very durable material, recyclable, does require high water usage. Improper production could lead to leaching of heavy metals.	Tensile str: 150-850 MPa M_P: ~1200 °C M_S: ~500 °C Made non-stick with proper seasoning. Prone to rust, can be brittle,	~€2/kg Some consumer surplus losses expected as the material is very heavy.
Ethylene Propylene Diene Monomer rubber [213–216]	Seals, pumps and valves. Can be used to create thermoplastic vulcanizates.	Generally considered safe. Releases toxic fumes when burned, so fire safety measures should be taken.	Insoluble in water. Using volatile organic solvents during synthesis. Not biodegradable. Recycling is in start-up phase.	Tensile str: 7-25 MPa M_P: - (thermoset polymer) M_S: 150 °C Good heat, chemical and weather (UV) resistance. Not oili-resistant.	~€3/kg The production is energy intensive.
(High-Density) Polyethylene $(CH_2CH_2)_n$ 9002-88-4 [217,218]	Cutting boards, gloves, conveyor belts and tubing.	In solid form considered as safe and non-toxic. Can be toxic if inhaled or absorbed as vapor/liquid. If additives (e.g. plasticizers) are used, migration can occur.	Water solubility: very low. Can transform into microplastics and contribute to plastic pollution. Volatile organic compounds can be used and released during disposal.	Tensile str: ~30 MPa Flex mod: 300–1500 MPa M_P: ~320 °C M_S: ~100 °C Hard to flexible, transparent, good moisture barrier, excellent resistance to chemicals and oils.	Pellets: ~€1/kg
Polypropylene $(C_3H_6)_n$ 9003-07-0 [219]	Bakeware, utensils, pumps and valves.	Highly flammable. Can release harmful substances when exposed	Persistent. Can transform into microplastics and contribute to plastic pollution.	Tensile str: 20–40 MPa Flex mod: 1200-1600 MPa M_P: ~160 °C M_S: ~120 °C	Pellets: ~€3/kg

		to high temperatures. Considered safe under normal conditions.		Properties are flexible. Good stress resistance, but sensitive to mould.	
Polyamide 66 $(C_{12}H_{22}N_2O_2)_n$ 32131-17-2 [220–222]	Conveyor belts, pipes, cooking tools (e.g. spatulas), within kitchen appliances (e.g. coffee machines) and food handling gloves.	Microplastic particles are possibly toxic. Releases toxic fumes when used above 300 °C. Generally considered safe.	Not biodegradable. Can transform into microplastics and contribute to plastic pollution.	Tensile str: ~80 MPa Flex mod: ~1200 MPa M_p: ~260 °C M_S: ~150 °C Rigid, good heat stability and chemical resistance.	~€3/kg The production is energy intensive.
Polybutylene $(C_4H_8)_n$ 9003-28-5 [223,224]	Piping, sealants, adhesives and non-stick coatings.	Generally considered safe for food contact. Some migration of additives (e.g. plasticizers) can occur. Can degrade at high temperatures.	Water solubility: very low. Can transform into microplastics and contribute to plastic pollution. Can degrade due to UV.	Tensile str: ~30 MPa Flex mod: ~750 MPa M_p: ~130 °C M_S: 90 °C Flexible, hydrophobic and chemical resistance.	Pellets: ~€5/kg
Silicone (polysiloxanes) $(OR_2SiOSiR_2)_n$ 63394-02-5 [225–228]	Seals, conveyer belts, gaskets, baking mats.	Some people can be allergic to silicone. Leaching of additives or leftover reagents is possible. Overall, the material is considered safe.	Biodegradation has been shown, but this depends on the composition. Recycling is challenging. Low toxicity for aquatic life, but this can accumulate.	Tensile str: 0.1-150 MPa Flex mod: ~5 MPa M_p: - M_S: ~250 °C Water repellent. Good UV and chemical resistance.	~€30/kg Thicker belts leading to lower heat conductivity through the belt resulting in lower output.
Produced polymer layer (e.g. organosilicon) by plasma technology Tradename: PLASLON® [229]	Non-stick coating for pans/cookware, suitable for enamel, glass, stoneware, and porcelain.	Identified as food safe. Can make use of polymers that have health concerns (e.g. polyurethanes).	Uses a dry chemical process, so no volatile solvents are used. Can make use of polymers that have environmental concerns.	Mechanical properties are hard to state as different polymers can be used. Non-stick, high mechanical resistance and oleophilic.	€20-150/litre and additional fees for application. Low energy consumption.
Stainless steel Alloy of iron and carbon. CAS depends on composition (e.g. 65997-19-5) [230–232]	Conveyor belts, pans, bowls, tanks, refrigerators, baking trays.	Migration risk of nickel, chromium, and manganese, but these are already under regulation. Not scratch	Recyclable and durable. Large CO_2 emissions and water usage during production.	Ten str: 400–1000 MPa Flex mod: ~200 GPa M_p: ~1400 °C M_S: ~800 °C Not non-stick, but high heat	~€5/kg. Higher energy and productions costs. Equipment needed is very different from current PFAS

		resistant and can therefore harbour bacteria. Overall, considered safe.		and chemical resistance.	equipment. Some consumer surplus losses, as it is not non-stick and heavier.
Polystyrene (C8H8)n 9003-53-6 [233–236]	Food trays and inside electrical appliances (e.g. blenders, refrigerators and microwaves).	Made up of benzene and styrene (carcinogenic), so workers exposure. Microplastic variant has been found to be toxic and cause dysfunctions. Migrates at high temperatures or acidity.	Persistent, not biodegradable. Can transform into microplastics and contribute to plastic pollution. One of the main ocean pollutants.	Tensile str: ~50 MPa Flex mod: ~3100 MPa M_p: ~220 °C M_S: ~90 °C Lightweight, insulating, very mouldable and chemically resistant.	~€1/kg The production is energy intensive.
Polyether block amide Block copolymer of polyamide and polyether. Tradename: PEBAX [237–239]	Conveyor belts, tubing, hoses, within appliances (e.g. coffee machines) and utensils (e.g. spatulas).	Considered safe under normal conditions. There are some concerns on migration of contaminants, especially at high temperatures or acidic conditions.	Water solubility: very low. Generally considered biocompatible.	Tensile str: 30-60 MPa Flex mod: 10-500 MPa M_p: 130-175 °C M_S: - Chemical resistant, lightweight and usable at very low temperatures.	Pellets: €20-50/kg
Cross-linked polyethylene $(CH_2CH_2)_n$ crosslinked 9002-88-4 [240]	Tubing in plumbing.	Typically not used with FCM applications due to migration concerns.	Water solubility: very low. Can transform into microplastics and contribute to plastic pollution. Volatile organic compounds can be used and released during disposal.	Tensile str: 20-30 MPa Flex mod: 400-900 MPa M_p: - (thermoset) M_S: 120 °C Very flexible, chemical resistance.	Pellets: ~€5/kg Has a long service life.
Nitrile rubber $(C_3H_3N)_n(C_4H_6)_m$ 9003-18-3 [241–245]	Seals, gaskets, tubing and gloves.	Can cause allergic reactions. Rubber dust (processing) and fumes (high temperatures) are known to be carcinogenic.	Not biodegradable, can result in microplastics, and recycling is challenging.	Tensile str: ~20 MPa M_p: -(thermoset) M_S: ~125 °C Oil, heat, and chemical resistance.	~€3/kg The production is energy intensive and requires personal protection equipment for workers.

		Mainly worker exposures.			
Polyvinyl chloride $(CH2CHCl)_n$ 9002-86-2 [246–248]	Belts, pumps and valves.	Have been found to contain many additives, which can be harmful to human health. One of the most common microplastic found in the human body.	Dioxins are released with incineration, which have been indicated to be endocrine disruptors for many organisms. Large source of microplastics.	Tensile str: 15-100 MPa Flex mod: 2.7-3.0 GPa M_p: ~170 °C M_S: ~80 °C High chemical resistance and does not conduct electricity.	~€3/kg Thicker conveyor belts leading to lower heat conductivity resulting in lower output.

9.5.2 Packaging

Due to time constraints unable to look into possibly interesting substitute substances: Bamboo, palm leaf, elephant grass, wheat straw.

Table 11: Detailed multi-criteria analysis of PFASs and substitute substances in packaging applications.

Substance Chemical formula CAS Reference	Common applications	Effects on health	Effects on the environment	Mechanical & physical properties	Effects on costs
PFASs					
PTFE $(C_2F_4)_n$ 9002-84-0 [188–190]	Food packaging: e.g. baking paper, films, coating of cans, foils, disposable plates. Feed packaging. Additive for other plastics to get non-sticking properties.	Decomposes and releases toxic fumes when heated above 400 °C. Considered safe under normal conditions.	Solubility in common solvents: none. Very persistent. Full mineralization at 800 °C.	Tensile str: ~30 MPa Flex Mod: 500-700 MPa M_p: ~330 °C M_S: 260-290 °C Water/oil repellent and non-stick.	PTFE powder: ~€20/kg Producer surplus losses are expected due to concerns for the use of PFASs in packaging by consumers.
FEP $(C_3F_6.C_2F_4)_n$ 25067-11-2 [191,192]	(Shrinkable) films, flexible packaging.	Degrades and releases toxic fumes when heated above 400 °C. Considered safe under normal conditions.	Water solubility: very low. Highly persistent. Full mineralization possible with incineration.	Tensile str: 20-30 MPa Flex mod: ~500 MPa M_p: ~260 °C M_S: ~200 °C Water/oil repellent and non-stick.	FEP pellets: ~€20/kg Producer surplus losses are expected due to concerns for the use of PFASs in packaging by consumers.
PFA $(C_2F_4)_n$-$(C_2F_3OCF_3)_m$ 26655-00-5 [193–195]	Bags, pouches, wraps, and liners.	Releases toxic fumes when used above 300 °C. Considered safe under normal conditions.	Water solubility: very low. Highly persistent. Full mineralization possible with incineration.	Tensile str: ~30 MPa Flex mod: 690 MPa M_p: ~300 °C M_S: ~205 °C Grease resistance and moisture barrier.	PFA pellets: ~€40/kg Producer surplus losses are expected due to concerns for the use of PFASs in packaging by consumers.

PFPEs $F(CF(CF_3)CF_2O)_n-C_2F_5$ 60164-51-4 [202,203]	PFPEs are used in the production of certain food packaging films that require high resistance to oils, fats, and other food substances. These films help protect the integrity and safety of food products during storage and transportation.	Releases toxic fumes when used above 350 °C. Considered safe under normal conditions.	Water solubility: very low. Highly persistent. Low bioaccumulation potential. Low toxicity to aquatic life.	Tensile str: 1-10 MPa Flex mod: - M_p: - M_S: ~240 °C Water repellent and great chemical resistance.	PFPE oils: €200–1000/kg Producer surplus losses are expected due to concerns for the use of PFASs in packaging by consumers.
Polychlorotrifluoroethylene $(CF_2CFCl)_n$ 9002-83-9 [249–252]	Food packaging & high barrier films.	Low toxicity. Pyrolysis can lead to generation of toxic compounds. Considered safe under normal conditions.	Not soluble in water. Hard to recycling. Very persistent.	Tensile str: ~36 MPa Flex mod: ~1.2 GPa M_p: ~220 °C M_S: ~190 °C Excellent chemical resistance.	Bulk prices not found, ~€70 for 25 grams. Producer surplus losses are expected due to concerns for the use of PFASs in packaging by consumers.
FKMs Various (per)fluoroelastomers made up of (CH_2CF_2) and $(CF_3CF{=}CF_2)$, $(CF_2{=}CF_2)$ and/or $(CF_3OCF{=}CF_2)$ [200,201]	Protective linings, packaging inks.	Releases toxic fumes when used above 350-400 °C. Generally not intended for FCM, as there is a concern for migration of contaminants.	Water solubility: very low. Persistent. Full mineralization possible using superheated water and a strong base.	Tensile str: 10–30 MPa Flex mod: 100–500 MPa M_p: 150-300 °C M_S: 175-280 °C Excellent chemical resistance and high temperature stability.	FKMs: ~€10–100/kg Producer surplus losses are expected due to concerns for the use of PFASs in packaging by consumers.
Perfluoroalkyl phosphinic acids $C_nF2_{n+1}(CH_2)_mPO(OH)_2$ 40143-77-9, 40143-79-1, 52299-27-1, 63225-54-7 [253–255]	Coating e.g. for packaging toys and foodstuff.	Toxicity trends are still unclear and hard to determine.	Has been indicated to negatively affect aquatic life by inducing oxidative stress. Highly persistent. Long-range transport potential.	Varies greatly. Water- and oil-resistant. Thermally stable and spread easily as a coating.	Varies greatly. Producer surplus losses are expected due to concerns for the use of PFASs in packaging by consumers.
Perfluoroalkyl phosphonic acids $C_nF_{2n+1}PO_3H$	Coating for polyethylene film used e.g. for	Zebrafish studies have indicated effect	Highly persistent. Long-range	Varies greatly. Water- and oil-resistant. Thermally stable	Varies greatly. Producer surplus losses are expected

40143-77-9, 40143-78-0, 52299-26-0, 63225-55-8 [255-257]	packaging toys and foodstuff.	on neurotoxicity.	transport potential.	and spread easily as a coating.	due to concerns for the use of PFASs in packaging by consumers.
PAPs $PO_4H(-CH_2CH_2(CF_2)_nF)_m$, n = 4, 6, 8, 10 or 12, m = 1, 2 or 3 57678-01-0, 57678-03-2, 57677-95-9, 678-41-1, etc. [110,258,259]	Barrier coating, release agent,	Biotransformation of PAPs in the human body increases the burden of perfluoroalkanoic acids. Endocrine disruption and reproductive toxicity.	Water solubility: 2×10^{-6} – 6×10^{-3} mol/L Bioaccumulation factor: 10×10^2 – 12×10^5 Half-life: 4 – 36670 days	Varies greatly, no general average values were found. M_p: 50 – 200 °C Oil-repellent, non-stick	No bulk prices were found. Producer surplus losses are expected due to concerns for the use of PFASs in packaging by consumers.
Substitutes					
Chitosan $(C_6H_{11}NO4)_n$ 9012-76-4 [260-262]	Coatings for paper and board packaging for food. Films.	Non-toxic and even allowed to be present in food.	Sustainable (compostable, recyclable or biodegradable) bio-based material.	Tensile str: 30-70 MPa Decomposes around 300 °C Very high oil and grease resistance. Antimicrobial, and antifungal.	~€30/kg
Polyphenylene sulfide $(C_6H_4S)_n$ 26125-40-6 [206]	Liners.	Generally considered to be safe and non-toxic.	Not solvable in common solvents.	Tensile str: 50-80 MPa Flex mod: 3800-4200 MPa M_p: ~280 °C M_S: ~220 °C	~€5/kg
Polylactic acid $(C_3H_4O_3)_n$ 26100-51-6 [263-265]	Bowls, take-out containers, clamshells, lids, food trays, and portion cups.	May contain additives that can leach out at relatively low temperatures. Overall considered safe.	Non-toxic renewable feedstock, naturally occurring, biodegradable.	Tensile str: ~60 MPa Flex mod: 4 GPa M_p: ~165 °C M_S: ~55 °C Easy to process, transparent.	~€10/kg
(High-Density) Polyethylene $(CH_2CH_2)_n$ 9002-88-4 [217,218]	Food packaging: plastic wraps, cling films, (freezer) bags, pouches, containers, trays, milk jugs and disposable tableware.	In solid form considered as safe and non-toxic. Can be toxic if inhaled or absorbed as vapor/liquid. If additives (e.g. plasticizers) are used, migration can occur.	Water solubility: very low. Can transform into microplastics and contribute to plastic pollution. Volatile organic compounds can be used and released during disposal.	Tensile str: ~30 MPa Flex mod: 300-1500 MPa M_p: ~320 °C M_S: ~100 °C Hard to flexible, transparent, good moisture barrier, excellent resistance to chemicals and oils.	Pellets: ~€1/kg
Polypropylene $(C_3H_6)_n$	Food packaging: containers, lids,	Highly flammable.	Persistent.	Tensile str: 20-40 MPa	Pellets: ~€3/kg

9003-07-0 [219]	disposable tableware, microwavable packaging, bottles and bakeware. Feed packaging. Generic packaging: household and industrial products packaging.	Can release harmful substances when exposed to high temperatures. Considered safe under normal conditions.	Can transform into microplastics and contribute to plastic pollution.	Flex mod: 1200-1600 MPa M_p: ~160 °C M_S: ~120 °C Properties are flexible. Good stress resistance, but sensitive to mould.	
Polyamide 66 $(C_{12}H_{22}N_2O_2)_n$ 32131-17-2 [220–222]	Films, sheets, storage containers and disposable cutlery.	Microplastic particles are possibly toxic. Releases toxic fumes when used above 300 °C. Generally considered safe.	Not biodegradable. Can transform into microplastics and contribute to plastic pollution.	Tensile str: ~80 MPa Flex mod: ~1200 MPa M_p: ~260 °C M_S: ~150 °C Rigid, good heat stability and chemical resistance.	~€3/kg The production is energy intensive.
Natural waxes (e.g. bees wax, candelilla wax) [265–267]	Coatings for bags, boxes, wrappers and liners.	Allergic reactions can occur. Can contain impurities or contaminants (e.g. pesticides, environmental pollutants). Direct contact may cause skin irritation.	Not tested as biodegradable. Naturally occurring. Often coated using organic solvent. Harvesting particular from beeswax or carnauba palm trees is considered unsustainable.	M_p: ~70 °C Cannot be used at warm temperatures due to low melting point. Very hydrophobic. Can increase shelf-life of food. Antimicrobial.	~€20/kg
Polybutylene $(C_4H_8)_n$ 9003-28-5 [223,224]	Food packaging: films, bags, wraps, films and can coatings.	Generally considered safe for food contact. Some migration of additives (e.g. plasticizers) can occur. Can degrade at high temperatures.	Water solubility: very low. Can transform into microplastics and contribute to plastic pollution. Can degrade due to UV.	Tensile str: ~30 MPa Flex mod: ~750 MPa M_p: ~130 °C M_S: 90 °C Flexible, hydrophobic and chemical resistance.	Pellets: ~€5/kg
Silicone (polysiloxanes) $(OR_2SiOSiR_2)_n$ 63394-02-5 [225–228]	Seals within packaging and storage bags.	Some people can be allergic to silicone. Leaching of additives or leftover reagents is possible. Overall, the	Biodegradation has been shown, but this depends on the composition. Recycling is challenging. Low toxicity for aquatic life, but	Tensile str: 0.1-150 MPa Flex mod: ~5 MPa M_p: - M_S: ~250 °C Water repellent.	~€30/kg

		material is considered safe.	this can accumulate.	Good UV and chemical resistance.	
Polystyrene $(C_8H_8)_n$ 9003-53-6 [233–236]	Single use cups, food containers and films for take-out. As foam for general packaging for additional protection.	Made up of benzene and styrene (carcinogenic), so workers exposure. Microplastic variant has been found to be toxic and cause dysfunctions. Migrates at high temperatures or acidity.	Persistent, not biodegradable. Can transform into microplastics and contribute to plastic pollution. One of the main ocean pollutants.	Tensile str: ~50 MPa Flex mod: ~3100 MPa M_P: ~220 °C M_S: ~90 °C Lightweight, insulating, very mouldable and chemically resistant.	~€1/kg The production is energy intensive.
Polyurethanes $(ORCO_2NHR'NHCO)_n$ R = alkyl or aryl group from the polyol. *R'* = alkyl or aryl group from the diisocyanate. 9009-54-5, 51852-81-4 [208,209]	Plastic food packaging for acidic foods.	Highly flammable, monomer used (diisocyanates) is known to be hazardous (respiratory issues, skin irritation and sensitization) and is therefore restricted.	Usage of volatile organic compounds during production, persistent (microplastic formation), incineration leads to the release of harmful substances and recycling is difficult. Bio-based, enzymatically synthesized polyurethanes are on the rise.	Tensile str: 25-50 MPa Flex mod: 30-1800 MPa M_P: 170-230 °C or none if a crosslinked thermoset M_S: ~80 °C Water repellent, chemical resistance, easy to clean, flexible and versatile.	Polyurethane elastomers: ~€5/kg Manufacturing of polyurethanes is expensive due to high energy use.
Polyether block amide Block copolymer of polyamide and polyether. Tradename: PEBAX [237–239]	Stretch wraps and shrink films.	Considered safe under normal conditions. There are some concerns on migration of contaminants, especially at high temperatures or acidic conditions.	Water solubility: very low. Generally considered biocompatible.	Tensile str: 30-60 MPa Flex mod: 10-500 MPa M_P: 130-175 °C M_S: - Chemical resistant, lightweight and usable at very low temperatures.	Pellets: €20-50/kg
Cross-linked polyethylene $(CH_2CH_2)_n$ crosslinked 9002-88-4 [240]	As foam for general packaging for additional protection.	Typically not used with food applications due to migration concerns.	Water solubility: very low. Can transform into microplastics and contribute	Tensile str: 20-30 MPa Flex mod: 400-900 MPa M_P: - M_S: 120 °C	Pellets: ~€5/kg Has a long service life.

			to plastic pollution. Volatile organic compounds can be used and released during disposal.	Very flexible, chemical resistance.	
Poly(methyl methacrylate) $(C_5H_8O_2)_n$ 9011-14-7 [265,268–270]	Plates and bowls.	Releases toxic fumes when burned, so fire safety precautions should be taken. Made with toxic monomers.	Biocompatible and recyclable, but not biodegradable.	Tensile str: 40-70 MPa Flex mod: 2.5-3.5 GPa M_p: 200-250 °C M_S: 80 °C Water- and grease resistant, transparent.	~€250/kg

9.5.3 Cosmetics

Table 12: Detailed multi-criteria analysis of PFASs and substitute substances in cosmetic applications.

Substance Chemical formula CAS Reference	Common applications	Effects on health	Effects on the environment	Mechanical & physical properties	Effects on costs
PFASs					
PTFE $(C_2F_4)_n$ 9002-84-0 [111,188–190,271]	Dental floss, pressed powders, loose powders (e.g. setting powders), nail enamel, shaving gels, foundations, skin creams, mascaras and brow liners.	Considered safe under normal conditions.	Solubility in common solvents: none. Very persistent. Low emission quantities.	Used for its chemical resistance, heat resistance, UV filter, strong adhesion, low water absorption and bulking properties.	PTFE powder: ~€20/kg
Polyperfluoromethylisopropyl ether $CF_3O[CF(CF_3)CF_2O]_n(CF_2O)_mCF_3$ 69991-67-9 [111,272]	Skin creams and oils, facial cleansers, shampoos, shaving creams, lip liners, lip balms, sunscreens, setting powders/sprays and makeup primers.	Unknown or uncertain toxicity effects.	Low emission quantities. Persistent but low bioaccumulation concerns.	Used for its skin conditioning property.	No bulk prices were found.
Perfluorononyl dimethicone $C_{12}H_{24}OSi_2C_9F_{19}$ 259725-95-6 [111,273,274]	Eye and lip pencils, eye shadows, lipsticks, hair sprays and sunscreens.	Generally considered safe to use in cosmetics. Indications of immunotoxicity and carcinogenity.	Low emission quantities. Some studies show adverse effects on aquatic life. Persistent.	Used for its skin conditioning property.	No bulk prices were found.

Perfluorodecalin $C_{10}F_{18}$ 306-94-5 [111,275,276]	Skin creams and oils, facial cleansers, shampoos, masks, shaving cream, lip balm and exfoliants.	Flammable. Minor toxic effects have been shown.	Low emission quantities. Persistent. Bioaccumulating substance.	Used for its skin conditioning, solvent, detangling and skin barrier function improvement properties.	~€1000/kg
PAPs $PO_4H(-CH_2CH_2(CF_2)_nF)_m$, n = 4, 6, 8, 10 or 12, m = 1, 2 or 3 57678-01-0, 57678-03-2, 57677-95-9, 678-41-1, etc. [110,258]	Emulsifier, viscosity agent, surfactant and antistatic agent.	Can degrade (oxidation) into perfluorinated carboxylates. They can directly enter the human body via dermal absorption, causing potential health risks.	Low emission quantities. Water solubility: $2 \times 10^{-6} - 6 \times 10^{-3}$ mol/L Bioaccumulation factor: $10 \times 10^2 - 12 \times 10^5$ Half-life: 4 – 36670 days	Used to provide hydrophobic properties for improved durability and wear.	No bulk prices were found.
Octafluoropentyl methacrylate $C_{10}H_5F_8O_2$ 355-93-1 [111,277–279]	Shampoos, hairsprays, conditioners and hair styling products.	Can cause eye irritation, skin irritation and respiratory issues.	Low emission quantities. Persistent.	Used for its binding property.	No bulk prices were found. €277/25mL
C9-15 fluoroalcohol phosphate N/A, C_9-C_{15} 223239-92-7, 74499-44-8 [111,280,281]	Foundation.	Endocrine disruption (moderate) and non-reproductive organ system toxicity (moderate).	High persistent and bioaccumulating. Degrades into fluorotelomer alcohols and perfluoroalkanoic acids. Low emission quantities.	Used for its skin conditioning property.	No bulk prices were found.
Substitutes					
Polylactic acid $(C_3H_4O_3)_n$ 26100-51-6 [264,282]	Beauty wipes	May contain additives that can leach out at relatively low temperatures. Overall considered safe.	Low emission quantities. Non-toxic renewable feedstock, naturally occurring, biodegradable.	Easy to process, transparent.	~€10/kg
Natural waxes (e.g. bees wax, Carnauba wax, Candelilla wax, Rosa Damascena Flower Wax, Jojoba wax) [265–267,283,284]	Used on nylon dental floss.	Allergic reactions can occur. Can contain impurities or contaminants (e.g. pesticides, environmental pollutants). Direct contact may cause skin irritation.	Not tested as biodegradable. Naturally occurring. Often coated using organic solvent. Harvesting particular from beeswax or carnauba palm trees is	Cannot be used at warm temperatures due to low melting point. Very hydrophobic. Antimicrobial.	~€20/kg

			considered unsustainable.		
Silicone (polysiloxanes) $(OR_2SiOSiR_2)_n$ 63394-02-5 [225-228,285]	Lip pencils, antiperspirants sunscreens, haircare and skincare products.	People can be allergic to silicone. Leaching of additives or leftover reagents is possible (harm hormone function). Overall, the material is considered safe	Low emission quantities. Biodegradation has been shown, but this depends on the composition. Recycling is challenging. Low toxicity for aquatic life, but this can accumulate.	Water repellent. Good UV and chemical resistance. Can help improve texture of the product and smooth the skin.	~€30/kg
Synthetic waxes (e.g. zinc oxide, boron nitride) 8002-74-2, 1314-13-2, 10043-11-5 [286-288]	Pressed/loose powders, creams, face masks, nail care, foundations, mascaras and sun care products.	Can cause allergic reactions, but overall classified as not hazardous and do not penetrate the skin.	Not water soluble. Non-renewable and can perturb ecosystems if the nanoparticles are present in large quantities. Low emission quantities.	Provides water resistance and can make the product and skin smooth.	Varies.
Mineral oils (e.g. tea tree oil) [111,289,290]	Within dental floss.	Causes acne and skin issues.	Low emission quantities. Unable to process further due to time constraints.	Used for its moisturizing effect.	Varies.
Polyvinylpyrrolidone [111,291,292]	Hair sprays, gels, mousses and within skincare such as creams and lotions.	Allergic reactions can occur	Water soluble. Low emission quantities.	Used for its film-forming properties and as stabilizer and binder.	Unable to find (bulk) prices.