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REPLACEMENT OF POLYMERIC PFAS IN INDUSTRIAL APPLICATIONS WITH HARSH ENVIRONMENTS

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Glossary

ACM	Acrylic elastomer
AFFF	Aqueous film forming foam
CAS	Chemical abstracts service
CCM	Catalyst-coated membrane
CL	Catalyst layer
CLP	Classification, Labelling, Packaging
DGS	Dry gas seal
EFSA	European Food Safety Authority
EoL	End of life
ETFE	Ethylene tetrafluoroethylene
FEP	Fluorinated ethylene propylene
FFP	Flow field plate
FFKM	Perfluoroelastomer
FKM	Fluorocarbon-based fluoroelastomer
FP	Fluoropolymers
GDL	Gas diffusion layer
HT-PEMFC	High temperature proton exchange membrane fuel cells
k_{ow}	Water-octanol-partition coefficient
MEA	Membrane-electrode-assembly
MPL	Micro-porous layer
MSWI	Municipal solid waste incineration
NBR	Acrylonitrile/butadiene elastomer
PAN	Polyacrylonitrile
PBI	Polybenzimidazole
PEM	Proton exchange membrane, polymer electrolyte membrane
PEMFC	Proton exchange membrane fuel cell

PFA	Perfluoroalkoxy polymer
PFAAs	Perfluoroalkyl acids
PFAS	Per- and polyfluoroalkyl substances
pPFAS	Polymeric per- and polyfluoroalkyl substances
PFCA	Perfluoroalkyl carboxylic acid
PFHxS	Perfluorohexane sulfonic acid
PFNA	Perfluorononanoic acid
PFOS	Perfluorooctane sulfonic acid
PFOA	Perfluorooctanoic acid
PFPE	Perfluoropolyethers
PLC	Polymers of low concern
P-sufficient	Persistence-sufficient
PBT/vPvB	Persistent, bioaccumulative, toxic / very persistent, very bioaccumulative
PMT/vPvM	Persistent, mobile, toxic / very persistent, very mobile
PTFE	Poly(tetrafluoro ethylene)
SVHC	Substance of very high concern
UBA	Umweltbundesamt

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Introduction

Per- and polyfluoroalkyl substances (PFAS) are man-made substances which contain multiple C–F bonds. Several thousand substances qualify as PFAS[1–3] – ranging from gases, liquids and solids like polymers . PFAS share unique physicochemical properties[4] like an extraordinary chemical and thermal stability and unique hydrophilic and lipophilic characteristics[5] which led to their use in many different areas[6]. The draw-back of their inertness is that they are persistent in the environment – in particular low molecular weight PFAS have been found in soils, ground water, seas, and oceans[2,7–9]. The toxicity of a few low molecular weight PFAS is established[10], other PFAS are non-toxic and qualify as biomedical or food contact materials. For the majority of PFAS, there are no in-depth studies of their potential impact on human health and environment available.

The persistence of PFAS in the environment (which is a trait of all PFAS) and local contaminations with toxic PFAS sparked initiatives to regulate the use of PFAS[11,12]. The European Chemicals Agency ECHA published a far-reaching restriction proposal aiming at phasing out PFAS with exempting only a few applications. For regulatory purposes, the restriction proposal considers PFAS as a »class of materials«. The grouping of all PFAS as a class is justified by their persistence in the environment. As a precautionary measure, the restrictions apply to all PFAS in order to prevent the accumulation of persistent and potentially toxic substances in the environment, regardless of having established the toxic effects on human health and environment of the specific substance[13].

The current study focusses on a sub-group of polymeric PFAS, fluoropolymers (FP) and perfluoropolyethers (PFPE) which are used in technical applications where they must be able to endure in harsh environments. The study is divided in three parts:
The first part reviews the benefits and potential hazards of PFAS. In addition, the rationale behind different currently applied and proposed regulatory measures is discussed. The discussion, whether or not polymeric PFAS and in particular fluoropolymers should be regulated in the same way as other, lower molecular weight PFAS, is reviewed. The second part of the study summarizes interviews with researchers and engineers who work with application which currently rely on FP and PFPE and where an adequate replacement is needed should the restriction proposal come into place. The possibilities and difficulties to find adequate replacement materials is discussed. The third part of the study reviews position statements of industries and professional organizations on the proposed PFAS restrictions. The concerns regarding the potential impact of a PFAS ban are summarized.

Different sources were used for the three parts of the report. The first part is based on peer-reviewed scientific literature and on documents published by government agencies and regulatory bodies. The scientific approach and the peer reviewing process should warrant that a balanced representation of the current state of knowledge is presented in a scientific paper. A fundamental question for regulating PFAS are the conclusions which can be drawn from the scientific literature. Policy making has to come to terms with many unknowns in this area and has to find a compromise between conflicting interests. Similar scientific findings can result in different recommendations for policy making, depending on the standpoint of the scientist who authors the paper. A marine biologist studying the contamination of oceans with PFAS might come to different recommendations than a researcher involved in fuel cell production who is faced with the challenge to replace fluoropolymers in the near future. It is likely that both scientists are driven by the impetus to protect the environment: the marine biologist by reducing the contamination of the oceans with chemical substances and the engineer by providing a technology which reduces CO_2 emissions. Both points of view are valid, and we try to give a balanced account of different standpoints.

The second part of the report is based on interviews with scientists and engineers working in industry on products and components which contain fluoropolymers or PFPE. Research papers from universities or research institutions often describe pre-competitive research with a »technology readiness level«[14] TRL 1 – 6, studying the feasibility of replacing PFAS with other substances or materials. An actual substitution of PFAS will correspond to work on TRL 8 – 9 and will be the task of industrial engineers and scientists. In their perspective, production processes, service life, and economic viability of a product play an important role. Several case studies are presented, where the challenges of finding adequate replacement materials for fluoropolymers or PFPEs are highlighted and where despite intense research efforts it is not yet clear whether a replacement will be available soon.

The third part of the paper is based on position papers of professional organizations and industries. It is the nature of a position paper to »lobby« for the standpoint of its author. In general, a position paper will benefit from a representation of different standpoints (and many papers succeed in doing so), but the foremost purpose of a position paper is to present the position of its author.

The sources of the first part of the report have the benefit of a peer review which ideally enforces a balanced representation of the state of knowledge. The sources of part two and three of the report do not have the benefit of a peer review. The scientific literature, however, focusses seldomly on research activities which failed to achieve their goal or where there is no suitable approach visible to solve a problem. Difficulties to find adequate replacements for PFAS are most likely not as well documented in the peer reviewed scientific literature as cases, where an adequate replacement can be presented. The discussions with scientists and engineers working in industry contribute therefore to a balanced representation on the chances and challenges replacing PFAS.

3
Per- and Polyfluoroalkyl Substances

3.1
Classification of PFAS and Scope of the Study

Classification of PFAS

Per- and polyfluoroalkyl substances (PFAS) form a subset of the »fluorinated substances«, i.e. of the group of organic or inorganic substances which contain at least one fluorine atom. Buck et al. define PFAS as »highly fluorinated aliphatic substances that contain one or more C atoms on which all the H substituents have been replaced by F atoms, in such a manner that they contain the perfluoroalkyl moiety C_nF_{2n+1} –« [15]. Buck suggested a widely accepted terminology for PFAS (see Figure 1).

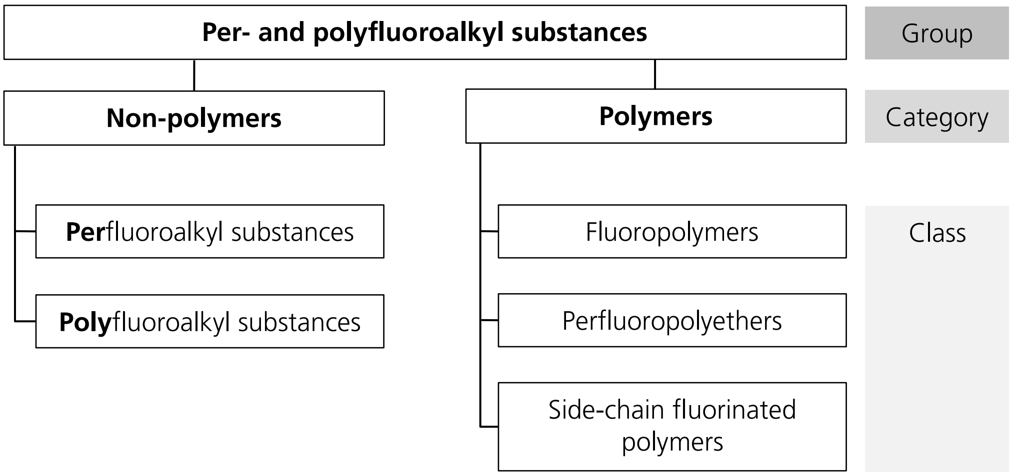


Figure 1: Terminology for PFAS suggested by Buck *et al.*

Perfluoroalkyl substances are defined as »aliphatic substances for which all of the H atoms attached to C atoms in the nonfluorinated substance from which they are notionally derived have been replaced by F atoms« (except for carbon atoms associated with functional groups), and **polyfluoroalkyl substances** are defined as »aliphatic substances for which of the H atoms attached to at least one (but not all) C-atoms have been replaced by F atoms, in such a manner that they contain the perfluoroalkyl moiety C_nF_{2n+1} –« [15].

Fluoropolymers denote polymers with a Carbon-only backbone with Fluorine directly attached to the Carbon backbone, **perfluoropolyethers** are polymers with a Carbon and Oxygen backbone where Fluorine atoms are directly attached to the Carbon atoms of the backbone. **Side-chain fluorinated polymers** are non-fluorinated polymers of variable composition with fluorinated side chains bonded to the main chain. The OECD recently refined the terminology suggested by Buck [1]. The OECD scheme distinguishes the categories »**perfluoroalkyl acids**« (PFAAs), »**polyfluoroalkyl acids**« (PolyFAAs), »**PFAA precursors**« (i.e. substances that can degrade of metabolize to PFAAs) and »**other PFAS**«. In the OECD scheme, fluoropolymers and perfluoropolyethers are considered as »other PFAS« whereas side-chain fluorinated polymers are categorized as »PFAAs precursors«. Since the scientific literature uses both terminologies, both schemes are referred to in the current study.

Scope of the Study

The current study focuses only on the classes »fluoropolymers« and »perfluoropolyethers«, categorized as »polymeric PFAS« in the scheme of Buck and as »other PFAS« in the OECD scheme. The other categories are nonetheless relevant – they can play a role e.g. as processing agents in the production or as degradation products of polymeric PFAS and need to be considered if the environmental impact of fluoropolymers and perfluoropolyethers is discussed.

3.2
Why Have pPFAS Found Widespread Use?

Fluoropolymers and perfluoropolyethers have exceptional physical-chemical, thermal and biological properties which lead to their wide-spread use in many areas [16–18]. Compared to other thermoplastics they show a high flexibility at low temperatures, a high melting point and a high thermal stability. They are inert, i.e. they show a high resistance to chemicals, photolysis, oxidation, hydrolysis and biological degradation. Fluoropolymers are biocompatible, they typically are low in leachables. Highly crystalline fluoropolymers show a low permeability to gases and vapors and a low water absorptivity and adsorptivity. They exhibit a low coefficient of friction and a high wear resistance and a low tendency to particle formation. In industrial and consumer applications pPFAS are considered high performance polymers.

Most of the outstanding properties of PFAS can be traced back to the unique properties of the Carbon-Fluorine bond and the size of the Fluorine atom: compared to other bonds involving a Carbon atom, the C–F bond shows the highest bond strength[19]. The stability of the carbon chain increases if more Hydrogen atoms bonded to the carbon chain are replaced by Fluorine[5]. Due to the size of the Fluorine atom, perfluorated carbon chains tend to adopt a rod-like, »smoother, streamlined dynamic molecular shape«[5]. The rod-like shape facilitates an ordered packing of fluorinated carbon chains which explains many of the bulk properties and the tribological properties of fluoropolymers[5]. The on a molecular level smooth surface of fluorinated carbon chains leads to their hydrophobic character[20]. In summary: the specific characteristics of the C–F bond and the Fluorine atom explain many of the outstanding properties of polymeric PFAS; this explains at the same time, why finding a replacement for fluoropolymers and perfluoropolyethers is a challenging task.

3.2.1
The C-F Bond

The unique chemical, thermal and biological stability of fluoropolymers can be attributed to the strength of the Carbon-Fluorine bond. Since Fluorine is the most electronegative element (see Table 1), the C–F bond is highly polar and resembles in its characteristics an ionic bond rather than a covalent bond[19].

Table 1: Electronegativities of selected elements on the Pauling scale[19]

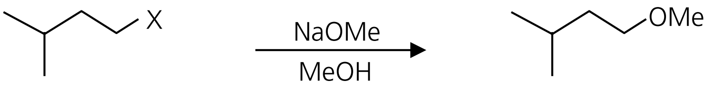
H 2.1				
Li 1.0	C 2.5	N 3.0	O 3.5	**F** **4.0**
Na 0.9	Si 1.8	P 2.1	S 2.5	Cl 3.0
K 0.8				Br 2.8
Cs 0.7				I 2.5

The ionic (polar) character of the C-F bond concentrates the electron density close to the F-nucleus. Furthermore, the C-F bond is quite short and has a high bonding dissociation energy. Furthermore, the free electron pairs of the fluorine atom shield the C-F bond sterically. Therefore, the C-F bond is very much less susceptible to typical organic nucleophilic substitution reactions like C-Cl, C-Br or C-I bonding systems. Compared to bonds with other elements, the bond dissociation energy of the C–F bond is the highest and its reaction rate (e.g. in a nucleophilic substitution) is the lowest, see Tables 2 and 3.

Table 2: Bond dissociation energies of common covalent bonds[19]

Bond	Bond Dissociation Energy in kcal/mol
C-F	105.4
C-H	98.8
C-O	84.0
C-Cl	78.5
C-N	69.7

Table 3: Rates of halide ions as leaving groups in a nucleophilic substitution[19]



Halide Ion	Relative Reaction Rate
F^-	1
Cl^-	71
Br^-	3500
I^-	4500

If several Fluorine atoms are bonded to a Carbon atom, the C–F bond strength is further increased[5]. Furthermore, the C-C bond strength increases if Hydrogen atoms bonded to Carbon are replaced by Fluorine[5,21,22].

3.2.2
Bulk- and Surface Properties

The stability of the C–F bond also influences the physical bulk properties of fluoropolymers. A branching of the main chain would require rupturing the C–F bond: as a result, the polymerization reaction yields highly linear macromolecules. Due to the size of the Fluorine atoms, the perfluoroalkyl chains adopt a rod-like shape (a helical all-trans conformation) with a – on a molecular level – smooth surface[5,17]. The rod-like shape of the molecules facilitates an ordered packing of the chains to form polymeric solids with an exceptional high degree of crystallinity and – for polymers – high density. The low permeability and adsorptivity [20] and good tribological properties [23] of selected fluoropolymers can be explained by the high degree of crystallinity and the smooth surface of the polymer chains.

The hydrophobic character of fluorinated surfaces is largely a steric effect linked to the van-der-Waals radius of Fluorine: a Fluorine-terminated surface is due to the size of the Fluorine atom not corrugated but rather smooth. DFT and molecular mechanics calculations showed that because of the smooth surface, the electrostatic field decays rapidly with increasing distance to the surface which in turn results in its hydrophobic character[20].

3.3
Why is the Widespread Use of PFAS Seen Critical?

Due to their extensive use and chemical inertness, certain PFAS turned out to be ubiquitous environmental contaminants. Perfluorinated compounds can be detected in many environmental media, in food and drinking water, and in humans[24].

3.3.1
Pathways of PFAS into the Environment

The variety of uses of PFAS leads to various emission pathways. PFAS used in consumer goods will result in widespread emissions by individual households, e.g. by contaminated waste water. Specific uses of PFAS, e.g. in production facilities, as fluorinated aqueous film-forming foam (AFFF) used as fire-extinguishing agent, or emissions from sites related to PFAS containing waste result in localized contaminations of the environment[2].

Steininger carried out a study on emissions of seven PFAS (including perfluorocarboxylic- and perfluorosulfonic acids) from households into the sewage system[25]. She concluded that perfluorocarboxylic acids like perfluorooctanoic acid (PFOA), perfluorohexanoic acid (PFHxA), perfluoroheptanoic acid (PFHpA) and perfluorononanoic acid (PFNA) are present in personal care products (e.g. suntan lotions or concealers). PFOA and perfluorosulfonic acids like perfluorooctane sulfonic acid (PFOS) and perfluorohexane sulfonic acid are present in textiles, e.g. as impregnating agents. Personal hygiene and laundering textiles result in the emission of contaminated wastewater.

PFAS contaminations (e.g. PFOA, PFOS or perfluoroalkyl ether acids) were frequently recorded close to fluorochemical production sites[26–28]. Wang *et al.*[8] estimate that a significant percentage of the historical PFAS emissions is associated with the fluoropolymer production. PFAS-containing aqueous film forming foams have been used to extinguish fuel fires since the 1960s. Where these agents were used accidentally (to fight fires, e.g. in airports) or frequently (e.g. in training areas for fire fighters), elevated PFAS levels were detected in soil and in ground water[29–31]. Waste water treatment plants processing PFAS-contaminated sewage are a further source of PFAS contamination (either as effluent or by PFAS-contaminated sludge), in particular if industrial wastewater is processed[31–33].

3.3.2
PFAS Contamination in Central Baden: the »Rastatt Case«

Close to Rastatt and Bühl, a contamination with PFAS was detected which most likely can be traced back to PFAS-contaminated compost which was deposited on agriculturally used areas during the years 1999 - 2008[34]. The »Rastatt case« can be used to illustrate the consequences of a PFAS contamination for the affected area. The source of the PFAS contamination is currently still topic of a legal dispute[35], however, it is suspected that a compost manufacturer added PFAS-contaminated paper sludge originating from paper processing plants to the compost.

The deposition of PFAS-contaminated compost on fields led to a contamination of the soil and the ground water. The contaminated areas are by now identified. Due to the size of the contaminated area, a remediation is currently no realistic option.

A numeric model of the PFAS transport in the ground water gave some insight into the spatial and temporal development of the PFAS contamination of wells. A large-scale remediation of the affected ground water reservoir in the Rastatt area is currently not possible. As a consequence, the use of ground water has to be regulated and adjusted. Some waterworks had to be decommissioned due to a high PFAS contamination of the ground water. Other water supply companies use activated carbon filters to purify contaminated ground water. Depending on the contamination levels, the abstraction of water from wells for irrigation of agricultural areas is restricted unless the contaminated water underwent a similar purification process.

The affected agricultural businesses need to apply measures in order to minimize the contamination of crops with PFAS. These measures range from growing crops which are less prone to accumulate PFAS over applying suitable irrigation techniques and purifying the irrigation water to performing a pre-harvest monitoring of the PFAS levels of the products.

In summary, there are currently no realistic options for a remediation of the PFAS-contaminated soils in the Rastatt-area. For the foreseeable future, restriction will apply to the agricultural use of affected areas and to the use of ground water for drinking water or for irrigation. The measures for ensuring sufficiently low levels of PFAS in drinking water and in agricultural products are costly and need to be continued.

3.3.3
Hazards Arising from Selected PFAS

The presence of PFAS in the environment leads to the exposure of humans to PFAS: either by the contamination of the food chain with PFAS or the presence of PFAS in the air or in house dust. A review by Fromme *et al.*[24] summarizes the results of studies on the presence of selected PFAAs in human plasma and serum: perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA) and perfluorohexane sulfonic acid (PFHxS) can be detected in the general population in Europe, Asia, Australia and North America.

Most of the studies on human health impact of PFAS focus on the substances mentioned above. The European Commission asked the European Food Safety Authority in 2020 to give a scientific account of the risks to human health related to perfluorinated compounds present in food. The review focused on the three PFAAs PFOA, PFOS and PFHxS and on perfluorononanoic acid (PFNA)[10]. Currently, these four PFAAs contribute most to the serum levels of PFAS in humans. In animal models, adverse effects of these substances were observed (including an increased liver weight, decreased levels of thyroid hormones, impaired development of mammary glands, increased fetal and/or neonatal mortality, a reduction in fetal weight and/or postnatal growth or a reduced response to vaccination and a reduced resistance to infection).

Epidemiological studies on humans showed that

- exposure to PFOS and PFOA are associated with a reduced antibody response to vaccinations,
- exposure to PFOS and PFOA are associated with an increased propensity for infections,
- exposure to PFOS, PFOA and PFNA are related to an increased cholesterol levels and increased levels of the liver enzyme alanine transferase,
- PFOS and PFOA »may well be associated with birth weight«.

According to the authors, the studies available at the formulation of the EFSA study show *no conclusive evidence* for an association between the exposure to PFAS and asthma, allergies, cardiovascular diseases, diabetes, obesity, reproductive outcomes in both males and females, neurodevelopment outcomes, growth in infancy and childhood, neurobehavioral, neuropsychiatric, cognitive outcomes or thyroid function, changes in kidney function, low bone mineral density, osteoporosis or carcinogenicity in humans.

The authors base their recommendations for tolerably weekly intakes of the sum of PFOA, PFOS, PFHxS and PFNA on the effects on the immune system since »the findings of a decreased immune response were considered robust since they were consistently observed for the two studied PFASs in rodents (PFOA, PFOS) and in humans«. For the other findings of the epidemiological studies on humans, they recommend further research into the mode of action and longer-term consequences.

The research on the human health impact of PFAS is still in progress. Recently, in November 2023, a working group at the International Agency for research on Cancer came to the conclusion that PFOA should be »classified as "carcinogenic to humans" (Group 1) based on "sufficient" evidence for cancer in experimental animals and "strong" mechanistic evidence in exposed humans« and that PFOS should be »classified as "possibly carcinogenic to humans" (Group 2B) based on "strong" mechanistic evidence«[36].

3.4
Regulatory Measures

The frequent occurrence of »misuse« scenarios and the continuous transfer of PFAS into the environment by PFAS-containing consumer- and technical products led to growing concern regarding the emission and accumulation of highly persistent PFAS in the environment. Scientists published statements (the »Madrid Statement« and the »Zürich statement«) recommending regulatory and additional research efforts to manage PFAS [37,38]. The growing concern regarding persistent PFAS resulted regulatory measures which are now in place (in California, e.g. for carpets, firefighting foam, treatments for textiles, leathers and fiber-based food packaging, see[39]) and to proposals to regulate PFAS, like the »Proposal for a Restriction of Per- and Polyfluoroalkyl Substances«[40] by the European Chemicals Agency ECHA.

3.4.1
PFAS as a Class

The existing and proposed regulatory measures have in common that PFAS are grouped as a »class« which consists of several thousand, partially very different substances [1]. The Madrid statement[41] and the Californian listing of PFAS as a class of »Potential Priority Chemicals«[42], both published in 2015, are early documents which propose regulations that treat PFAS as a class. This deviates from the approach to regulate substances as it is taken e.g. by the REACH regulation: here, each substance is assessed individually whether or not it is for example »persistent, bio-accumulative and toxic« (PBT) or »very persistent and very bioaccumulative« (vPvB) [43]. In order to understand the rationale behind changing the approach to regulate chemicals which raise concern to the environmental and / or human health, it is instructive to study the arguments which led to regulatory measures restricting the use of PFAS in California – as Bălan *et al.* state: »the California Green Chemistry Hazard Traits and SCP regulations offer a more comprehensive, precautionary approach to assessing potential adverse impacts of PFAS and can serve as a model for other regulatory agencies aiming to address potential PFAS impacts comprehensively«[12].

The core argument for extending regulations to the entire class of PFAS is that regulating individual PFAS is ineffective or – due to the large number of PFAS – not feasible in order to prevent the build-up of a potentially hazardous substance in the environment.

The phase-out of some longer chain perfluoroalkyl acids (PFAAs) which led to their substitution with shorter chain PFAAs is given as an example of an ineffective regulatory measure. Bălan *et al.* argue that »The approach of regulating only individual PFAS or a limited subset of PFAS has led to the replacement of those PFAS with other members of the class that have less well-characterized hazard profiles«[12]. The replacement material is possibly as hazardous as the original material and is therefore potentially a »regrettable substitution«.

Hence, a central problem for regulating the use of PFAS is that the majority of these substances – the OECD identified approximately 4700 PFAS[44], the U.S. Environment Protection Agency identified 12034 substances as PFAS[3] – have not been sufficiently studied yet with regard to their potential impact on environment and human health. This lack of knowledge becomes critical since PFAS are very persistent or degrade into PFAS which are very persistent in the environment. The failure to restrict the use of a hazardous PFAS in time can result in an accumulation of this substance in the environment. The exposure of humans to this substance will be difficult or impossible to reverse: »The potential for widespread exposures will remain for as long as PFAS continue to be used and concerns over their fate and transport remain inadequately addressed«[12]. Coupled with »with growing evidence for human and ecological health hazards for the impurities, metabolites, and degradation products of the subset commonly used in consumer products«[12], regulatory measures should apply not to individual PFAS but to PFAS as a class as a precautionary measure.

Bălan *et al.* differentiate in their analysis the hazard traits of different categories of PFAS according to the OECD classification[1]. Of particular concern are perfluoroalkyl acids (PFAAs). PFAAs combine several hazard traits (e.g. very high persistence, high mobility, bioaccumulation). The negative impact of four PFAAs on human health has been studied in detail: perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorohexane sulfonic acid (PFHxS), and perfluorononanoic acid (PFNA)[10], other PFAAs are suspected to have adverse effects on human health[12] (see also section 3.3.3). According to Bălan, PFAAs constitute only approximately 1% of all PFAS, however, approximately 85% of all PFAS can be considered as PFAA precursors – i.e. substances which can degrade of metabolize to PFAAs. PFPEs and fluoropolymers do not degrade to PFAAs under typical environmental conditions. They decay to PFAAs only under misuse conditions or when heated between 180°C and 800°C (FP). However, perfluoroalkyl carboxylic acids (PFCA) have been processing aids in the production of fluoropolymers, and a substantial part of the environmental contamination with PFCAs stems from the FP-production[8]. Bălan concludes: »It is, therefore, our opinion that environmental releases of and exposures to PFAAs cannot be regulated without regulating the manufacture, use, and end-of-life fate of the other PFAS«.

3.4.2
The »P-Sufficient« Approach

The Californian class-approach to regulate PFAS led to an intense scientific debate on the grouping of PFAS. Cousins *et al.* pointed out that the existing EU REACH regulation provides the possibility to classify substances as »Substances of Very High Concern« (SVHC) if they are either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)[45]. In the latter case, it is not necessary to provide information on the toxicity of the substance (which is – in case of PFAS - often the »bottleneck« for assessing the substance).

The German Umweltbundesamt (UBA) proposes to consider the mobility in addition to the bioaccumulation as a criterion for classifying substances as SVHC[46], i.e. persistent, mobile and toxic (PMT) substances or very persistent and very mobile (vPvM) substances should be also the focus of regulatory actions. The rationale for including the mobility of a substance as a criterion for regulation is that substances which are mobile in an aquatic environment pose a potential hazard for drinking water resources.

Bioaccumulation and mobility are assessed with the water-octanol-partition coefficient (k_{ow}). Bioaccumulative substances typically show a high k_{ow} (i.e. they are hydrophobic and lipophilic), mobile substances in an aquatic environment show a low k_{ow} (i.e. they are hydrophilic and lipophobic). Cousins states that under the current used k_{ow} criterion for bioaccumulation and the proposed k_{ow} criterion for mobility, the vPvB and vPvM criterion can be summarized to a »very persistent« (vP) criterion[45] – substances (if they can be brought into solution) are either hydrophobic or hydrophilic. As a result, a high persistence would be sufficient criterion to define a group of chemicals which requires attention from the regulatory bodies (as it was done by the Californian authorities) – if mobility should be considered as a critical factor for assessing the hazard potential of substances.

3.4.3
Existing and Proposed Regulatory Measures

The approach to manage PFAS as a class of chemicals described above formed the base of the legislative measures which are now in place in California. The same approach forms the base of the restriction proposal for PFAS presented by the European Chemical Agency ECHA. However, the legislative measures derived from the class-approach in California differ from the legislative measures proposed in the EU. In California, the class-approach is the base to regulate the use of PFAS for specific applications – all of them in the area of consumer goods (e.g. the use of PFAS in rugs and carpets[47], as treatments for textiles and leathers[48] and fiber-based food packaging). If necessary, exceptions are made and the use of PFAS are permitted – e.g. the use of PFAS as a flame retardant is still permitted for carpeting used in airplanes.

This contrasts with the proposed legislation in the EU: instead of identifying specific areas where the use of PFAS should be restricted, a general ban of the production and use of PFAS is proposed. Specific applications of PFAS are identified where the future use of PFAS should be permitted, like the use as active substances in plant protection and biocidal products and as active substances in human and veterinary medical products. For a range of other applications, a longer transition phase is allowed for before the ban of PFAS comes into place.

3.5
Criticism on the »Class Approach«

The approach described above of grouping a very diverse set of substances into one chemical class for regulation has sparked criticism from different sides. A critique on the class approach stems from Buck *et al*[49]. A central argument of the supporters of managing PFAS as a class is that an analysis of the potential hazards of an individual PFAS is impractical and not feasible due to the large number of PFAS. The number of PFAS was determined e.g. by identifying all CAS-registered substances which qualify as PFAS which resulted in a total number of 4730 substances[44]. Buck criticizes that this number includes substances which were never commercialized, were only produced in small quantities for research purposes or which were phased out of production. Furthermore, it also includes substances which are already regulated since they are used as pharmaceuticals, agrochemicals, refrigerants, blowing agents or propellants. When focusing on »commercially relevant« PFAS, Buck *et al.* identify 256 substances. This suggests that a substance-by-substance hazard analysis for the commercially relevant substances might actually be feasible.

3.5.1
Polymeric PFAS and the Status »Polymers of Low Concern«

Another commonly stated criticism on the »class approach« to regulate PFAS are conflicts with existing classifications which are used to regulate chemical substances. In particular the classification of fluoropolymers as »Polymers of Low Concern« (PLC) is discussed in the scientific literature. The criteria for PLC defined by the OECD include:

- A high molecular weight ($M_n > 1000$ Da) and a low amount of oligomers (< 1%) and a negligible amount of monomers remaining in the polymer.
- No reactive functional groups or ionic groups.
- A polymer composed of the elements H, N, O, Si, S, F, Cl, Br or I bonded to the Carbon atoms of the main chain.
- A low solubility in aqueous or fatty media.
- A high abiotic stability (UV-degradation, hydrolysis, oxidation) and biotic stability (degradation by aerobic / anaerobic microorganisms and degradation *in vivo*).

Polymers which fulfill the criteria for PLC »are those deemed to have insignificant environmental and human health impacts«. Henry *et al.* and Korzeniowski *et al.* showed that a group of fluoropolymers representing approximately 96% of the global commercial market for fluoropolymers satisfy the criteria for PLC[18,50].

A number of countries agreed to the PLC definition and properties, including the USA, Australia, China and Japan; the EU did not adopt the definition of Polymers of Low Concern. However, according to Henry *et al.* it is »highly unlikely that fluoropolymers meeting the PLC criteria would exhibit the criteria of an SVHC under REACH«[18] where REACH is the EU-framework to assess the impact of chemicals on environment and human health. Fluoropolymers are persistent, but they are practically insoluble in water or octanol. Due to their high molecular weight, one assumes that they are not able to penetrate the cell membrane[a]. Henry concludes that they are not bio-available and therefore not toxic or bioaccumulative. As a result, they do not meet the PBT or vPvB criteria under REACH. Due to their negligible solubility in water or octanol, they also do not meet the criteria for a mobile substance – they neither fulfil the PMT or vPvM criteria proposed by the UBA. As a consequence, it is difficult to argue that the »p-sufficiency« approach which is based on the solubility of a substance either in aqueous or fatty media is in the same way applicable to fluoropolymers as it is applicable to soluble PFAS. Henry *et al.* and Korzeniowski *et al.* therefore argue that fluoropolymers which satisfy the requirements of a PLC should be exempted from the PFAS-ban.

Lohmann and Cousins *et al.* criticize several aspects of the argumentation that »polymers of low concern« pose no danger to environment and human health. Their main point of critique is that the risk analysis for fluoropolymers should not focus only on their use phase. They point out the »history of pollution from fluoropolymer production«[51]: the presence of perfluorooctanoic acid (PFOA) and perfluorononanoic acid (PFNA) and their salts in the environment is largely a result of emissions which occurred during the production of fluoropolymers[8]. Therefore, in addition to their use phase, the production and the end of life-phase of fluoropolymers need to be considered for an assessment of their environmental impact.

Furthermore, they point out that the statement »polymers with a molecular weight above 1 kDa cannot pass the cell membrane« needs to be treated with the necessary caution: it was shown that polymer nanoparticles are able to pass the cell membrane[52,53].

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[a] Whether or not polymers with a sufficiently high molecular weight are able to pass the cell membrane is a topic of controverse discussions, see the section below on the paper of Lohmann *et al.*

Pharmacological research can give a first estimate of the extent macromolecules and polymer nanoparticles can pass the cell membrane. Matsson and Kihlberg state that a »severely limiting permeability [at molecular sizes] above 1000 Å, i.e. at a MW of approximately 1000 Da« is observed for transmembrane diffusion[54]. The permeability coefficients of nanoparticles used for drug delivery transport mechanism are up to now smaller than the permeability coefficients transmembrane diffusion. In summary, the statement »polymers with a molecular weight above 1 kDa cannot pass the cell membrane« should be stated more precisely: polymers with a MW of 1 kDa and polymer nanoparticles can in principle pass the cell membrane, but both transport mechanisms occur at a very low rate – and this rate will drop with increasing molecular weight. Lohmann as well as Matsson point out that this is still a topic of »ongoing research with many unknowns«[51].

Lohmann *et al.* give a detailed account of all aspects which need to be considered during the life-cycle of fluoropolymers – ranging from emissions of low molecular weight PFAS and leachables during production and processing, the emission and creation of nanoparticles during processing, use phase and disposal up to the release of low molecular weight PFAS during uncontrolled burning between 250°C and 600°C. Although they conclude that there is »no sufficient evidence to consider fluoropolymers as being of low concern for environmental and human health«, they suggest to »to move toward the use of fluoropolymers in closed-loop mass flows in the technosphere and in limited essential-use categories, unless manufacturers and users can eliminate PFAS emissions from all parts of the life cycle of fluoropolymers«.

3.5.2
Life Cycle of pPFAS: Production

Low molecular weight PFAS (including some PFAAs which were phased out: PFOA and PFNA) were used as polymerization aids in the production of fluoropolymers. Emissions of these processing aids and their replacements have been frequently identified as source of environmental damage at the production sites of fluoropolymers[8]. In order to achieve a »clean« production of fluoropolymers, there are two approaches which fluoropolymer manufacturers follow to reduce and avoid the emissions of PFAS during the production process[55]. One option is to reduce the emissions of PFAS processing aids to levels »as low as reasonably practicable or achievable«[56] by a containment strategy involving abatement techniques and recovery. The other option is to modify the polymerization processes in a way that they do not need PFAS processing aids.
An containment strategy implemented by industry resulted in a recapture rate of 98% for fluoroemulsifiers[57], and current research aims at improving the recapture rate[58]. However, an absolute »zero-emission rate« of fluorinated processing agents will be only feasible if non-fluorinated processing agents are used or processes are developed which do not require the use of surfactants[55]. In recent years, progress has been made in the transition to PFAS-free production processes for fluoropolymers[59,60], and Sales *et al.* estimate that with current technologies 80% of the global fluoropolymer production can be achieved without using fluorinated processing aids, where the main fluoropolymers by production volume (PTFE, PVDF and FKM) can be produced to 100% without using fluorinated processing aids[61].

3.5.3
Life Cycle of pPFAS: End of Life & Recycling

Within the EU, approximately 85.5% of FP-waste is thermally destroyed (e.g. in municipal solid waste incineration (MSWI) or metal recycling), 3.4% is recycled and 13.1% is disposed in landfills[62]. Due to their chemical stability, it is unlikely that fluoropolymers disposed in landfills will decompose into low molecular weight PFAS. However, they will eventually disintegrate into microplastics by mechanical stresses and weathering – similar as it is observed for other polymers[63]. Reducing the release of microplastics from landfills is an emerging field of technology[64], possible remediation strategies include the treatment of leachates, microplastics degradation or »landfill mining« in the context of a circular economy.

The thermal decomposition of FP has been extensively studied. Améduri's review paper[65] gives an overview of reaction pathways and reaction products at different decomposition temperatures. The degradation products depend on the conditions under which the thermal decomposition occurs, e.g. temperature, atmosphere (presence of oxygen or an inert atmosphere), morphology of the polymer and residence time at elevated temperatures. The »open burning« under uncontrolled conditions of FP or any other polymer will in general result in hazardous decomposition products and is »unacceptable and unsafe«[65]. The majority of all polymer waste is however incinerated under controlled conditions (where incineration is defined as a high-temperature flaming process that occurs in open air space which requires constant energy input). The decomposition of FP under the conditions of municipal solid waste incineration is currently a field of active research. Aleksandrov *et al.* carried out an incineration study of PTFE on a pilot combustion facility at the Karlsruhe Institute of Technology[66]. PTFE was incinerated using wood pellets as »fuel«. Incineration tests with and without adding PTFE to the combustion chamber were compared. The flue gas was analyzed for 31 PFAS; 11 of the targeted 31 substances could be detected. For the detected PFAS, there was no statistically significant difference between the tests with and without adding PTFE to the combustion chamber – which led to the conclusion that the detected PFAS are associated with a »background contamination« and were not created by incinerating PTFE. They conclude that »municipal incineration of PTFE using best available technologies is not a significant source of studied PFAS and should be considered an acceptable form of waste treatment«.

Fluoropolymers have currently a low recycling quota (3.4%) – considering the costly and energy-intensive production processes of FP and the fact that fluorspar (a raw material required for the production of FP) is listed as a »critical material«[67], it is worthwhile to study possibilities to recycle fluoropolymers. A review of the current state-of-the-art of FP-recycling is given by Schmidt-Rodenkirchen *et al.*[68]. Mechanical recycling is established for clean, single-component thermoplastic fluoropolymers in particular in the area of pre-consumer recycling. There are different approaches in development for chemical recycling. Ionomers which are used in chemical reactors, fuel cells or electrolyzers can be dissolved in suitable solvent – the polymer solutions are purified and can be used to produce new membranes. During the purification process, costly materials like catalysts can be recovered. Perfluorinated polymers can be »depolymerized«, i.e. broken down into monomers which are subsequently used to synthesize fluoropolymers. Finally, there are different processes available to »mineralize« FP waste, i.e. to convert it back into fluorspar. Processes for depolymerizing fluoropolymers have reached the pilot plant scale (TRL 8), the technology readiness levels of processes to mineralize fluoropolymers range from TRL 4 – TRL 6.

4
Case Studies Based on Interviews with Freudenberg Business Groups

4.1
Proton Exchange Membrane Fuel Cells

A fuel cell is an electrochemical cell which is used to convert the chemical energy of a fuel into electricity. An example is the oxidation of Hydrogen and the reduction of Oxygen. Depending on the field of application, there exist different types of fuel cells[69]. The proton exchange membrane fuel cell (PEMFC) is a versatile type of fuel cell which operates at lower temperatures (20°C – 80°C) and is suited for mobility applications or as emergency power supply. Of all types of fuel cells, the PEMFC has currently the highest potential for being mass-produced.

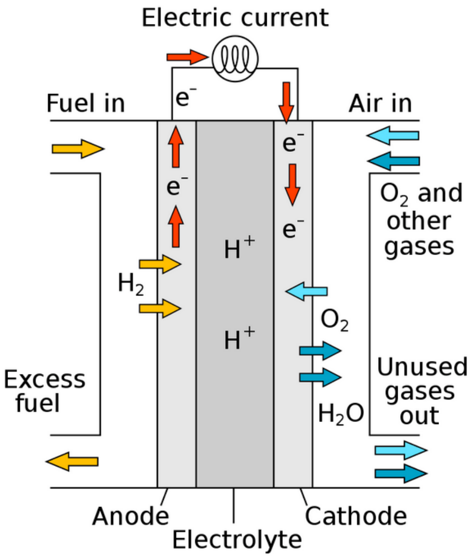

Figure 2: Schematic view of the set-up of a fuel cell. Source: I. Sakurambo – solid oxide fuel cell, Public Domain, http://en.wikipedia.org/wiki/File:Solid_oxide_fuel_cell.svg, accessed Oct. 1st, 2024

At the anode, H_2 is oxidized to 2 H^+ + 2 e^-. The protons travel through the proton exchange membrane (PEM) which separates the anode from the cathode. At the cathode O_2 + 4 H^+ + 4 e^- is reduced to 2 H_2O. The electrons travel from the anode to the cathode and provide the electrical power to the device for which the fuel cell is the power source (see Figure 2).

A PEMFC typically consists of a series of different layers, the so-called membrane-electrode-assembly (MEA)[70] (see Fig. 3). The PEM at the center of the MEA is backed on both sides with the catalyst coated layers (CCL) which are electrically contacted with the flow field plates (FFP). The CCL consists of the catalyst layer (CL), the micro-porous layer (MPL) and the gas diffusion layer (GDL). The proton exchange membrane and the catalyst coated layers of state-of-the-art PEMFC contain both fluoropolymers.

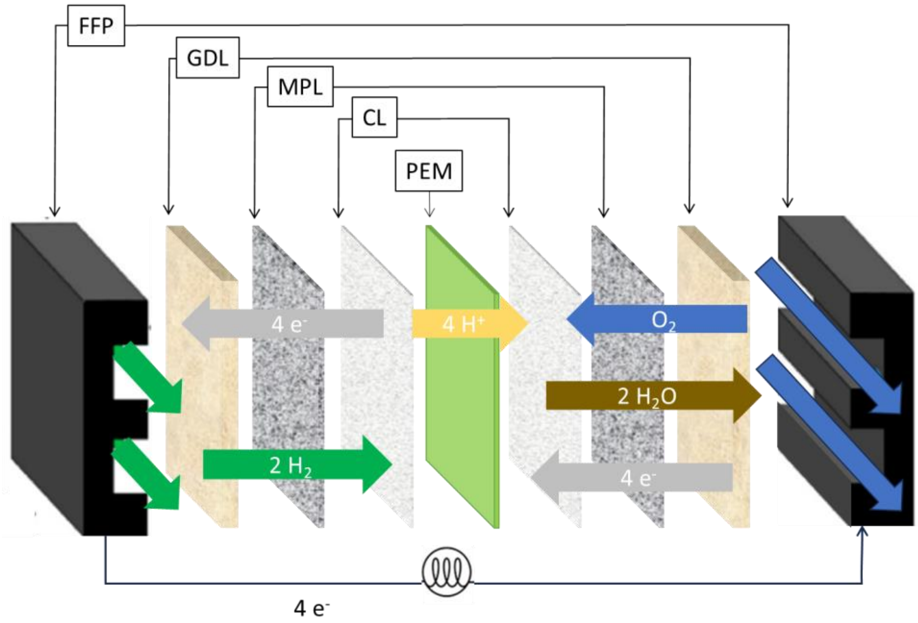

Figure 3: Composition of the membrane-electrode-assembly. FFP: Flow Field Plate, GDL: Gas Diffusion Layer, MPL: Micro-Porous Layer, CL: Catalyst Layer, PEM: Proton Exchange Membrane. Sketch following Sazali[69].

4.1.1
The Proton Exchange Membrane

The core functionalities of the PEM are:
- non-conducting to e^-
- permeable to protons
- non-permeable to H_2 and O_2

These core functionalities have to be maintained also in a reactive environment at elevated temperatures. PEMFC operate at temperatures up to 80°C, in the reactions radicals or aggressive side products (like H_2O_2) are formed. State-of-the-art are perfluorinated sulfonic acid-based Nafion® membranes. Nafion is an ionomer, the proton transport occurs through channels with hydrogenated SO_3^- (+ H_3O^+) groups. For an efficient proton transport, the water content of the membrane and in particular of the proton-conducting channels needs to be managed. The performance of »hybrid Nafion« membranes is optimized by additives, e.g. to maintain the required water content of the channels at elevated temperatures or increase the chemical stability with radical scavengers[71]. A chemical attack of the membrane could result in pinholes which would render the membrane permeable to H_2 and O_2, furthermore, the reaction products would »poison« the catalyst and reduce the efficiency of the fuel cell. Commercially used fuel cells are designed for 30000 - 50000 operating hours, the chemical stability of the components is therefore essential for their reliability.

The ECHA restriction proposal[40] states with respect to alternatives for PFAS for fuel cells that »there is sufficiently strong evidence for the existence of technically feasible alternatives for membrane applications in PEM fuel cells, with hydrocarbon membranes, PEEK membranes being mentioned as relevant alternatives identified through ongoing R&D« and that »there is sufficiently strong evidence for the existence of alternatives for reinforcement materials for use in PEM fuel cells, with promising undertakings in relation to replacing PTFE by fluorine-free compounds like electrospun polybenzimidazole-type materials«. These statements are, however, not backed by references to scientific publications.

In recent years, research focused on replacing fluoropolymers as base material for PEM. Hydrocarbon-based (e.g. polyphenylene-[72–74] , polybenzimidazole[75–78] or poly(ether ether ketone)[79]-based) ionomers have been investigated. The research showed that it is possible to achieve the core functionalities listed above with these materials and to assemble PEMFCs with a (short term) performance comparable to Nafion-based PEMFC. However, there is to our knowledge currently no data on the long-term performance (e.g. for operating periods longer than 10000 hours) available in the scientific literature which would give some insight into the long-term stability of the novel ionomers in harsh environments. Some publications show that PFAS-free PEM exhibit significant shortcomings in selected performance indices when compared to a Nafion membrane[80–82]. The need to investigate the long-term performance is also recognized by researchers working on substitute materials for Nafion membranes. Escorihuela *et al.* state in their review on polybenzimidazole (PBI)-based HT-PEMFC from 2020 that additional research efforts are necessary to achieve a long-terms stability of these materials[75], such as »reducing the degradation rates of the polymeric membranes present owing to the operation at high temperatures«, enhance the »chemical stability towards peroxide and radical attacks« and »maintain the proton conductivity for extended periods of time«.

Comparative studies on the long-term performance of fuel cells are more frequently carried out by industry, for example to assess less costly alternatives for Nafion membranes. Since these studies are frequently covered by non-disclosure agreements, they are seldomly published. Cellcentric reports on some internal reliability tests in a comment submitted to the ECHA during the consultation process[83]. Cellcentric states that »the life cycle test showing massive internal leakage of the various PFAS-free hydrocarbon membrane configurations after 400 hours of operation at the latest« in a test involving five stacks.

4.1.2
The Gas Diffusion Layer and the Micro-Porous Layer

The oxidation of Hydrogen and the reduction of Oxygen occur in the catalyst layer which is in direct contact to the GDL and MPL, where the catalyst is applied in a separate production step either to the MPL or the PEM. In addition, both layers mechanically stabilize the PEM and form the electrical contact of the MEA to the flow field plates. The core functionalities of the GDL and MPL are:

- to provide a substrate for the catalysts for the chemical reactions,
- to efficiently supply the catalysts with a flow of reactants (H_2 and O_2),
- to conduct electrons from / to the reaction site,
- to remove the reaction product H_2O from the fuel cell – at a rate which avoids condensation (and would clog the micro-porous- or gas diffusion layer) but still supplies enough water to the PEM for the proton transport,
- to prevent poisoning of the catalyst layer and membrane.

The gas diffusion layer consists of a carbon-fiber non-woven. The micro-porous layer is composed of carbon particles. The catalyst layer is coated in an additional manufacturing step either on top of the MPL surface (gas diffusion electrode route) or on top of both membrane surfaces (CCM route). GDL and MPL have a graded porosity which is designed for an optimal supply of the catalyst with reactants and an optimal removal of the reaction products. In order to achieve the required functionalities, GDL and MPL need to have the following properties:

- GDL and MPL must be conductive.
- GDL and MPL must be (electro)chemically stable in a harsh environment, i.e. in the presence of radicals and aggressive by-products and at elevated temperatures (up to 100°C).
- GDL and MPL must be hydrophobic in order to reduce the condensation of water vapor and facilitate the quick removal of liquid water. Both guarantee a sufficient supply with reactant gases to maintain a competitive performance.
- GDL and MPL have to provide the mechanical stability of the PEM, the GDL needs to be flexible enough to form an electric contact to the flow field plate.

Fluoropolymer, in particular PTFE and FEP, are essential for achieving the necessary chemical and thermal stability of the GDL (and, thus, the reliability of the GDL) and its functional performance in terms of water transport. In addition, PTFE plays an essential role in the production process of the GDL and MPL, see Figure 4.

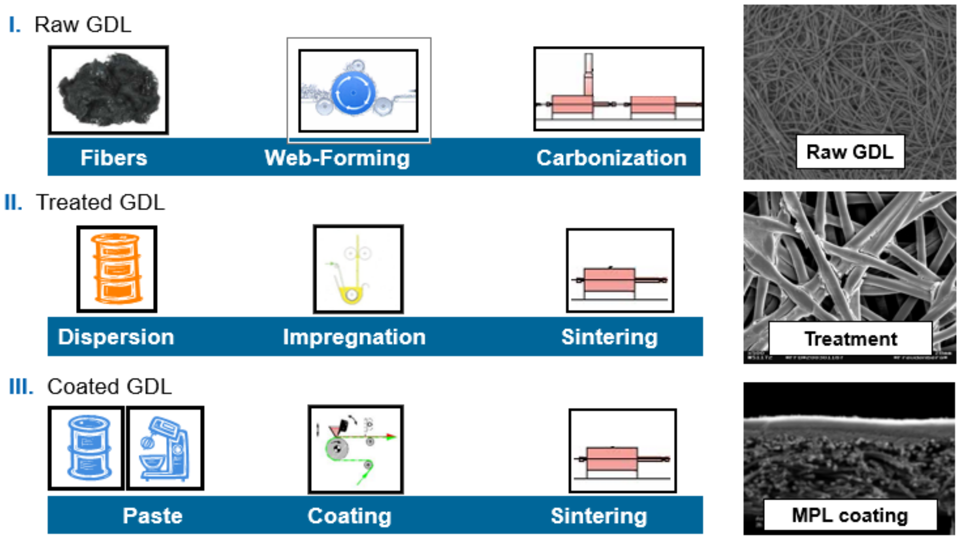

Figure 4: Production of GDL and MPL. Source: Freudenberg

The non-woven raw GDL is formed from poly(acrylonitrile) (PAN) fibers which are carbonized to a carbon fiber network. An impregnation and sintering step is used to coat the raw GDL with a PTFE layer. The PTFE layer combines three functions: it can acts as a binder which stabilizes the non-woven, it renders the non-woven hydrophobic while being able to resist the aggressive chemical environment and operating temperatures. Similar processing steps are used to coat the GDL with the MPL, where PTFE serves similar functions (binder, chemical stabilization and rendering the MPL hydrophobic) as in the previous step. In terms of processing, PTFE has some advantages: it is available as nanoparticles which facilitates the coating of very small porous structures, and the high glass transition temperatures of PTFE ensure a high mechanical stability at regular operating temperatures of up to 120°C (e.g. due to low creep).

Since the unique properties of PTFE provide several core characteristics of the GDL and MPL and are in addition closely linked to the production process, the scientific literature on PFAS-free GDL is sparse. This is also reflected in the ECHA restriction proposal[40]. Whereas there are alternatives specified for membrane applications and reinforcement materials, replacement materials for the GDL are not mentioned.

There are few articles on alternative architectures and materials for the GDL and MPL and different attempts to replace PTFE as hydrophobizing agents. Lee *et al.*[84] give a review on alternative approaches to generate the GDL and MPL, ranging from electrospun non-wovens, over different machining techniques and using metal foams or aerogels to 3D-printing porous substrates. All the approaches to obtain alternative architectures for the GDL and MPL have in common that they require a hydrophobizing step to adjust the wettability of the porous structures. Lee *et al.* discuss the possibilities to replace PTFE as hydrophobizing agent, but most alternatives (like polyvinylidene fluoride- or perfluoropolyether-based substances) rely on fluorinated carbon moieties in order to achieve the hydrophobic character. Thomas *et al.* grafted diazonium salts onto the carbon substrate[85], which were subsequently functionalized with fluorinated groups (4-(trifluoromethyl)-aniline or 3,5-bis(trifluoromethyl)aniline).

Table 4 shows the hydrophobic character for a wide variety of polymers in terms of their contact angle with water [86].

Polymer	**critical surface tension in mJ/m²**	**Contact angle [°]**
Polyvinyl alcohol (PVOH)	37	51
Polyvinyl acetate (PVA)	35.3	60.6
Nylon 6 (polycaprolactum, aramid 6)	43.9	62.6
Polyethylene oxide (PEO, PEG, polyethylene glycol)	43	63
Nylon 6,6	42.2	68.3
Nylon 7,7	43	70
Polysulfone (PSU)	42.1	70.5
Polymethyl methacrylate (PMMA), acrylic, plexiglas)	37.5	70.9
Nylon 12	37.1	72.4
Polyethylene terephthalate (PET)	39	72.5
Epoxies	44.5	76.3
Polyoxymethylene (POM, polyacetal, polymethylene oxide)	37	76.8
Polyvinylidene chloride (PVDC, Saran)	40.2	80
Polyphenylene sulfide (PPS)	38	80.3
Acrylonitrile butadiene styrene (ABS)	38.5	80.9
Nylon 11	35.6	82
Polycarbonate (PC)	44	82
Polyvinyl fluoride (PVF)	32.7	84.5
Polyvinyl chloride (PVC)	37.9	85.6
Nylon 8,8	34	86
Nylon 9,9	34	86
Polystyrene (PS)	34	87.4
Polyvinylidene fluoride (PVDF)	31.6	89
Poly *n*-butyl methacrylate (PnBMA)	29.8	91
Polytrifluoroethylene	26.5	92
Nylon 10,10	32	94
Polybutadiene	29.3	96
Polyethylene (PE)	31.6	96

Polychlorotrifluoroethylene (PCTFE)	30.8	99.3
Polypropylene (PP)	30.5	102.1
Polydimethylsiloxane (PDMS)	20.1	107.2
Poly t-butyl methacrylate (PtBMA)	18.1	108.1
Fluorinated ethylene propylene (FEP)	19.1	108.5
Hexatriacontane ($C_{36}H_{74}$)	20.6	108.5
Paraffin	24.8	108.9
Polytetrafluoroethylene (PTFE)	19.4	109.2
Poly(hexafluoropropylene)	16.9	112
Polyisobutylene (PIB, butyl rubber)	27	112.1

Except for fluoropolymers, polyolefins, polydimethylsiloxane, poly t-butyl methacrylate and polyisobutylene show contact angles with water which are above 100°. Polyolefines are mentioned as potential binders for gas diffusion layers by Lysenko[87], however, without referring to concrete research papers. There are no reports on the use of poly t-butyl methacrylate or polyisobutylene as binders or hydrophobizing agents (where polyisobutylene does not possess a sufficient temperature stability[88] for the use in fuel cells). Few papers report on siloxane-based hydrophobizing agents[89–92]. The researchers demonstrate the performance of the GDL, however, reports on the long-term performance are lacking (Joo *et al.*[90] refer to 12h-tests, Ko *et al.*[92] explicitly mention only tests of 10 min. duration). Furthermore, some of these publications lack a measurement on an adequate reference GDL. Joo *et al.* only apply the hydrophobization with PDMS to a GDL already loaded with 5 wt.% PTFE, and Ko *et al.* test their siloxane-treated GDLs in comparison to a »pristine« GDL without PTFE-hydrophobization.

Published research on PFAS-free gas diffusion layers is – to our knowledge – limited to the few publications on siloxane-based hydrophobizing agents. These research papers describe initial attempts to achieve a PFAS-free GDL. They partially lack tests on relevant reference systems and only refer explicitly to experiments testing the systems for durations shorter than one day – there is no information on their long-term behavior. Silicon is considered a »poison« for Pt-catalysts[93] – this might explain that research on siloxane-based hydrophobizing agents appears to be in its infancy. As a consequence, this research can be associated with TRL 3-4; significant research efforts are required (including work on the long-term performance and production of PFAS-free GDL) to obtain a market-ready product.

4.1.3
Perspectives on PFAS-free PEMFC

Since the production of the gas diffusion layer (GDL) with micro-porous layer (MPL) and the proton exchange membrane (PEM) require distinct production processes, the perspectives of obtaining PFAS-free designs of these components are discussed separately.

The **proton exchange membrane** can be in principle designed without using fluoropolymers – in the scientific literature, there are reports on e.g. hydrocarbon, PBI or PEEK-based PEM which exhibit the required core functionality of a PEM. However, scientific papers on substitute materials focus on a validation in laboratory environment with a technology readiness level below TRL 7. Reports on the long-term performance of the PFAS-free membranes are still sparse. Thus, the development level of the novel, PFAS-free PEM cannot be compared with a current hybrid Nafion membrane. Research on Nafion membranes for fuel cells dates back to the 1960ies. A review paper on »recent advances in perfluorinated ionomer membranes« from 1996 states that »due to the enormous number of publications in these fields only those which appeared after 1988 will be discussed here«[94]. A current, state-of-the-art Nafion PEM is based on research which was carried out in the last decades by a large number of academic research groups as well as the R&D departments of companies like Gore Inc. and Dupont-Nemours. The development of a PFAS-free PEM can be based on the knowledge gained by the development of Nafion membranes. However, considering that one of the open questions is the long-term stability of the PFAS-free membranes[75] (i.e. a question that requires time-consuming testing), the required progress to reach a development stage which makes the scale-up of the production of PEMFC to a large-scale industrial level possible may take a significant time-period. Since the outcome of research is difficult to predict, estimates of time periods which are required to reach a research goal must be treated with the necessary caution. In the case of PBI-based high temperature PEM fuel cells, Escorihuela states in a review paper published in 2020 that »degradation of the membrane at high temperatures and acid leaching« limit the use of PBI-based HT-PEMFC[75]. He estimates that »phosphoric acid leaching remains a problem to be solved in the next decade«. Provided, that problems with acid leaching and high temperature stability can be resolved until 2030, one still needs to progress from a working prototype to a large-scale industrial production. A period of approximately 15 – 20 years is therefore probably a fair estimate for the time required for the commercialization of PBI-based HT-PEMFC.

Currently, there are only few reports in the scientific literature on concepts for designing a PFAS-free **gas diffusion- and micro-porous layer** which reach the level validation in a laboratory environment (TRL 4). Replacing PTFE as a binder is challenging since several traits of PTFE make it »the material of choice«: its chemical inertness, its hydrophobic properties, as well as not being a catalyst poison and its processability at high temperatures – which is beneficial for the production process of the GDL and MPL. Replacing the functions of PTFE in the GDL and MPL with one or more materials would inevitably result in significant changes in the production process and would possibly require different concepts for the GDL and MPL[84]. In conclusion, there are to our knowledge no concepts for a PFAS-free GDL and MPL on a development level which is suitable for a large-scale industrial production.

In summary, the development of an entirely PFAS-free fuel cell would require a significant and time-consuming research and development effort. Critical issues are the long-term stability of PFAS-free PEM and the lack of technically mature concepts for a PFAS-free GDL and MPL. When estimating the research effort required for a PFAS-free fuel cell, it is essential to keep in mind that the functionality of a fuel cell is determined by the interaction of its component: the GDL, the catalyst and the PEM. For the existing, PFAS-based fuel cells, decades of research resulted in an optimized interplay of these components. Optimizing the interplay of PFAS-free components with respect to their chemical and thermal characteristics and their performance and lifetime under operating conditions is a formidable task. Avoiding fluoropolymers in the design of a fuel cell would result in a significant set-back for the efforts to ramp-up the large-scale industrial production of PEMFC and electrolyzers, which is currently on the way to satisfy the need of these devices for the transition to a fossil-free energy supply.

4.2
Sealing Technology

There are numerous applications for seals and gaskets, ranging from dental drills, chemical reactors, automotive transmissions, filling lines for food and beverages, dosing units for pharmaceuticals, wind turbines, ship engines or aircraft engines. A range of polymers and elastomers are used in sealing applications in order to match the requirements of the individual applications. Fluoroelastomers and PTFE-based materials combine several characteristics which make them unique materials in sealing technology:

- PTFE and fluoroelastomers like FKM and FFKM show an excellent heat resistance. Compared with EPDM or HNBR, they can endure process temperatures above 140°C without loss of tensile strength and elongation at break.
- Fluoropolymers resist aggressive or corrosive media.
- Fluoroelastomers exhibit an outstanding heat and oil resistance[4] and show a low degree of swelling in contact with various media[95].
- Fluoropolymers show a low transfer of flavor when in contact with food or beverages[96].
- PTFE and fluoroelastomers show low permeation coefficients[97].
- Due to their low uptake of gases, fluoroelastomers are less prone to being damaged under explosive decompression.
- Selected fluoropolymers are not cytotoxic and pass the requirements for being used as biomedical material or as material in the pharmaceutical industry.
- Selected fluoropolymers pass the requirements for a food contact material[98,99].
- In particular PTFE exhibits a low coefficient of friction (also without the presence of a lubricant) and low wear rates[100].

Seals and gaskets are often essential for the safe and reliable functioning of a device: the premature wear or failure of a dynamic seal in an engine will lead to the loss of the lubricant and to the failure of the engine; the break-down of a gasket in a chemical plant might result in the leakage of hazardous chemicals.

Fluoropolymers are frequently the »material of choice« in sealing applications if the sealing material has to fulfill multiple requirements: e.g. an excellent high-temperature resistance and the compatibility with lubricants, or fulfilling the requirements for a food-contact material, a high resistance against aggressive cleaning procedures and a low tendency to absorb and transmit flavors. Fluoropolymers are costly materials, they are typically only used, if their performance cannot be reached by other, cheaper polymers. Since many unique properties of fluoropolymers are linked to the characteristics of the C–F bond, finding an adequate replacement is a challenge – in particular if the replacement has to fulfill several requirements.

4.2.1
Compressor Dry Gas Seals

A gas seal is used to seal the shaft of a compressor. Typical applications of compressors are oil and gas processes, pipelines, refinery equipment and petrochemical and chemical industries. Dry gas seals (DGS) become increasingly important for decarbonization of the industry: they are essential for hydrogen- and ammonia transport, as well as for CO_2 capture and -storage. Table 5 shows four use-cases in the areas of carbon capture, utilization and storage (cases a and b) and hydrogen transformation (cases c and d). These use cases require compressors with dry gas seals which operate at high or cryogenic temperatures and/or at high pressures.

Table 5: Use cases in the field of carbon capture, utilization and storage and hydrogen transformation, and their DGS specifications: The challenging specifications which currently require PTFE as seal material are printed in italics.

Use case	Medium	Design Temperature		Design pressure
		T_{min}	T_{max}	
a) Carbon capture, utilization and storage	CO_2 with up to 14% water vapor	-50 °C	230°C	*200 bar*
b) High pressure gas reinjection	super-critical CO_2, H_2S	-50 °C	230°C	*425 bar*
c) Cryogenic Hydrogen	100% Hydrogen	*-250°C*	80°C	65 bar
d) Green Ammonia	75% Hydrogen, 25% Nitrogen	0°C	200°C	*186 bar*

A tandem seal is used in the four use cases shown above. Tandem seals are typically used for safety reasons if flammable gases are compressed. Figure 5 shows the set-up of a tandem seal.

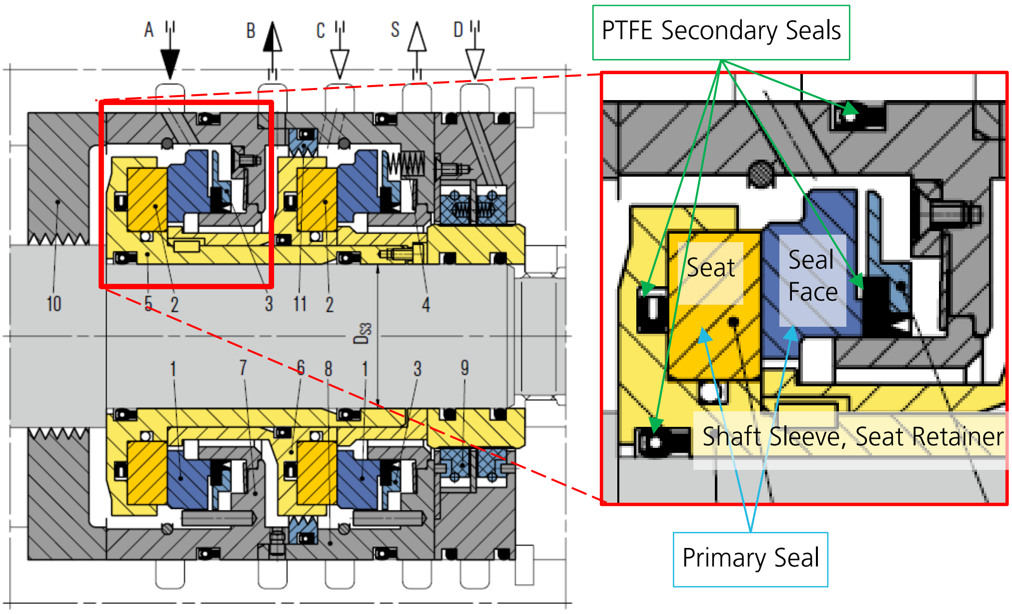

Figure 5: Tandem seal (dry gas seal). Source: EagleBurgmann

The primary seal consists of seat and seal face. Dry gas seals are used for the compression of gases like Hydrogen. Seat and seal face are made of silicon carbide with a DLC (diamond like carbon) coating. Between seat and seal face there is a gap of approximately 1 – 3 µm.

PTFE seals are used as deformable secondary seals in radial and axial direction, e.g. between shaft and sleeve, and stationary seal ring and housing. They are required to seal possible secondary leak paths. In particular, the secondary seal between the shaft and the primary seal must be wear-resistant, because this dynamic sealing element experiences axial vibrations in the range of 30-50 µm at 250 Hz during operation. The required lifetime of this seal is currently 5 years.

Since they are in contact with the medium on the processing side of the compressor (e.g. H_2, NH_3, CO_2, or H_2S), they must exhibit the required chemical resistance to the medium and must endure the required design temperature and design pressure.

PTFE is chosen as material for the secondary seals since it endures harsh environments:

- it is chemically resistant against aggressive media (e.g. NH_3 or H_2S),
- it is suitable for cryogenic and/or high temperature applications (see Table 6),
- it is – due to its low uptake of gases under high pressure – suitable for high pressure applications: in contrast to typical elastomers, no »explosive decompression« (i.e. outgassing of solved gas during rapid decompression) occurs which would destroy the seal.

Table 6: Typical temperature limits of secondary seals; Source: API 682 4th Edition (Shaft Sealing Systems for Centrifugal and Rotary Pumps)

Material	**ISO/DIN 1629**	**ASTM D1418**	**Minimum Temperature °C (°F)**	**Maximum Temperature °C (°F)**
Fluoroelastomer	FKM	FKM		
Hydrocarbon service			-7 (20)	176 (350)
Water-based service			-7 (20)	121 (250)
Perfluoroelastomer (high temperature)	FFKM	FFKM	0 (32)	290 (554)
Perfluoroelastomer (chemically resistant)	FFKM	FFKM	-7 (20)	260 (500)
Nitrile	NBR	NBR	-40 (-40)	121 (250)
Ethylene propylene diene	EPDM	EPDM	-50 (-58)	150 (302)
Tetrafluoroethylene propylene	FEPM/TFE	FEPM/TFE	-7 (20)	210 (410)
Polytetrafluoroethylene	PTFE	PTFE	-270 (-454)	315 (599)
Flexible graphite	-	-	-240 (-400)	480 (896)

PTFE is used in the use cases shown in Table 4 as material for the secondary sealing elements since it combines good sealing properties with the suitability for cryogenic applications (case c) or the suitability for high pressure applications. The performance of PTFE for these applications is related to its low uptake of gases and broad range of service temperatures.

4.2.2
Perspectives on PFAS-free Secondary Sealing Elements in Dry Gas Seals

PTFE combines material properties which make it »the material of choice« for the applications presented above. For cryogenic applications, only flexible graphite is a potential replacement material. However, flexible graphite exhibits a too low deformability and is too brittle to serve as a secondary seal in the tandem seal. Poly (ether ether ketone) (PEEK) would be a potential substitute at high operating temperatures. However, PEEK is considerably stiffer than PTFE and cannot adapt its shape in order to close a gap. Furthermore, PEEK does not have the friction and wear performance of PTFE.

In high pressure applications, a replacement with elastomers is problematic due to their significantly higher absorption of gases at high pressures and the resulting susceptibility for explosive decompression. Explosive decompression in elastomers is avoided if the decompression rate is limited to 20 bar/min – this would, however, result in a decompression time of 20 Minutes for an operating pressure of 400 bar. For many applications, this is not desirable or feasible.

Identifying a substitute material which would make a replacement without changing the design of the DGS possible is therefore highly unlikely. Designing PFAS-free DGS would therefore require significant R&D efforts. In addition, the question remains, how the existing gas seals will be maintained if the PTFE based secondary sealing elements are not any more available: dry gas seals are costly components which contain value-added materials. They are designed for a long product life with a typical service interval of 5 years. During service, the secondary sealing elements are replaced. If fluoropolymers would be exempted from the PFAS ban, the compressor dry gas seal would be an exemplary case, where a defined EoL scenario (recycling or controlled disposal) of the PTFE components could be implemented, and a further use of PTFE seals would support the concept of the »inner circles« (maintenance and repair) of a circular economy.

4.2.3
Engine Seals

Fluoropolymer-based seals are frequently used in engines if a long lifetime of the seal is essential in order to avoid frequent maintenance operations. This applies e.g. for seals for large diesel engines which are used in ships or large electric generators, or for seals used in wind engines. For ships, a standard maintenance overhaul in the dry dock is typically scheduled every five years. If the electric power supply e.g. of an isolated community relies on a large electric generator, one aims at as long as possible time periods between maintenance periods of the generator in order to avoid frequent down-times of the power supply. An exchange of seals in a wind engine can be extremely complex and costly – and in some cases not feasible. PFAS-free seals will in general fail earlier under the operating conditions, where a fluoropolymer seal can reach 40000 operating hours without failure.

Noordermeer and Masen analyze the possibilities of replacing PFAS-based elastomeric rotary propeller seals in marine shipping transport[101]. Elastomeric rotary seals used in the stern tube of the propulsion system of a ship need to fulfill the following requirements:

a) Suitable for a high continuous operating temperature (minimum of 130 °C), for operating periods of at least 5 years.
b) Long-term chemical resistance towards oil: limited or preferably no tendency to swell.
c) Long-term chemical resistance towards (salt-)water.
d) Sufficient mechanical properties: sufficient tensile and tear strengths, fatigue strength and abrasion resistance.
e) A static modulus (or alternatively hardness) sufficient to carry the axial force exerted by the Garter spring.
f) A low compression set (permanent deformation under compression or creep) at room temperature, at 0 °C and at operating temperatures of various durations.
g) A brittleness temperature in marine applications ≤ -5 °C.

FKM (fluorocarbon-based) elastomers are used as materials for rotary propellor seals in the stern tube. Noordermeer and Masen discuss PFAS-free alternatives like NBR (acrylonitrile/butadiene rubber), HNBR (hydrogenated nitrile - butadiene rubber), high ACN - NBR (NBR with a high acrylonitrile content), ACM (acrylic rubber) or CR (chloroprene rubber). All PFAS-free elastomers do not exhibit the required temperature resistance; in addition, some do not reach the required mechanical characteristics and brittleness temperature (ACM, high ACN-NBR) or the long-term resistance to oil and salt water (HNBR, CR). Noordermeer and Masen conclude[101]: »Experiences over the past decades show that no alternatives exist that match the combination of characteristics required to substitute FKM. Replacing FKM in propeller shaft seals is practically not realistic and will require at least many years of research«.

PTFE seals are used in the ship's diesel engine due to their high temperature resistance and low swelling tendency in media. PTFE replaced silicone rubber which was previously used for this application. Silicone rubber has the disadvantage of exhibiting a strong swelling behavior when in contact with mineral oil or mineral oil-based media. In order to avoid strong dimensional changes of the seal during operation, the silicone rubber seals were delivered pre-swollen – which requires additional effort in preparation and handling and is not a preferrable solution. In addition, the service life achieved is much shorter compared to FKM or PTFE seals.

In the automotive sector, FKM is the »state of the art« material for crankshaft seals. Since these radial shaft seals experience high thermal loads during operation, FKM components show a significantly higher lifetime than NBR or HNBR components. FKM-based crankshaft seals can easily reach an operational performance of 300 000 km. As a result, it is likely that these crankshaft seals do not need to be replaced during the lifetime of the engine. This avoids oil spillages and high maintenance costs. An innovative alternative to conventional crankshaft seals is a gas-lubricated mechanical face seal (Levitex® - seal)[102]. These seals are more costly than conventional crankshaft seals, however, they significantly reduce frictional losses and, as a consequence, CO_2 emissions. The Levitex® - seal uses fluoropolymers as secondary sealing elements. These secondary sealing elements can potentially be replaced with ACM-based sealing elements. The effect of this replacement on the lifetime of the seal needs, however, to be investigated.

4.2.4
Gearbox Seals

Gear motors are used in electric power systems of various production lines. These production lines are frequently running in shift work, i.e. in a continuous 24 hour operation, six days per week. The reliability of the production line depends on the reliability of its electric drive – and the lifetime of gear motors is often determined by the lifetime of its shaft sealings. A continuous shift operation results in approximately 7000 operating hours per year. In order to avoid frequent down-times of the production line due to repair or maintenance of the electric drive, maintenance intervals in the order of 20 000 h are desirable. Frictional and thermal loading influence the wear and aging of the elastomer components of the seal. The excellent chemical and thermal resistance of FKM elastomers contribute to a sufficient lifetime of the seal, in particular for applications with high rotational speeds. In principle, FKM elastomers can be replaced by PFAS-free elastomers (e.g. NBR) which would result in costs due to additional maintenance intervals and down-times of the production line.

4.2.5
Hydraulic Seals

PTFE is frequently used as material for dynamic sealing elements for translatory motions. Very high contact pressures are typical for these applications. Compared to other materials, PTFE exhibits low frictional forces under these conditions. The compliance of PTFE lies between the compliances of elastomers and the compliances of those thermoplastic polymers which would be an adequate replacement for PTFE as sealing material in hydraulic applications. As a consequence, elastomers will be prone to gap extrusion, and thermoplastic polymers are not flexible enough to form a tight seal between the frictional partners. So the pressure resistance of PTFE seals is significantly higher than that of elastomer or TPU seals.

4.2.6
Seals in the Food & Beverage Industry

Materials used in food processing equipment need to be physical durable, inert, chemical resistant, heat and/or cold resistant, and hygienic (i.e. they have to be smooth, not sensitive to fouling and be able to withstand aggressive cleaning cycles)[103]. Fluoropolymers are commonly used in food processing equipment like bottling plants or filling lines as O-rings, valve seals or seals in sensors, pumps, heat exchangers and filters. The use of fluoropolymers in the food and beverage industry underlines their status as »Polymers of Low Concern«: only polymers which do not pose a danger to human health are allowed as food contact materials. When comparing the performance of different polymers and elastomers used in food processing equipment with respect to resistance to detergents / disinfectants, food substances and other loads, fluoropolymers frequently show the best overall performance[103]. Table 6 shows that it is in principle possible to find replacement materials for fluoropolymers if only a limited number of requirements have to be fulfilled: EPDM, silicone rubber of styrene-butadiene rubber show a comparable resistance to detergents and disinfectants as a perfluoro-elastomer or PTFE. However, if the application requires for example a sufficient resistance of the seal material in contact to vegetable oil, only the fluoropolymers show a good performance.

The low tendency of fluoropolymers to absorb media also results in a low uptake and transmission of flavors. This is an important quality for sealing materials in the food and beverage industry where a carry-over of flavors can result in off-flavors of the product. Figure 6 shows the uptake of orange oil in different elastomers: EPDM rubber (ethylene propylene diene monomer rubber), HNBR (hydrogenated nitrile butadiene rubber) and VMQ (silicone rubber) show a significant uptake of the substance. This results – in addition to the carry-over of flavors – in a deterioration of the mechanical properties of the sealing materials. The fluoroelastomers FKM and Fluoroprene® XP do not show a significant interaction with orange oil.

A study by Gottman *et al.* of the »Dienstleistungszentrum ländlicher Raum« supported by the program »Industrielle Gemeinschaftsforschung« of the German Ministry of Economics and Climate Action (BMWK) confirms the significantly higher uptake of aroma compounds in EPDM compared to FKM[96]. Gottman *et al.* could also show that cleaning cycles were not able to remove the aroma compounds from the EPDM rubber – an adaption of the cleaning process does not solve the problem the carry-over of flavors once a sealing material like EPDM is contaminated with aroma compounds.

Table 7: Chemical and physical resistance of thermoplastics and Elastomers (source: Moerman and Partington[103]). 3: High resistance, 2: good resistance, 1: low resistance, 0: no resistance

Materials of construction		Detergents or disinfectants							Food substances			Physical factors			
		Mild alkaline	Alkaline	Strong alkaline	Alkaline + NaOCl	Alkaline + NaOCl + corrosion inhibitor	Mild acid + corrosion inhibitor	Mild alkaline disinfectant	Salt water	Acid food	Vegetable oil & fat	Steam 125°C	Hot water	Cold resistance < -25°C	Ozone
Thermoplastics	Acetal Plastic (POM)	3	0	0	0	0	0	3	3	0	3	0	1	3	0
	Polyamide Plastic (PA)	3	1	1	1	1	1	3	3	1	3/2	3	2/1	3	0
	Polyvinylchloride (PVC)	3	3	3	3	3	3	3	3	3	3	1	2	0	3/2
	Polyurethane (PU)	3	2	0	0	0	2	3	3	1	3	1	3	3	3
	Polycarbonate (PC)	0	0	0	0	0	1	3	3	2/1	3	1	2/1	2	2/1
	Teflon (PTFE)	3	3	3	3	3	3	3	3	3	3	3/2	3	3	3
	Polyethylene (PE)	3/2	3/2	2	3	3	3	3	3	3	3	0	3/2	1	2/1
	Polypropylene (PP)	3	3	3	3	3/2	3	3	3	3	3/2	2	3/2	1	0
	PVDF	3	2	2	3/2	3/2	3	3	3	3	3	3	3	3	3
	Tefzel®	2	2	2	3	0	2	2	3	2	3	3	3	2	3
	Polyethertherketone (PEEK)	3	3	3	3/2	3/2	3	3	3	3/2	3	3	3	3	3
	Polystyrene (PS)	3	3	3/2	3	3	3	3	3	3	0	0	1	3	1
	Acrylonitrile butadiene styrene	3	3	3	0	0	3	3	3	3/2	1	2/1	3	3	1
Elastomers	Neoprene	3	3	3	1	1	1	3	3	3	1	3	3	3	1
	Nitrile rubber (NBR)	2	2	2	2	2	2	3	3	2/1	3	0	3	3	1
	Silicone rubber	3	3	3/2	3	3	3	3	3	2	2	1	3	3	3
	EPDM	3	3	3	3	3	2	3	3	2	1	3/2	3	3	3
	Perfluor-elastomer	3	3	3	3	3	3	3	3	3/2	3	3	3	1	3
	Styrene butadiene rubber	3	3	2	3	3	3	3	3	3/2	0	1	3	3	0

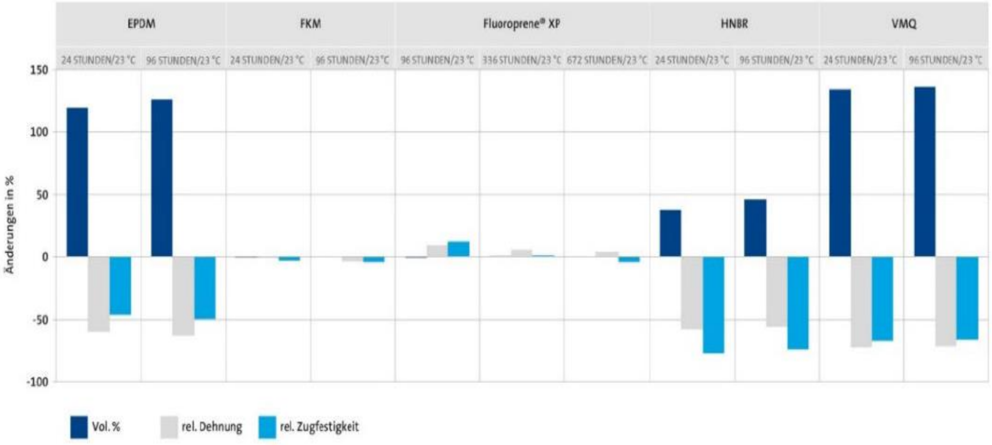

Figure 6: Uptake of orange oil and subsequent charge of mechanical characteristics for EPDM, FKM, Fluoropren XP, HNBR and VMQ. Source: Freudenberg sealing technologies

4.2.7
Perspectives on Replacing Fluoropolymers in Sealing Technology

For sealing applications, there are materials with a range of material properties available. If the number of requirements posed by a specific application on a seal is limited, there exists a fair chance that an adequate replacement material can be identified. For these applications, fluoropolymers will have been most likely already replaced by the substitute material for economic reasons since fluoropolymers are costly materials.

If fluoroelastomers and PTFE are currently the only materials which meet all the requirements of an application, a replacement will result in a loss of performance. This will be the case where a material has to endure a combination of harsh environmental conditions, e.g. high temperatures and contact to lubricants or aggressive media. Another example are applications where a limited uptake of media by the seal is essential. This is for example the case in the food and beverage industry where the sealing material should not absorb flavors and must meet the additional requirements for food contact materials or in high pressure applications where a rapid drop in gas pressure should not result in the destruction of the seal by explosive decompression (see section 4.2.1).

In some cases, the loss of performance of a seal by replacing fluoroelastomers or PTFE can be compensated by more frequent maintenance operations and a precautionary replacement of the seal before it fails. This is for example feasible for electric drives of production lines – where maintenance and down-time of the production line will create additional costs. In some cases (e.g. in offshore wind turbines and ship engines) a premature and unplanned replacement of a seal is not possible.

If fluoroelastomer- or PTFE-seals can be replaced, it is not for sure that the replacement seal can be designed in the same dimensions as the original seal. This raises the question of the availability of spare parts necessary for maintenance. The lack of spare parts will result in a premature decommissioning of an otherwise still functioning equipment.

4.3
Lubricants in Contact with Pure Oxygen and for Harsh Environments

Perfluoropolyether (PFPE) are lubricants which can be applied over an extraordinary wide temperature range, show a low spreading tendency, they are chemically inert, non-toxic and do not easily dissolve in media. These properties make them for example suitable as lubricant for contact with food, beverages and drinking water. Furthermore, it is important to note that alternatives to fluoropolymers are basically all cheaper to produce – therefore product alternatives without fluoropolymers are always the economically more viable solution. The cost pressure on the manufacturer side, e.g. vehicle manufacturers and suppliers, will always mean that fluoropolymers are only used where it is absolutely necessary.

Although PFPE are excluded from the discussion in the scientific literature on »polymers of low concern«[18,50], based on the information provided in Safety Data Sheets and written information by suppliers[a] it is likely that they qualify for this status.

4.3.1
Lubricants in Contact with Pure Oxygen

Special care has to be taken when selecting materials for the use in oxygen environments or oxygen-enriched environments. Materials which are not flammable in normal atmosphere can burn violently in oxygen, sometimes to the point of explosion[104]. This also applies to lubricants: oils and greases can ignite spontaneously in an oxygen at-

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[a] A confidential dossier of Solay supports the status of PFPE as »polymers of low concern": Chapter 1.1.1 table 1 Solvay's PLC portfolio and Annex III, table 9, Physicochemical of Solvay PFPE

mosphere. In order to prevent accidents, the »Deutsche Gesetzliche Unfallversicherung« DGUV publishes lists of materials which are suitable for use in oxygen atmospheres. Lubricants are listed in the »lists of materials which are suitable for use in oxygen atmospheres«[105]. Several research laboratories test the suitability of materials for the use in oxygen atmospheres using the following test set-ups:

- Gaseous oxygen impact tester for valves and components: This apparatus is used for testing valves, hoses, and components for burn-out safety on exposure to gaseous oxygen impacts.
- Apparatus for determining the autogenous ignition temperature in high pressure oxygen: The test apparatus allows to determine the autogenous ignition temperature of nonmetallic materials in oxygen at high temperatures and at high pressures.
- Testing the reactivity of nonmetallic materials with liquid oxygen on mechanical impact: This apparatus is used for testing the reactivity of nonmetallic materials with liquid oxygen on mechanical impact. In general, a nonmetallic material is not compatible with liquid oxygen if reactions occur at a certain impact energy.

Due to their chemical inertness, fluorinated lubricants are suitable for the use in oxygen atmospheres. PFPE can be used up to 200 °C and 200 bar. For moderate temperatures as 60 °C, significantly higher pressures (up to 450 bar) can be applied. Replacement lubricants are only safe for lower pressures: lubricants based on Silicon oil or polyglycole can only be used up to 60°C at 40 bar.

Phasing-out PFPE as lubricant for oxygen environments will therefore require redesign of oxygen conducting devices to lower pressures and operating temperatures which will result in a lower performance of these devices. The redesign will need to be done by companies active in the field of technical gases, e.g. Praxair, Flowserve, Linde, Müller Gas Equipment A/S, CRYOSTAR S.A.S and AIR LIQUIDE.

4.3.2
Lubricants for Bearings in High Temperature Applications

Lubricants for high temperature applications like conveyor systems in furnaces or dampers and bearings in furnace systems should allow a continuous use at temperatures higher than 180°C – 200°C. Since PFPE is chemically inert and non-toxic, certain PFPE grades have the »H1 approval« for lubricants with incidental contact with food. These PFPE grades are for example used for conveyer systems in industrial bakeries. The high temperature applications require a high oxidative stability and low losses due to evaporation of the lubricant, otherwise lifetime lubrication is not possible. The system would either need frequent maintenance and re-lubricating, a re-design or the use of a central lubrication.

PFPE lubricants are suitable for high temperature applications; other high temperature resistant lubricants have shortcomings: silicone greases show a high spreading tendency which limits their ability to build-up a sufficient lubricating film, they are therefore not suitable for rolling contacts. A possible alternative are urea-polyester greases; however, the performance of these lubricants still needs to be investigated – due to the hydrocarbon-component, the long-term performance at high temperatures will be most likely limited.

5
Position Statements from Industry and Environmental Groups

5.1
A Survey of Concerns and Criticism on the ECHA Proposal

In response to the restriction proposal for PFAS published by the ECHA[40], as of September 26, 2023, more than 5600 comments were submitted from more than 4400 organizations[106].

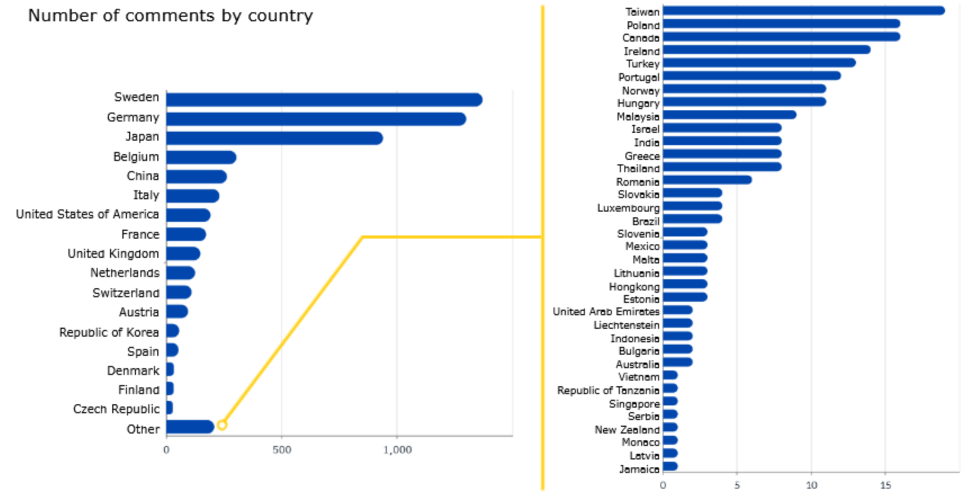

Figure 6: Number of comments by country; due to a national campaign, the number of comments from Sweden is relatively high. Source: https://www.echa.europa.eu/-/echa-receives-5-600-comments-on-pfas-restriction-proposal

In the following, a review of a selection of position papers from industry and professional organizations is presented. Since the line of argumentation is in some of the position papers comparable, the arguments are grouped in categories.

5.1.1
Concerns Regarding Procedural Details of the Proposed Regulation

In many position papers, the restriction proposal of the ECHA is compared to existing regulations for chemicals, e.g. the REACH regulation. A common criticism is the disproportionality of the impact of the restriction proposal and the (established) hazard potential of the majority of the PFAS[107–109] – where the definition of the hazard potential of the REACH regulation is used as benchmark: »an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis«[110]. They conclude that the ECHA restriction proposal is in conflict with the established REACH regulation if substances are banned which do not possess a hazard potential. Fluoropolymers which are classified as PLC are given as an example for substances which are not banned under the REACH regulation. In addition, the approach to regulate PFAS as a class is in conflict with article 69 of the REACH regulation[111] which requires an approach addressing the hazard potential of individual substances[108].

The wide scope of the PFAS restriction proposal considering PFAS as a class includes substances which are already regulated by other regulations[107,112], e.g. regulations for »Fluorinated Greenhouse Gases«.

Another concern are difficulties to implement the proposed ECHA regulation. Companies which are located in the center of the supply chain need to establish whether or not the goods or components they process contain PFAS. Since PFAS are not yet sufficiently implemented in the »Classification, Labelling, Packaging« regulation, the identification of PFAS for the engineering industry is difficult and in some cases impossible[107,113].

The PFAS restriction proposal considers exempting PFAS from a ban in »essential uses« which are necessary for the functioning of the society (e.g. certain medical or pharmaceutical applications). The essential-use concept is criticized since the criterion »essential for the functioning of society« is difficult to grasp. A use which is not considered essential at the present time might well develop into a use which is considered essential in the future. However, if the PFAS restriction proposal comes into place, innovations resulting in essential uses will be hindered[114].

It is recognized that regulations can trigger innovation – however, the necessary time frame to achieve these innovations needs to be considered for the grace periods defined for phasing-out chemicals. An unrealistic time-frame hinders innovation[109] and makes it impossible to carry out the required research to find alternatives[115].

A recent statement of the »Forum for Exchange of Information on Enforcement« of the ECHA lists several concerns regarding the enforceability of the restriction proposal[116] which were addressed by position papers professional organizations and industries. These concerns include issues regarding the substance identification, scope of the regulation (i.e. how substance mixtures and articles are covered), the overlap with existing legislation and the analyses of substances.

5.1.2
Concerns Regarding the Availability of Adequate Replacement Materials

Many position papers state that PFAS are in general very costly materials. As a result, they are used for good reasons and would have been replaced if an alternative would have been available[112]. For many applications adequate replacement materials which endure high temperatures, high pressure, UV radiation, high frictional resistance, or exposure to aggressive chemicals are despite intense research efforts not available. These areas include

- the food industry[112],
- the automotive industry[117],
- the energy sector (e.g. fuel cells and electrolyzers)[118],
- the optics, photonics, analytical and medical technology industry[115],
- the engineering industry[107],
- the semiconductor industry[119],
- the sealing manufacturers[120],
- the pump manufacturers[121].

The professional organizations conclude that a PFAS ban without the availability of adequate replacement material would in many cases result in technological set-backs, negative consequences for European industries and the development of innovative technologies in Europe and the migration of manufacturing processes and companies to non-EU countries.

5.1.3
Concerns Regarding the Impact on Production Processes

The replacement of a component made from PFAS or containing PFAS by a PFAS-free component has a potential impact on the manufacturing process (as already pointed out for the use-case fuel cell, section 4.1.3). For example, PFAS-free gaskets or seals with an adequate performance possibly require different dimensions than polymeric

PFAS seals or gaskets. As a consequence, the design of the product containing the seal or gasket also needs to be adjusted.

An example illustrating the complexity of the replacement of PFAS-containing components are which consist optical photolithography systems which are used to manufacture advanced and powerful microchips[115]. These are highly complex systems containing optics which need to work highly precise in an extremely clean environment. Lithography optics use UV light to produce microchips with structures in the nanometer-range – therefore, UV-resistant materials like PFAS are used in these systems. Replacing these materials is a challenging task since even minute amounts of degradation products would compromise the manufacturing process which requires an extremely clean environment. Even if adequate replacement materials should be developed, the adjustment of the optical photolithography systems (which consist of approximately 100 000 parts) to the replacement materials would require a tremendous effort.

In other areas, PFAS are used as processing aids, for example in the semiconductor industry[119] and the chemical industry (here also for synthesizing high-value-added fluoropolymers[113]). If no adequate substitute for these processing aids is available, a ban of these processing aids would have also severe consequences for the industries relying on the products produced with these processing aids.

5.1.4
Concerns Regarding »Regrettable Substitutions«

Fluoropolymers are often the material of choice due to their durability in harsh environments. As a result, they are persistent in less aggressive environments with the potential consequences on environment and human health discussed above. The question arises whether adequate replacement materials would necessarily also endure and be persistent in less aggressive environments, i.e. would be a »regrettable substitution«. An open letter to the Bundesanstalt für Arbeitsschutz und Arbeitsmedizin points out this difficulty and raises the question whether or not the approach to propose a ban of fluoropolymers based on their persistence without considering the potential persistence of replacement materials is – from a procedural point of view – consistent[122].

5.1.5
Concerns Regarding Conflict with Current Political Goals

A commonly voiced concern in the position papers is that the proposed PFAS restriction conflicts with several other political goals.

Transition to a circular economy. Central components of a circular economy are the »inner circles« which aim at a long and intense use phase of goods. PFAS-free alternatives which result in a shorter lifetime of the product conflict with the goal to produce durable products. The »inner circles« also address the maintenance, repair and refurbishment of goods. A ban of PFAS (which would affect, for example, seals or gaskets made from polymeric PFAS) would have a significant impact on the availability of spare parts needed to maintain and repair equipment. If the relevant components cannot be manufactured in the same dimensions with replacement materials, a repair or maintenance of an otherwise functioning product is not any more possible.

Decarbonization of the industry and the transition to electromobility. PFAS and in particular fluoropolymers are essential components for fuel cells, hydrolyzer and Li-ion batteries. They are also difficult to replace on compressors for a Hydrogen network which is needed for an energy supply based on Hydrogen. A ban of PFAS would result in a severe technological set-back in these technology field and would make it impossible to reach the goals which were set to fight the climate change.

Diversification of supply chains. A ban of PFAS would lead to a migration to non-EU countries of those industries for which no adequate replacement materials or substances are available, or for which PFAS-free production processes are not economically viable. Examples for industries affected by a PFAS ban are the semiconductor and microelectronics industry, the industries supplying components for a transition to a sustainable energy supply (e.g. industries which manufacture fuel cells, hydrolysers and Li-ion batteries) and parts of the chemical industry (e.g. companies which produce high-value added fluoropolymers). These industries are partially supplying critical materials or components for EU-industries (e.g. PTFE for the medical industry and microchips for the engineering and automotive companies) and are supplying components which are critical for achieving political goals like the transition to electromobility, a circular economy or a sustainable energy supply. The proposed PFAS ban would conflict with recent attempts to strengthen these industries in the EU.

6

Discussion of Different Alternatives to Protect Health and Environment

Aim of the current study is an account of the possibilities to replace polymeric PFAS in harsh industrial environments. The study was triggered by the restriction proposal for per- and polyfluoroalkyl substances by the European Chemical Agency ECHA [40].

The ECHA proposal chooses a novel approach to regulate potentially hazardous substances: instead of applying a substance-by-substance hazard analysis, PFAS are considered as a class of materials which will be phased out and banned with only exempting a few applications of PFAS. This approach was pioneered by the California Department of Toxic Substances Control[12] which justified regulatory measures on a class of materials as a precautionary measure based on the persistence and potential (but not proven) harmfulness of these material.

Whether or not PFAS can be treated as »a class of materials« which can or should be subject to unified regulatory criteria is a central question in the scientific debate over the restriction of PFAS[45]. Since the majority of commercially relevant fluoropolymers fulfill the OECD classification »polymers of low concern«, a scientific debate has evolved whether fluoropolymers should be exempted from the general PFAS regulations[18,45,51].

In this debate, two approaches to discuss the status of pPFAS as »polymers of low concern« can be distinguished. The discussion can focus on the material properties of the polymers [18,50], or it can include the entire life-cycle of the polymers from production to EoL [45,51].

- Henry *et al.* and Korzeniowski *et al.* focus on the properties of fluoropolymers and come to the conclusion that fluoropolymers are not hazardous and should be considered as substances of »low concern«[18,50]. They focus on the use-phase of fluoropolymers and argue that a selection of fluoropolymers which represents approximately 96%of the global fluoropolymer market fulfill the OECD-criteria for »polymers of low concern«. Korzeniowski *et al.* conclude that they »should be considered distinctly different and should not be grouped with other PFAS for hazard assessment or regulatory purposes«.
- Cousins *et al.* and Lohmann *et al.* come to a different conclusion[45,51]. They argue that in particular the emissions during production and disposal of fluoropolymers need to be included into the assessment of their status. Possible hazards occurring during the processing and use phase (e.g. emission of nanoparticle or potential leaching-out of low molecular weight substances) need also be considered. Lohmann *et al.* conclude that »there is no sufficient evidence to consider fluoropolymers as being of low concern for environmental and human health«. However, for technical applications they recommend »to move toward the use of fluoropolymers in closed-loop mass flows in the technosphere and in limited essential-use categories, unless manufacturers and users can eliminate PFAS emissions from all parts of the life cycle of fluoropolymers«.

Considering that the production of fluoropolymers was in the past a frequent source for the contamination of the environment with toxic low molecular weight PFAS [26,27], the »life-cycle view« is a plausible choice to discuss the status of fluoropolymers as »polymers of low concern«.

Despite the opposing conclusions on the status of pPFAS as »polymers of low concern«, both sides agree on the need for a safe production and disposal of pPFAS and that fluoropolymers should be not exempted from the use in industrial applications, provided certain precautionary measures are fulfilled. The side which does not consider pPFAS as »polymers of low concern« demands a higher level of precautionary measures during use in order to minimize potential adverse effects of pPFAS on human health and environment.

The regulatory measures proposed by the ECHA to minimize the risks to the environment and human health related to the use of PFAS [40] aim at a severe restriction of the production and use of PFAS and go beyond the measures proposed by Cousins *et al.* and Lohman *et al.* for fluoropolymers.

In the following, two possible future pathways for polymeric PFAS (fluoropolymers and perfluoropolyethers) are discussed; both pathways aim at comparable results with respect to protecting health and environment but differ in their impact on society.

- **»Pathway 1«:** Polymeric PFAS are treated regulatory **in the same way as low molecular weight PFAS** and the restrictions are put in place. As a consequence, the use of pPFAS will be phased out. This will require research efforts to find adequate replacements for pPFAS.
- **»Pathway 2«:** Fluoropolymers and PFPEs are treated regulatory **different from the low molecular weight PFAS** and are exempted from the regulatory measures (which is contrary to the currently proposed regulation). Their future use will be permitted, with a higher level of control and restrictions during their use phase. At the same time, efforts are required to ensure their safe production, safe use and safe disposal / Eol.

Both pathways will require research efforts and innovations. The outcome of research and the occurrence of the required innovations is not predictable. Therefore, it is a priori difficult to judge whether the research required for pathway 1 – to find adequate pPFAS-free solutions for industrial applications – has a higher chance to succeed than the research required for pathway 2 – to achieve a safe production, use phase and EoL of pPFAS.

Resources (financial means, time, skilled personnel) to perform research are in most cases limited. Therefore, it might be worth considering which of the two pathways described above is more productive, efficient and projectable to achieve the goal of minimizing the risks to the environment and human health related to the use of PFAS.

Pathway1, the phasing-out the production and use of low molecular weight and polymeric PFAS except for a few well-defined essential use categories would warrant a significant decrease of the future exposure of the environment with PFAS. Finding replacements for polymeric PFAS is, however, a formidable task: different unique properties of pPFAS lead to their widespread use in a large variety of different industrial applications. Polymeric PFAS are often parts of complex or highly integrated systems. For some applications, there is currently no replacement material or even prospective replacement material available. In a worst-case scenario, the equipment needs to be decommissioned or operated outside of the EU.

Polymeric PFAS are often the material of choice because of their extraordinary chemical stability. A replacement material needs therefore to possess a similar resistance to aggressive environments and is potentially also persistent in a natural environment with typically less aggressive conditions. As a result, there is a fair chance for »regrettable substitutions« which fail to achieve the goal to avoid the potential release of persistent substances (in this case PFAS-free) into the environment. Thus, additional efforts will be necessary to achieve a safe use-phase and disposal for the persistent replacement materials (as it would be the case for pPFAS, if a future use of pPFAS was permitted).

Furthermore, a phasing-out of pPFAS will affect the transition to a sustainable economy: it will for example have a direct effect on the availability of technical components necessary for the decarbonization of the economy (fuel cells, hydrolysis plants, compressor for a hydrogen network, etc.) and on the availability of spare parts (e.g. seals and gaskets) which are needed for the »inner circles« of a circular economy.

Pathway 2, exempting polymeric PFAS from the future ban of production and use of PFAS would enable a future production and use of pPFAS. In order to reach the goal of minimizing the risks to the environment and human health related to PFAS, research needs to focus on achieving a safe and clean production, use phase and EoL of pPFAS.

A safe production of pPFAS will require safe surfactants and processing aids for the polymerization of fluoropolymers and means to monitor the environment around production plants to be able to detect and to quickly react to unwanted contamination. Some manufacturers have taken steps in this direction[59,60], and this path should be followed consistently. Production sites should be operated in countries where regulations for a safe production of chemicals are in place and enforced.

Research into the different streams at the EoL of pPFAS-containing components is necessary to ensure a safe disposal or recycling. The risks of different means of disposal (e.g. landfills, incineration) need to be further assessed. Depending on the outcome, waste streams potentially need to be redirected to safe disposal options or to recycling pPFAS. In addition, it should be investigated whether the efforts for a safe management of pPFAS at the EoL can be in integrated into efforts to build up a circular economy.

Both pathways, the phasing-out of production and use of pPFAS or the future use of pPFAS in a safe manner, require significant efforts. The widespread use of pPFAS in industry in a large variety of different complex and integrated applications and the current lack of suitable replacement materials for some applications make it difficult to map out the path which leads to an adequate replacement of pPFAS. Based on the position statements from different industrial sectors, it is likely that large parts of the industry will be impacted and involved in time-consuming efforts to replace pPFAS, seeking solutions for their highly specialized applications. Despite intensive research, the outcome of these efforts remains currently for several applications uncertain, like for instance those outlined in the case studies in section 4.

The efforts required to achieve a safe production, use phase and EoL of pPFAS are not necessarily less challenging than finding adequate replacements. However, a focused effort on the safe production and disposal or EoL of fluoropolymers and PFPEs provides – if successful – a general solution for the variety of applications which would benefit from a future safe use of pPFAS (including applications urgently needed for a transition to a sustainable economy).

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