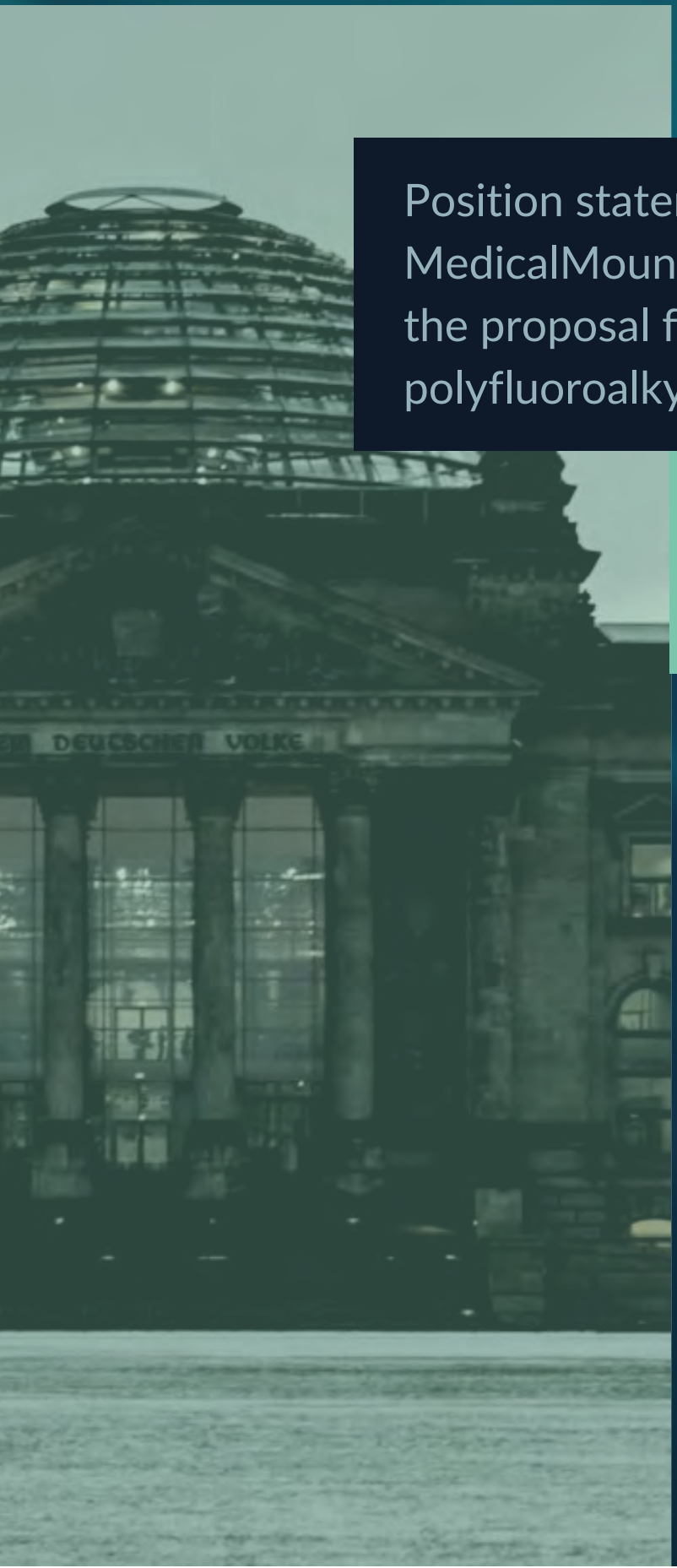
MedicalMountains

Position statement by MedicalMountains GmbH on the proposal for a restriction on per- and polyfluoroalkyl substances (PFASs)



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POSITION STATEMENT

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1. Summary

Catheter tubes getting stuck in the ureter.
Coronary guide wires becoming twisted in arteries.
People die far too early because stents are no longer available.
Cardiac pacemakers and dialysis machines are a thing of the past.
Operating rooms with no modern anesthesia devices or respirators.
No way of carrying out endoscopic colorectal cancer screenings.
Having to open up the abdomen as much as possible to perform procedures on the gall bladder or appendix.
No ultrasound, magnetic resonance imaging and computer tomography for diagnostics.
Neurostimulation implants used to treat epilepsy, Parkinson's or Alzheimer's disease are disappearing.

This is not the screenplay for a crisis movie. This is a scenario for the future. A future of medical technology without per- and polyfluoroalkyl substances (PFASs). A future in which clinical interventions are set back decades. A future in which **the well-being of the patient is no longer the main focus**. A future of anachronistic patient care[1]. But it doesn't have to be that way!

Do you want to accept treatment procedures and implants of inferior quality for yourself or your families? Although the - still - existing state of the art is proven to be safe? At this time, there is a need for political will to ensure that fluoropolymers and fluoroelastomers in particular can be used without restrictions in areas where they offer an unquestionable benefit to society. In medical technology, for the well-being of patients, but also in other socioeconomically relevant areas of industry.

This position statement from MedicalMountains GmbH provides information on the background and effects of the current PFAS restriction process proposed by the European Chemicals Agency (ECHA). The process is connected to the "Chemicals Strategy for Sustainability Towards a Toxic-Free Environment"[2] published in October 2020. The aim is to provide better protection for people and the environment while strengthening the competitiveness of industry within the European Union. We are firmly committed to these objectives.

More than that, we see it as our duty to intervene with all the means at our disposal when the protection of people, patients and Europe as a center of industry is at risk. That is precisely what we fear will happen if the ECHA proposal to restrict PFASs takes effect in its current form.

It is absolutely right to impose strict regulations or even total bans on the use of unsafe low-molecular-weight PFASs, and some have already been initiated[3]. However, it is equally important to take a nuanced view of this highly complex issue. The "Broad Restriction Proposal" does not differentiate between PFASs that are actually hazardous and those that are

[1] see Impacts on medical technology
[2] see Background
[3] see Chronology of the restriction

not. The individual risk assessment and appraisal of "use cases" has been dropped[4]. The only binding element is longevity or persistence. This attribute should not in itself be seen as good or bad, however; it is simply a neutral statement relating to time. It takes a lot of energy to break the strong bond between carbon and fluorine. On the one hand, this creates a unique biocompatibility, low friction, thermal and chemical stability and dielectric strength, all properties that are essential in safe medical devices for patients[5]. On the other hand, the compounds cannot be broken down under natural conditions, either biotically (with bacteria) or abiotically (with light, heat). However, non-implantable medical devices follow a tight product flow (manufacturer – user – disposal company) that virtually eliminates the possibility of any uncontrolled discharge of PFAS-containing materials into the environment[6].

Rather than banning tens of thousands of substances in one go, what is required is a nuanced, risk-based approach. Fluoropolymers play only a minor role in emissions and, moreover, are disposed of safely.

In this context, it is important to know that: Medical technology is already one of the most strictly regulated sectors, with elaborate approval and control procedures. This includes a requirement to prove the biocompatibility of any medical device that comes into contact with the body. In the case of fluoropolymers, this is required when they are used as materials (such as in tubes) or as coatings (such as in catheters or guide wires). There have been a number of tests showing that they pose **no danger to humans**. The safety of the products has been confirmed by years of use and large quantities of clinical data, for example from the use of PFAS-containing implants. Finally, Regulation (EU) 2017/745 on medical devices (Medical Device Regulation, MDR) sets a very high bar for CMR (carcinogenic, mutagenic or reprotoxic) substances.

PFASs are not all carcinogenic, despite frequent reports to the contrary. Fluoropolymers in particular can be implanted without posing any risk because they are chemically and physically very different from unsafe PFASs[7]. They meet the criteria for "polymers of low concern". This understanding is already widely accepted in places such as Australia and the United Kingdom[8].

Fluoropolymers "of low concern," which present no potential risk to humans or the environment and are essential for medical technology, should therefore be immediately excluded from the restriction process.

There are currently no known alternative materials that could combine all the properties of fluoropolymers and fluoroelastomers[9]. This means that, even with the longest possible derogation in terms of time, a general PFAS ban would have a substantial impact on crucial areas.

Below is a non-exhaustive list of some products and applications that would be affected because their key (therapeutic) functions are based on fluoropolymers:

[4] see Abandonment of "essential use" and specific risk assessment
[5] see PFASs in medical technology
[6] see Emissions and emission prevention
[7] see Fluoropolymers "of low concern"
[8] see Assessments from outside the EU
[9] see Lack of alternatives

- Anesthesia, respiration and respirator systems
- Incubators for newborn infants
- Cardiopulmonary bypass machines
- Syringe drivers
- Minimally invasive surgery and endoscopy
- Electrosurgery
- Surgical instruments and suture material
- Pacemakers, guide wires, stents, joints and other implants
- Cardiac catheters and other catheters
- Many electronic devices, including functional diagnostics, computers, pumps, bulbs
- Flame-retardant cables, tubes and seals
- CT, MRI, ultrasound
- Orthoses
- Dialysis applications
- Analytical systems such as chromatography (e.g. tumor marker detection)
- Vacuum processes

A general restriction on PFASs would have serious consequences for the well-being of patients all over the world. It would make it impossible to maintain the current standard of care in areas like minimally invasive surgery. It would also prevent innovations based on PFASs.

In Europe, certain industries are counting on a derogation. However, this has not been fully thought through and creates new problems: The production and availability of high-performance polymers in Europe must also remain guaranteed[10]. It is therefore important to consider and allow individual emulsifiers used for manufacturing fluoropolymers. Uniform emission standards across Europe make **safe production possible**! Unfortunately, because of the uncertain outlook, some companies have already shifted their production to non-EU countries. This goes against the EU's current efforts to keep supply chains for future technologies in Europe. Fluoropolymers are essential for medical technology as well as chip production and green hydrogen production. Without them, the targets set out in the European Chips Act and the "Green Deal" would be unachievable and all the efforts made would have been for nothing.

The production and availability of high-performance polymers in Europe must be guaranteed. Otherwise, we run the risk of creating new dependences, particularly on Asian manufacturers. What is more, we risk losing Europe's position as a high-tech location. It would make European resilience impossible.

In view of the expected impacts, as a society we now need to have a discussion: What are we prepared to give up, and what do we want to gain from doing so? Medical devices will not improve if we get rid of all PFASs. We need **nuanced consideration of harmless fluoropolymers in the areas where they are truly important**. A six-month public consultation is not enough. Nor can the final decision be left to the authorities,

[10] see Impacts on medical technology

committees and European Commission to make on their own. Democratically elected bodies urgently need to be involved.

The pros and cons need to be weighed up in the public discourse.
If a nuanced, pragmatic approach is adopted, the various legitimate interests can be reconciled: protection of the environment and health, protection of patients, innovation and the leading industries of Europe.

In summary, our demands with regard to ECHA's restriction proposal are as follows:

- **The role of medical technology for individuals and society must be acknowledged more strongly and separated from "consumer products".**

- **Instead of a general restriction, PFAS should be evaluated according to a risk-based approach.**

- **Fluoropolymers that do not pose a risk to humans or the environment and are essential for patient care must be exempted and their use allowed beyond the 12-year time horizon.**

- **In the impact assessment, the serious consequences of a PFAS ban for patient care and safety must be considered, both currently and prospectively. Neither can the current standard of care be maintained, nor can innovations based on PFAS be developed.**

- **The impact of a PFAS ban on all of Europe as a business location must be considered if the EU wants to increase its resilience and reduce dependencies on non-European manufacturers and suppliers.**

- **Approaches by other countries, particularly with regard to fluoropolymers, should be considered as pragmatic options for action by the EU.**

Tuttlingen, June 2023.

2. Background

Essentially, PFASs are organic compounds with carbon chains of different lengths in which hydrogen atoms are replaced with fluorine atoms: either completely (perfluorinated) or partially (polyfluorinated). As defined by the OECD[11], the category includes virtually all substances that contain at least one fully fluorinated methyl group (-CF3) or methylene group (-CF2-) with no additional hydrogen, chlorine, bromine or iodine atoms. This group of substances contains more than 10,000 compounds. They are divided into long-chain and short-chain PFASs. Examples of short-chain PFASs are carboxylic and sulfonic acids (and the associated precursor compounds) with fewer than seven or six perfluorinated carbon atoms respectively[12]. They are excreted more quickly into human and mammalian organisms after absorption than those with longer carbon chains. Numerous substances called precursors are also used, such as PFASs interrupted by ether linkages. These precursors can be converted into persistent PFASs, among other things[13]. The most well known and most thoroughly researched of these are PFOS (perfluorooctane sulfonic acid or perfluorooctane sulfonate) and PFOA (perfluorooctanoic acid).

These industrial chemicals have been in use in many areas since the 1950s. These include or have included:

- Automotive industry
- Building materials
- Chemical industry
- Electronics and semiconductor industry
- Fire extinguishing foams
- Household products
- Laboratory technology
- Aerospace industry
- Medical technology
- Pesticides
- Pharmaceutical technology
- Textile impregnation
- Packaging
- Waxes/lubricants
- Detergents

A detailed compilation of where and why PFASs are used can be found as Annex I. The particular properties that PFASs have are crucial: they are water-, grease- and dirt-repellent and chemically and thermally stable. It takes a lot of energy to break the strong bond between carbon and fluorine. Under natural environmental conditions, neither biotic processes (using bacteria) nor abiotic processes (using water, air, light) help to break down PFASs. Once the substances enter into the environment they disperse, for example in water and sediment, but

[11] OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris.
[12] https://www.umweltbundesamt.de/themen/chemikalien/chemikalien-reach/stoffgruppen/per-polyfluorierte-chemikalien-pfc#wo-komme-ich-mit-pfc-in-beruhrung
[13] https://www.bfr.bund.de/de/fragen_und_antworten_zu_per__und_polyfluorierten_alkylsubstanzen__pfas_-242936.html

do not degrade (they are persistent). That is why they are described as “forever chemicals.” Some, especially long-chain PFASs, accumulate in organisms and along the food chain (they are bioaccumulating). Although short-chain PFASs are eliminated more quickly, they are very mobile. They are not retained in the ground and therefore quickly enter the ground water. Because of their low adsorption potential, short-chain PFASs are difficult to remove from the water during treatment. Short-chain PFASs are also taken up and stored by plants, thereby entering the food cycle and ultimately the human body.

In humans, PFASs like PFOA bind to proteins in the blood, liver and kidneys. The known health effects include an impaired immune response to vaccines and increased cholesterol levels. In 2020, the European Food Safety Authority (EFSA) set a new threshold for the most important PFASs accumulating in the human body. It is set at 4.4 nanograms per kilogram of body weight per week[14]. Animal studies have shown that many PFASs damage the liver and are developmentally toxic. However, they do not directly alter genetic material, and in animal studies they do not have a carcinogenic effect until they reach doses above those ingested by humans through food[15]. It is particularly important to assess transfer from mother to child during pregnancy and breastfeeding. The toxicological data on short-chain PFASs is limited[16].

[14] EFSA Panel on Contaminants in the Food Chain (2020), Scientific Opinion on the risk to human health related to the presence of perfluoroalkyl substances in food. EFSA Journal 2020;18(9):6223, 391pp. https://doi.org/10.2903/j.efsa.2020.6223

[15] German Federal Institute for Risk Assessment (2020), Frequently asked questions about per- and polyfluoroalkyl substances (PFAS). https://www.bfr.bund.de/de/fragen_und_antworten_zu_per__und_polyfluorierten_alkylsubstanzen__pfas_-242936.html

[16] Ibid.

3. PFASs in medical technology

PFASs have been used in medical technology for some time. The special properties of the fluoropolymers are decisive for the various areas of application[17]:

- Chemically inert: PTFE (see below) does not react with the chemicals commonly used for cleaning and reprocessing in hospitals; it is extremely resistant to all bases, many acids, alcohols, ketones, benzines etc.
- Thermally stable: PTFE has a melting point of 327°C, which means it can easily be hot-steam sterilized.
- Thermoplastic: Fluoropolymers can be adapted or attached to complex geometries.
- High dielectric strength: 20 kV/mm; high tracking resistance (the insulation resistance of the surface, particularly under the influence of moisture and impurities).
- Biocompatible: Fluoropolymers pass biocompatibility tests according to the applicable tests in the DIN EN ISO 10993 series.
- Biostability: The material maintains its function over the entire period of use (implants), even in aggressive body environments.
- No carcinogenic, mutagenic or reproductive toxic properties (non-toxic).
- Very low coefficient of friction: no stick-slip effects; the static friction is the same magnitude as the sliding friction, which means that the transition from still to moving happens without jerking.
- Excellent tribological properties: expanded polytetrafluorethylene (ePTFE) can be stretched plastically by 200 to 300% (e.g. for stents).

The following table shows typical fluoropolymers and their applications. The list does not claim to be exhaustive:

PVDF (Kynar®, Solef®); polyvinylidene fluoride	A biocompatible polymer with piezoelectric, ferroelectric and pyroelectric properties. Its hydrophobic surface means that biofilms cannot form on these materials. This is an important requirement for their use as materials. High resistance to gamma radiation.	
Areas of application in medical technology include	As a coating:	- Packaging - Tubes and seals
	As a material:	- Membranes in cochlear implants - Handles, connectors

[17] according to Banghard, Michael (2023), PFAS – Lebensrettende Eigenschaften der Fluorpolymere [Life-saving properties of fluoropolymers] (presentation)

PTFE/PFA (Teflon®) Perfluoroalkoxy, polytetrafluoroethylene	A biocompatible polymer with excellent anti-friction properties and chemical inertness.	
Areas of application in medical technology include	As a coating:	- Guide wires - Catheters - Stone catcher devices - Polypectomy loops - Anti-adhesion coating - Handles - Specular components - Obturator rods
	As a material:	- Multi-lumen catheters - Ultra-pure transfer pipes - Insertion instruments - Working channels in flexible endoscopes - Seals (e.g. luer lock) - Shrink tubes - Insulation for wires, cables and complex electronic components - Stents, prostheses - Filters

ECTFE (HALAR®); Ethylene chlorotrifluoroethylene	A biocompatible polymer with high dielectric strength (high resistance combined with high application temperature).	
Areas of application in medical technology include	As a coating:	- Electrosurgery/monopolar and bipolar high-frequency surgery - Biopsy forceps with high-frequency connection - Coagulation probes - Papillotomes for use in high-frequency surgery

The following PFASs are also used[18]:

- FEP (tetrafluoroethylene hexafluoropropylene polymer)
- FKM (fluorine rubber)
- PBSF (perfluoro-1-butanesulfonyl fluoride)
- PCTFE (polychlorotrifluoroethylene)
- MFA (methyl fluoroacetate)
- mPTFE (modified PTFE)

[18] Banghard, Michael (2023), PFAS – Lebensrettende Eigenschaften der Fluorpolymere [Life-saving properties of fluoropolymers] (presentation) supplemented with ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs), table A.103

Other areas of application for PFASs in medical technology include[19]:

- Implants, Neuroimplants
- Wound treatment products
- Inhalers (e.g. as a coating and propellant)
- Technical liquids for cleaning and heat conduction
- Gases (sterilization, anesthesia)
- Contact lenses, ophthalmic lenses
- Packaging
- Orthoses

It should also be noted that **PFASs are found not only in products, but also in production processes across all sectors**. PFASs are found in raw materials, auxiliary materials and working materials in particular, as well as in lubricators, insulators, fixings, seals, molds, mounting aids or tubes.

[19] ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs), section 1.3.1

4. Position statement by MedicalMountains GmbH

PFASs have **unique properties**. These include temperature resistance and dielectric strength, excellent autoclavability, chemical resistance, anti-friction properties and good biocompatibility. The use of PFASs **contributes significantly to advanced and safe patient treatment** in many areas of use. Here and in other industrial sectors, the immense stability of the substances brings indisputable benefits. In nature, this causes problems when critical PFASs accumulate and enter the human body. Until now, the benefits and risks have been weighed against each other on a case-by-case basis. Now there are plans to restrict an entire group of substances. This is understandable given that, in the past, banned substances have promptly been replaced with equally hazardous but unregulated compounds, contrary to the actual objective of the ban. The reduction of overall emissions and further regulation of chemicals handling are therefore unquestionably welcome. The objections are not directed at the dossier as a whole. However, the current process means that substances that can be used safely will also be banned. These points are set out below.

4.1. The role of medical technology in the restriction proposal

An attempt has been made in the dossier to establish as comprehensive an overview as possible of the various areas of application of PFASs and to link the restriction to matters such as emission savings, alternatives and (follow-on) costs. Following a consideration of the pros and cons, crop protection products, biocides and medicinal products were excluded from the rest of the process.

- The proposal highlights that the derogation relates to active substances. PFASs as coatings or in tubes, for example, cannot be described as “active substances” in a narrow sense. These types of medical device nonetheless rely heavily on the use of PFASs for their therapeutic properties, safety and performance. This makes the substances essential for their effectiveness. From this point of view, the derogation could also be applied to medical devices.

- What crop protection products, biocide products and medicinal products have in common is that they are all designed to target people and society directly, to provide safe food, to protect health, and to cure and prevent diseases. Those last two points also apply to medical devices. In the proposed restriction, however, they are just one area of application among many. It must once again be remembered that these are not consumer products or other industrial products. We depend on advanced, safe medical devices for so much more.

- The restriction proposal also notes that the use of crop protection products, biocide products and medicinal products is subject to special rules in the EU and that assessments and approval procedures are carried out by notified bodies with specific expertise and experience. The same is true of medical technology. The industry is highly regulated at both the national and the European level. Biocompatibility must be

proven in cases of contact with the body; carcinogenic, mutagenic and reprotoxic substances and substances with endocrine properties must not make up more than 0.1% of the total mass. Derogations must be based on scientific evidence and are subject to strict examination.

➔ **The role of medical technology for humanity and society should be seen as even more important than that of crop protection products, biocide products and medicinal products, and it should be even more clearly differentiated from other industries.**

4.2. Abandonment of "essential use" and specific risk assessment

In the past, products and applications have been examined to establish "essential use." This covers products that are necessary for health or to maintain the safety and function of society or for which there are no technically and economically viable alternatives. The main objective of the approval procedure under REACH is to replace substances that have particularly concerning properties in the near term if it is technically feasible and economically viable to do so. Users of these substances may continue to use them over a certain period of time if they show that they can handle the substance without risk, or at least with a low level of risk, and there are no comparable alternatives[20]. A general restriction on 10,000 substances represents a departure from this principle. What is more, the burden of proof as to why the use of PFASs is considered essential for society now lies with manufacturers and users.

The mention in REACH of "substances that have particularly concerning properties" above relates to ecological risk criteria (including endocrine substances) as well as effects on human health (including CMR substances). Previous restriction processes have targeted precisely these types of substance for removal from circulation or aimed to impose strict regulations on handling them, as has already been done with a number of PFASs. What is happening now, on the other hand, is that **restrictions are being imposed on substances even if their effects on humans and nature can be controlled and there are still no alternatives in sight**. No specific risk is being investigated.

➔ **Instead of a general restriction, PFASs should be evaluated using a risk-based approach and their "essential use" should be assessed.**

4.3. Fluoropolymers "of low concern"

There are different grades of PFASs. The properties of short-chain PFASs are different from those of long-chain fluoropolymers. Although they match the structural definition of a PFAS, they have very different physical, chemical, ecological and toxicological properties compared to other substances. Fluoropolymers make up their own family within the group of substances.

[20] German Federal Institute for Occupational Safety and Health (BAuA) (2021), REACH: Info – Beschränkungen und Verbote unter REACH [REACH: Info – Restrictions and bans under REACH] (1st edition)

The study by Henry et al.[21] shows, among other things, that fluoropolymers are thermally, chemically, photochemically, hydrolytically, oxidatively and biologically stable. They contain practically no monomer and oligomer residues and have minimal or no leachable components. Fluoropolymers are practically insoluble in water and are not transported over long distances. With a molecular weight of over 100,000 Da, fluoropolymers cannot penetrate the cell membrane. Fluoropolymers are not bioaccumulative, as demonstrated by toxicological studies of PTFE (acute and subchronic systemic toxicity, irritation, sensitization, local toxicity upon implantation, cytotoxicity, in vitro and in vivo genotoxicity, hemolysis, complement activation and thrombogenicity). Clinical studies on patients who have received permanently implanted cardiovascular medical devices containing PTFE show no chronic toxicity or carcinogenicity. The conclusion reached by Henry et al. (2018) is that fluoropolymers meet widely accepted assessment criteria for classification as “polymers of low concern” (PLCs) and that they are significantly different from other polymer and non-polymer PFASs and should therefore be considered separately for risk assessment or regulatory purposes. The OECD criteria for “fluoropolymers of low concern”[22] include high molecular mass, low persistence, non-significant bioaccumulation, low toxicity and negligible exposure. The substances investigated in detail were PTFE, ETFE (ethylene tetrafluoroethylene), FEP (fluorinated ethylene propylene) and PFA (perfluoroalkoxy). Korzeniowski et al.[23] have examined several fluoroplastics, fluoroelastomers and special fluoroplastics in more detail and have set out criteria for “polymers of low concern” in each case:

- Composition
- Molecular weight
- Ionic character
- Reactive functional groups
- Low-molecular-weight leachable components
- Particle size
- Structural composition
- Elemental composition
- Water and lipid solubility
- Stability
- Abiotic stability
- Biotic stability
- Thermal stability

All the substances that were examined met the requirements for classification as “polymers of low concern”. Including the four fluoropolymers from the previous study by Henry et al., a total of 18 fluoropolymers can thus be rated as "polymers of low concern."

[21] Barbara J Henry et al. (2018), A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers; Integrated Environmental Assessment and Management; Volume 14, Issue 3.
[22] OECD Environment, Health and Safety Publication (2008), Data analyses of the identification of the correlations between polymer characteristics and potential for health or ecotoxicological concern.
[23] Stephen H. Korzeniowski et al. (2022), A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers; Integrated Environmental Assessment and Management—Volume 19, Number 2.

- **PTFE**
- **ETFE** (ethylene tetrafluoroethylene)
- **FEP** (fluorinated ethylene propylene)
- **PFA** (perfluoroalkoxy)
- **PVDF** (polyvinylidene fluoride)
- **PVDF-HFP copolymer** (vinylidene fluoride hexafluoropropylene copolymer)
- **ECTFE** (ethylene chlorotrifluoroethylene copolymer)
- **ECTFE** (ethylene chlorotrifluoroethylene hexafluoroisobutylene terpolymer)
- **PCTFE** (polychlorotrifluoroethylene)
- **FEVE** (fluoroethylene vinyl ether copolymer)
- **EFEP** (1-propene, 1,1,2,3,3,3-hexafluoro-, polymer with ethylene and 1,1,2,2-tetrafluoroethylene)
- **CPT** (1,1,1,2,2,3,3-heptafluoro-3-[(trifluoroethenyl)oxy]propane polymer with chlorotrifluoroethylene and tetrafluoroethylene)
- **THV** (1-propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethylene and tetrafluoroethylene)
- **Perfluoro(alkenyl vinyl)ether polymer**
- **Sodium or potassium salts of perfluorosulfonic acid/TFE copolymer or perfluorocarboxylic acid/TFE copolymer**
- **FEPM** (tetrafluoroethylene propylene polymer)
- **FKM** (1-propene, 1,1,2,3,3,3-hexafluoro-, polymer with 1,1-difluoroethylene copolymer and terpolymers)
- **FFKM** (tetrafluoroethylene trifluoromethyl trifluorovinyl ether copolymer)

These are chemically stable, non-toxic, non-bioavailable, non-water-soluble and non-mobile materials that do not have any significant effects on the environment or human health. There is therefore an urgent need to proceed with the restriction process using scientifically based evidence and to remove families of substances that do not have the potential to pose risks to humans or the environment. PTFE has been particularly well studied. It can be considered neither carcinogenic[24] nor genotoxic[25] or toxic for reproduction[26]. Likewise, no effects on the immune system are known[27]. Skin exposure to PTFE has also been considered safe for a long time. This is evident, for example, in the use of PTFE needles for intravenous access[28]. In attempts to use PTFE as a filler for dietary products, it was found that the material cannot be absorbed through the digestive tract[29]. For particle sizes larger than 20 µm, the insoluble polymer cannot enter the bloodstream with reasonable certainty. It is therefore imperative that the restriction process be based on scientific evidence and exclude substance families

[24] Radulovic LL, Wojcinski ZW (2014), PTFE (Polytetrafluoroethylenel Teflon®). In: Wexler P, ed. Encyclopedia of Toxicology. 3rd ed. Amsterdam, Netherlands: Elsevier; 2014:1133-1136.
[25] Ibid.
[26] Davis et al. (1993), Effect of catheter composition on sperm quality. J Androl. 1993;14:66-69.
[27] Kim et al. (2013), Management of complicated multirecurrent pterygia using multimicroporous expanded polytetrafluoroethylene. Br J Ophthalmol. 2013;97:694-700.
[28] Smith et al. (1993), A comparison of winged steel needles and Teflon cannulas in maintaining intravenous access during gastrointestinal endoscopy. Gastrointest Endosc. 1993;39(1):33-36.
[29] Naftalovich et al. (2016), Polytetrafluoroethylene Ingestion as a Way to Increase Food Volume and Hence Satiety Without Increasing Calorie Content, Journal of Diabetes Science and Technology 2016, Vol. 10(4) 971 – 976

that do not pose a risk to humans or the environment. These are substance families that **have been used safely** in medical technology **for years**.

In the meantime, the disposal of fluoropolymers has also been scientifically investigated[30]. To show that PTFE can be converted almost completely and in order to establish the possible formation of low-molecular-weight PFASs, the incineration of PTFE was investigated under typical waste disposal conditions at the BRENDA pilot plant at the Karlsruhe Institute of Technology (KIT). Within the methodological limits, no statistically significant indications were found that any of the detected PFASs were produced in the incineration of PTFE. For this reason, the municipal incineration of PTFE using the best available technologies is not a significant source of the PFASs investigated and should be considered an acceptable form of waste treatment.

➔ **Fluoropolymers "of low concern," which present no potential risk to humans or the environment and are essential for medical technology, should be excluded from the restriction process.**

4.4. Lack of alternatives

The restriction proposal considers the availability of technically and economically feasible alternatives in order to determine derogations. As set out in the dossier, **there are currently no comparable substitutes for PFASs** in medical devices (except for gases) in sight, and it is highly probable that none will be found in the future.

PFASs combine a number of properties that will also need to be found in any alternatives. It may be that a substance behaves similarly well when it comes to biocompatibility, for example, but whether it also has the same anti-friction properties is another matter. The strong binding capacity of fluorine and carbon atoms cannot be transferred to just any given molecules or polymers. The dossier also mentions this. Replacing just one C-F bond with a C-H bond results in a material that is stiffer and less smooth. There are conceivable alternatives for some processes, but the higher coefficients of friction will make them more painful for the patient[31].

Here are three examples of alternative materials considered and their exclusion criteria for minimally invasive surgery:[32]:

- PEEK: non-flexible, poorer friction properties.
- Parylene: only limited adhesion to surfaces. Poorer adhesion means that it is only partially suitable for cleaning and reprocessing cycles. Highly hydrophobic, does not slide.
- High-density polyethylene (HDPE): high dielectric strength, poor friction properties, not thermally stable.

[30] Aleksandrov et al. (2019), Waste incineration of polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and poly-fluorinated alkyl substances (PFAS) in flue gas, Chemosphere, Vol. 226.
[31] ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs), section E.2.9.2.1.
[32] Banghard, Michael (2023), PFAS – Lebensrettende Eigenschaften der Fluorpolymere [Life-saving properties of fluoropolymers] (presentation)

Overall, no known polymers have been found that have the same or similar properties and do not adversely affect the well-being of the patient. Substitutes can only be used in individual cases where they have a particular required characteristic and the other properties can be disregarded. This means that substituting PTFE tubes with silicone ones is certainly worth considering if the area of application and risk management allow. However, the vast majority of PFASs cannot be substituted in this way.

In this context, **a 12-year derogation seems far too short**. Research and development projects first need to be initiated and appropriate lines of funding opened. It is impossible to predict what the results of these will be. They might not identify any substances at all with properties equivalent to those of PFASs. They might find substances that could be used in other industrial areas, but not in medical technology because of the high patient protection requirements. They may lead to the development of a few substitutes for very specific use cases. Overall, however, the level of uncertainty is extremely high. Although, as mentioned above, medical devices have a special role in the restriction procedure, it is also clear that: The manufacturers are companies that think economically. Strategic decisions must be made early given the length of the processes involved. Assuming that, over time, a viable PFAS alternative is found, it is likely that companies would not have enough time left to incorporate that substance into their own development processes, to obtain authorization for new or modified products and, finally, to market those products. All the safety criteria (biocompatibility, aging, sterilization, etc.) would need to be verified from scratch again for those products. At best, there would be a gap between the end of the derogation period and the (re-)authorization of a product. At worst, that point might never be reached, because the uncertainty combined with the expected high financial cost might lead companies to decide to discontinue the product or product line. Another possible consequence is that businesses might see this as an existential threat and stop operating entirely. A dramatic consequence for ensuring patient care, as we are currently seeing due to the increased requirements of Regulation (EU) 2017/745 Medical Device Regulation (MDR). Another realistic consequence is that companies see their existence threatened and cease operations completely.

The restriction dossier focuses in particular on persistence, or the long-lasting nature of PFASs. It should be assumed that any alternatives will share this property. This makes it all the more unlikely that it will be possible to use them.

A broader view is needed in this context. A restriction will affect medical technology directly, but also indirectly. PFASs can be found in auxiliary materials and working materials (such as lubricants) or in production system components (such as seals and tubes). PFASs are used in the production of semiconductors, which in turn are used in active medical devices. In those areas too, fundamental changes are expected that will impact on companies: they will need to invest in new assets and systems, which they will then need to integrate and validate in compliance with the regulatory framework.

➔ **In view of the high degree of uncertainty as to whether alternative substances with comparable properties can be found at all, the use of non-critical, essential PFASs such as fluoropolymers must continue to be authorized beyond the 12-year period. Manufacturers urgently need clarity and planning certainty in this area.**

4.5. Impacts on medical technology

A medical technology world without PFASs would have serious implications for patient care and safety. Life-sustaining interventions could no longer be performed due to a lack of instruments or products that also rely on fluoropolymers. **For example, surgeons revert to methods of decades past.** Instead of using the least possible trauma, standard procedures such as those on the gall bladder or appendix must again be performed with **opening of the abdomen as much as possible**. Catheters or guide wires without the usual sliding properties cause far more pain and, above all, a dramatically increased risk during use. Endoscopic colonoscopy is no longer available. Anesthesia and ventilation devices as we know them today are a thing of the past. High-performance polymers are no longer available for ultrasound, magnetic resonance imaging or computer tomography. Implants for neurostimulation, for the treatment of epilepsy, Parkinson's or Alzheimer's disease, are disappearing.

PFASs have played an important part in making processes safer (e.g. thanks to their excellent autoclavability) and increasingly gentle (e.g. thanks to the improved anti-friction properties of guide wires) or even in allowing them to exist at all to the extent that they do now (e.g. thanks to biopsy forceps with high-frequency connections). Not only that, but PFASs have also paved the way for minimally invasive surgery. These methods result in less trauma for the patients from the surgery, significantly shortening reconvalescence times. This reduces the length of postoperative stay in hospitals. Without PFASs, functional properties will be lost, making it necessary to return to obsolete methods or preventing operations from happening entirely. The following minimally invasive procedures would be among those affected[33]:

- Appendectomy (removal of the appendix)
- Hemicolectomy (removal of parts of the intestine)
- Splenectomy (removal of the spleen)
- Nephrectomy (removal of a kidney)
- Treatment of endometriosis (removal of ectopic uterine lining)
- Hysterectomy (removal of the uterus)
- Prostatectomy (removal of the prostate)

The use of PFASs in medical devices is therefore established and “state of the art.” This means there is evidence that the substances used do not entail any risk to patients. This aspect plays almost no part in the proposed restriction. The focus here is on emissions – discharge into the environment. Medical devices will not improve if we get rid of PFASs – on the contrary. At the same time, there is a requirement (e.g. from Regulation (EU) 2017/745 on medical devices, EU MDR) to conduct a risk/benefit assessment to reduce the patient risk to a minimum. This results in a contradiction if the use of PFASs is the only option, for example in order to achieve the highest possible cleanliness and physical safety during use.

The medical technology sector is dominated by small and medium-sized companies, which are currently already burdened by regulatory requirements, in particular regulation (EU) 2017/745 on medical devices (EU-MDR). In recent years, several medical devices have been taken off

[33] Banghard, Michael (2023), PFAS – Lebensrettende Eigenschaften der Fluorpolymere [Life-saving properties of fluoropolymers] (presentation)

the market as the cost of documentation, evidence and finally (re-)approvals is no longer proportionate to the expected profits. If a procedure needs to be re-run, for example because of a significant change, even supposedly “simple” products will end up costing six-figure sums. These are often, though not always, niche products with very narrow areas of application for rare operations. The next wave of discontinuations is building up now with this newly initiated restriction process. The already limited availability of medical devices is threatening to get even worse. In view of this, the restriction procedure would exacerbate existing problems on the one hand and create new ones on the other. Existing problems exist because costs have risen significantly in recent years (including raw material and energy prices, fees for laboratories and notified bodies) and medical technology is also suffering from a shortage of qualified personnel, making it very difficult to recruit or finance additional staff. New problems arise because these already limited resources are tied up for an unforeseeable period of time and put under additional burden. A typical sequence would look like this: First, an inventory is made of where PFASs are used in the company. Then the search for alternatives begins - where are substitutes available, where not? At best, a substitute is found. A new development is started for existing products. Safety and performance requirements must be proven, and the safety of the substitutes (including biocompatibility) must be demonstrated. Approvals are renewed not only in the EU, but worldwide. Capacities are used solely to keep existing portfolios with modified materials on the market. Research and development are focused on PFASs. Fundamental new developments and innovative breakthroughs in other areas are not to be expected. These are precisely the consequences that the implementation of the EU MDR has already brought along. Not only in Germany, but throughout the EU. The next wave is now building up with the restriction procedure. Particularly affected, but not exclusively, would be products with a narrow field of application for rare interventions, i.e. niche products. The MDR-induced restricted availability would be further exacerbated.

However, the scenario described represents the best case. The "worst case" goes much further. The effort can become too high for many small and medium-sized companies and, in view of the already tense situation, can be the final deciding factor to cease operations completely. This is especially true if no alternatives can be found and the previous business model was based on fluoropolymers. **The medical technology landscape will continue to thin out**. The backbone of the industry, the medium-sized companies, is in danger of collapsing. Market shares of European manufacturers will shrink even more, and a European resilience strategy would be doomed to failure.

Another factor threatens to worsen the shortage: Although there are temporary exemption regulations for medical technology, a guaranteed availability of PFASs for the granted period is more than questionable. The first manufacturers of PFASs are withdrawing from the market, reducing production capacity or discontinuing it completely. Supply chains are breaking down. Or to put it another way: even if PFASs were allowed to be used in certain niche industries for another 12 years, it is questionable whether they will still be available to medical technology manufacturers at all.

In this context, the supply chains need to be more closely examined. Not all suppliers work solely for medical technology. Depending on requirements and design, certain components or coatings, for example, can be used in a whole range of industries. This implies that if only certain areas are excluded from the restriction, there is hardly anything to be gained. If, at the same time, a coating company runs out of fluoropolymers, this will have a direct impact on

those niches that are likely to continue using PFASs - in medical technology, with the consequences mentioned above. This would also make it increasingly difficult to obtain or be allowed to use replacement and consumable parts. Instruments and devices that are actually functioning could no longer be maintained or repaired. Against the background of sustainable goods cycles and a discussed "right to repair", this would be counterproductive.

This is another reason why an exemption for fluoropolymers must be thought of in larger scale. **Without supply chains that continue to function, socially relevant industries such as medical technology will not be able to survive**. Those PFASs that are absolutely necessary for the production of polymers (emulsifiers, etc.) must not be ignored. Banning these and other starting materials would be de facto equivalent to banning the production of fluoropolymers. The fact that emissions-neutral production is possible is shown by the example of Chemours: the company is investing 75 million euros in its plant in Dordrecht (Netherlands) in order to reduce PFAS emissions by 99 percent by 2030 compared with the base year 2017[34].

Above all, it is important to keep and strengthen these supply chains in the EU. In recent years, it has become painfully clear how dependent the European family of states is on non-European suppliers. For example, the European Chips Act is a direct result of this awareness. In 2023, the European Commission published a study on the extent to which key industries have unrestricted access to important raw materials[35]. Fluoropolymers are among the processed materials mentioned, for example in robotics and chip manufacturing. One conclusion is that the EU is heavily dependent on third countries, and China in particular, at various stages of the value chain. A blanket PFASs ban runs counter to all well-intentioned efforts. Instead of bringing value creation back to Europe, **dependence on non-European manufacturers is growing**.

Annex F of the restriction proposal deals with “reviews of uncertainties,” i.e. the uncertainty associated with the forecasts made. A definite increase in baseline manufacture and emissions is assumed, justified in part by the large number of patent applications associated with PFASs[36]. There are two conclusions that can be drawn from this: PFASs are high-tech substances with potential for innovation. A PFAS restriction takes away that potential, not just today but also in the future. Further development or redevelopment of medical devices based on PFASs will stop. Patients will be denied access to potentially better, safer and gentler surgeries. The dossier does also point out that the industry could secure new market shares as a driver of innovation for PFAS-free (medical) devices, but this is highly unlikely under the conditions described above. This is ultimately also confirmed in Annex F. It contains two points associated with a high level of uncertainty: the availability of alternatives and the introduction of those alternatives[37].

[34] https://www.chemours.com/en/pfas-advocacy/responsible-manufacturing
[35] JRC Science for Policy Report (2023), Supply chain analysis and material demand forecast in strategic technologies and sectors in the EU – A foresight study. https://single-market-economy.ec.europa.eu/publications/supply-chain-analysis-and-material-demand-forecast-strategic-technologies-and-sectors-eu-foresight_en
[36] ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs), table F.2
[37] ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs), section F.4

As in other areas, medical technology manufacturers will need to ensure in the future that maximum PFAS levels in materials are not exceeded. Many PFASs do not currently have CAS numbers. As such, they cannot be declared. It is not clear what needs to be searched for in material batches or what needs to be analyzed. Furthermore, some levels fall within ranges that are difficult to detect with certainty. Those levels can be as low as 25 ppb, or 0.025 milligrams per kilogram.

➔ **A restriction on PFASs will have serious consequences for medical technology. It would make it impossible to maintain the current standard of care in areas like minimally invasive surgery, and innovations based on PFASs would be prevented.**

4.6. Emissions and emission prevention

The proposed restriction aims to reduce the discharge of PFASs into the environment to as close to zero as possible. To this end, it looks at manufacture, use and disposal. For medical technology, a 400% increase in emissions is expected between 2025 and 2055[38]. The largest component in the dossier is fluorinated gases, followed by fluoropolymers and non-polymer PFASs (including precursors of perfluoroalkyl acids, PFAAs). In the case of polymer PFASs, it is assumed that 1% of the PFASs used are released. For fluorinated gases, discharge percentages of between 10% (gases used in industrial processes for medical applications) and 100% (e.g. propellants, anesthetics, contrast agents) are used.

It remains to be seen whether this forecast is completely accurate. However, it should be noted that significant contributions to emissions reductions are possible even at the manufacturing stage for PFASs. The medical technology sector procures these materials, but does not manufacture them. With a uniform European standard, it would be possible to achieve the highest level of "containing" even at the manufacturing stage. Steps have already been taken to achieve this (in the Netherlands, for example).

Medical devices are generally intended for specialist use by healthcare professionals. This also means that the **non-implantable devices follow a tight product flow** (manufacturer – user – disposal company) and **the possibility of any uncontrolled discharge of PFAS-containing materials into the environment is virtually eliminated**. The conditions for **the disposal of hospital waste are already strict**, both from a hygiene point of view and for environmental protection reasons. Medical devices are not only used safely, but also disposed of safely. These products also need to be separated from consumer products for which there is no regulated system at the end of the life cycle. However, the opportunities in this sector have not been exhausted. It is conceivable that a targeted recycling or return system for PFAS-containing products could be introduced so that discharge, which is already low, could be minimized further.

[38] ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs), section E.2.9

➔ **The emissions forecasts in medical technology refer mainly to fluorine-containing gases. Polymers play only a minor role and, moreover, are disposed of safely. The data basis and the conclusions that can be drawn from it must be questioned and re-evaluated.**

4.7. Assessments from outside the EU

The fact that PFAS emissions need to be reduced can be seen as a global consensus. However, countries outside the EU have different and in some areas much more nuanced processes, especially for fluoropolymers.

Australia

In 2017, an Expert Health Panel for PFASs was set up in Australia to advise the Australian government on the available knowledge, including important international reports and opinions from the public and other stakeholders. The panel concluded that although the scientific evidence is limited, the previous reviews and research have provided consistent reports of a connection with various health effects. The Environmental Health Standing Committee (enHealth) has published guidelines intended to help assess public health risks. As a precautionary measure, enHealth recommends that exposure to PFASs be minimized as far as possible while further investigations into the potential health effects are carried out[39].

The declarations contain information on the possible health effects of exposure to PFOS, PFOA and PFHxS. With regard to PTFE, it states that although the polymer is part of the PFAS family, it has a different structure and therefore different properties to PFOA, PFOS or PFHxS:

- PTFE is not water soluble – PFOA, PFOS and PFHxS are water soluble.
- PTFE is too large and too insoluble to be absorbed by organisms – PFOA, PFOS and PFHxS are easily absorbed by organisms.
- PTFE is not toxic to animals – PFOA, PFOS and PFHxS have a range of toxic effects in animals.

These differences mean that the regulatory authorities do not consider PTFE to be a chemical of concern for human health or the environment[40].

United Kingdom

In 2021, the UK government set the first restrictions to be introduced under the new chemicals regulation system, the UK REACH system[41]. A restriction is introduced when there is evidence of an unacceptable risk to human health and the environment. The review is carried out by the Health & Safety Executive (HSE) with the support of the Environment Agency (EA). Those bodies also examine the risk from PFASs. In the UK's most comprehensive analysis of these chemicals to date, HSE has identified the most common and harmful uses of PFASs and demonstrated what measures could be taken to control and deal with them.

[39] https://www.pfas.gov.au/about-pfas/affects
[40] https://www.pfas.gov.au/about-pfas/faq
[41] https://www.gov.uk/government/news/restrictions-under-new-chemical-regime-announced-for-first-time

According to the Regulatory Management Option Analysis (RMOA), restrictions do not need to be applied to low hazard groups or low risk uses. The "low hazard groups" category includes fluoroplastics and fluoroelastomers. These could be highlighted as derogations from a proposed restriction[42].

USA

The U.S. Environmental Protection Agency (EPA) published an Advance Notice of Proposed Rulemaking (ANPRM) in April 2023. It focuses on the potential identification of hazardous material discharges of PFASs as part of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[43] It aims to gather the latest scientific findings and information on PFASs. This step follows the regulatory proposal from September 2022 on classifying PFOA and PFOS as hazardous substances.

The EPA's roadmap sets out the concrete steps to be taken by 2024[44]. It defines three pillars: Research (investments in research and development and innovation to gain a better understanding of PFASs and their impact on health and the environment), restrict (comprehensive approach to proactively prevent PFASs from reaching quantities in the air, soil and water that are critical for humans and the environment) and remediate (expanded and accelerated remediation of PFAS contamination to protect human health and ecosystems). The production and processing of PFASs, metal finishing, airports, pulp and paper, landfill sites and the manufacture of textiles and carpets are all named as key industries with significant documented emissions.

Under "restrict," the objectives described are as follows:

- To use and harmonize all the available legal measures to control and prevent PFAS emissions and minimize the exposure of consumers and industry to PFASs.
- To entrench the responsibility of manufacturers, processors, dealers, importers, industry and other important users for limiting PFAS discharge and for dealing with risks.
- To set up volunteer programs to reduce PFAS use and discharge.
- To avoid or minimize PFAS discharges and emissions in all communities.

The EPA also plans to review past PFAS regulatory decisions. In this context, additional notification obligations may be imposed so that it can examine PFASs before they are used in a new, potentially questionable way.

➔ **Outside the EU, countries are taking a nuanced attitude and allowing the use of fluoropolymers to continue in some areas. It would be wise to take this view in the proposed restriction.**

[42] Analysis of the most appropriate regulatory management options (RMOA); Poly- and perfluoroalkyl substances (PFAS); Environment Agency (2023), section 6.2.4; https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf.

[43] https://www.epa.gov/newsreleases/epa-takes-important-step-advance-pfas-strategic-roadmap-requests-public-input-and-data

[44] https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf

5. Chronology of the restriction

5.1. PFOS

In October 2006, the European Parliament decided to restrict the use of **PFOS** to a small number of areas of use. The relevant Directive 2006/122/EC governs the *"approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (perfluorooctane sulfonates)"*[45]. On 20 June, a new version of Regulation (EU) 2019/1021 on "persistent organic pollutants," known as the "POP Regulation," came into force[46]. Annex I, Part A defines concentrations of no more than 10 mg/kg (0.001% by weight) for "perfluorooctane sulfonic acid and its derivatives (PFOS)" if PFOS is present in substances. In semi-finished products or articles or parts thereof, the limit is 0.1% by weight (calculated in relation to the mass of the structurally or micro-structurally distinct parts that contain PFOS), and less than 1 µg/m^2 of the coated material for textiles or other coated materials. This derogation is to be reviewed by the Commission *"(…) as soon as new information on details of uses and safer alternative substances or technologies becomes available"* so that

"(a) the uses of PFOS will be phased out as soon as the use of safer alternatives is technically and economically feasible;

(b) a derogation can only be continued for essential uses for which safer alternatives do not exist and where the efforts undertaken to find safer alternatives have been reported on;

(c) releases of PFOS into the environment have been minimised by applying best available techniques."

5.2. PFOA

Under the European Chemicals Regulation REACH, **PFOA** was identified as a chemical of particular concern and added to the REACH candidate list in 2013[47]. As a result, the rules were transferred to the POP Regulation. Since July 2020, it has no longer been permissible to manufacture and market PFOA. Delegated Regulation (EU) 2020/784[48] *"as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds"* sets the upper limit in substances, mixtures or products at 0.025 mg/kg, and for PFOA precursors at 1 mg/kg. By way of derogation, *"the manufacturing, placing on the market and use of PFOA, its salts and PFOA-related compounds"* is declared permissible in cases including those of invasive and implantable medical devices until July 4, 2025. The *"use of PFOA, its salts and/or PFOA-related compounds"* in medical devices other than implantable medical devices within the scope of application of Regulation (EU) 2017/745 was restricted until December 3, 2020. However, the EU Commission has been informed that the threshold value of 0.025 mg/kg is exceeded in some medical devices other than implantable devices and invasive devices (as *"unintentional impurities of PFOA and its salts"*). In order to avoid the ban on manufacturing such medical devices after December 3, 2020 and to give the manufacturers sufficient time to reduce the

[45] https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32006L0122&from=DE
[46] https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32019R1021&from=DE
[47] https://www.umweltbundesamt.de/themen/eu-verbietet-pfoa
[48] https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32020R0784&from=DE

levels of impurities, the unintentional trace contaminant (UTC) limit value was set at 2 mg/kg (Delegated Regulation (EU) 2020/784[49]). This derogation will be the subject of a review at a later time.

5.3. PFHxS

Perfluorohexanesulfonic acid (**PFHxS**) was added to the candidate list of substances of very high concern for authorization under the REACH regulation in 2017. PFHxS has been used in fire extinguishing foams, for textile impregnation, in cleaning and washing agents and in the production of semiconductors, to name a few examples[50]. PFHxS is one of the PFASs most commonly detected in human blood and has a very long half-life in humans of 8.5 years (range 2.2–27 years). It is associated with effects on the liver, serum lipids, cholesterol, thyroid hormones and nervous system development[51]. In 2022, PFHxS was included in Annex A of the Stockholm Convention. Its production, marketing and use have been prohibited in Switzerland since October 1, 2022.

Since February 25, 2023, the marketing, manufacture and use of perfluorinated carbonic acids with nine to fourteen carbonate atoms (PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA) has been restricted. A number of other PFASs, such as perfluorobutanesulfonic acid and "GenX" (ammonium-2,3,3,3-tetrafluoro-2-propanoate) are already identified under REACH as "substances of very high concern" (SVHCs) and included on the associated SVHC list with the aim of substituting them[52].

5.4. PFASs

Whereas the PFASs that have been regulated to date are those that have been found in the highest concentrations in the environment and that have established effects on the environment and human health, the current process covers the entire group of around 10,000 substances[53].

In its "Chemicals Strategy for Sustainability Towards a Toxic-Free Environment,"[54] in October 2020 the European Commission outlined that PFASs require *"special attention"* due to the large number of cases of contamination of soil and (drinking) water. One of the most important initiatives under the strategy is *"phasing out (…) the most harmful substances, which include among others (…) persistent substances such as per- and polyfluoroalkyl substances (PFAS), unless their use is proven essential for society."*

The measures planned by the Commission are:

to ban all PFASs as a group in fire extinguishing foams and other uses, with their use only permitted if it is essential for society;

[49] https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32020R0784&from=DE
[50] Stockholm Convention on Persistent Organic Pollutants; Persistent Organic Pollutants Review Committee (2018), Risk profile on perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds.
[51] Ibid.
[52] https://www.bmuv.de/faqs/per-und-polyfluorierte-chemikalien-pfas/
[53] Ibid.
[54] https://environment.ec.europa.eu/strategy/chemicals-strategy_en

to treat PFASs as a group for the purposes of the relevant legislation on water, sustainable products, food, industrial emissions and waste;

to deal with the issue of PFASs at the global level through relevant international forums and in bilateral political dialogues with third countries;

to establish an EU-wide approach and financial backing through research and innovation programs to identify and develop innovative methods of remediating PFAS contamination in the environment and in products;

to fund research and innovation for secure innovations for substituting PFASs within the framework of Horizon Europe.

This has led the European Chemicals Agency (ECHA) to enter into a consultation on a possible restriction on PFASs under REACH. At the request of the European Commission, a Member State or the ECHA may initiate the restriction procedure if there are concerns that a specific substance could present an unacceptable risk to human health or the environment. Furthermore, the ECHA may propose a restriction on products containing substances that are included in the list of substances requiring authorization (Annex XIV)[55].

The declaration of intention was published on July 15, 2021 (the "date of intention"). The reason given by the ECHA for the restriction is:

PFASs are persistent substances or ultimately transform into such substances, leading to irreversible environmental exposure and accumulation. Their water solubility and mobility has caused contamination of surface water, ground water, drinking water and soil in the EU and worldwide, which will persist in the future. It has proven very difficult and extremely costly to remove PFASs once they have been released into the environment. In addition, some PFASs have been proven to be toxic and/or bioaccumulable, both in terms of human health and the environment. If no measures are taken, their concentrations will increase further; it will be difficult to reverse their toxic and environmentally harmful effects.[56]

The "call for evidence" started on July 19, 2021. The proposal dossier contains background information such as the substance identity and justifications for the restriction. It provides information on the identified risks and alternatives to the substances and the costs and benefits for the environment and human health resulting from this restriction[57]. Stakeholders were given an opportunity to make comments and formulate arguments for derogations. The submission of the restriction dossier was initially scheduled for mid July 2022. In fact, authorities from Germany, Denmark, the Netherlands, Norway and Sweden did not submit the dossier until January 13, 2023. The Annex XV Restriction Report was published on March 22. The consultation process has been initiated on that basis and is set to end on September 25, 2023. This will be followed by a formation of opinion by the ECHA committees. It is not yet clear when the Committee will reach its decision on the proposal and when the restriction will take effect. This could happen in 2025.

[55] https://echa.europa.eu/de/regulations/reach/restrictions/restriction-procedure

[56] https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b. The German translations are not an official language version from the ECHA.

[57] Ibid.

6. Content of the restriction proposal

The dossier considers a wide range of areas of application for PFASs. These include:

- Materials with food contact and packaging
- Metal coatings
- Ski waxes
- Medical devices
- Fluorine-containing gases
- Transport
- Electronics and semiconductors
- Lubricants

Three areas are explicitly exempted from the restriction:

- Plant protection products
- Biocide products
- Medicinal products

On this point, the dossier states: "(…) it is recognized that the use of these substances is specifically regulated in the EU and evaluations and approval processes are carried out by designated bodies with specific expertise and experience. Hence, it is proposed to derogate the use of PFASs as active substances (but not the use of PFASs as co-formulants) (…) in the restriction proposal for PFASs."[58]

There are two possible actions for all the other areas of application: an immediate full ban following the restriction's entry into force and transitional period, or a derogation, usually with a time limit.

Restriction option (RO)	**Transitional period before the RO enters into force**	**Duration of the derogation**
RO1: "Full ban"	18 months	--
RO2: Ban with application-specific derogations	18 months	5 years after the end of the transitional period
		12 years after the end of the transitional period
		No time limit (for certain uses)

[58] ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs), section 2.2.3

A **five-year derogation** is proposed if there is sufficient strong evidence that

- there are no technically and economically feasible alternatives on the market at the time of entry into force, but potential alternatives to PFASs have been identified that are still in the development phase, or
- there are no known alternatives available on the market in sufficient quantity at the time of entry into force or the implementation of alternatives cannot be completed before the end of the transitional period.

A **12-year derogation** is proposed if there is sufficient strong evidence that

- there are no technically and economically feasible alternatives on the market at the time of entry into force (e.g. because no potential PFAS alternatives have been identified through research and development), making it likely that none will be available in the near future, or
- the certification or official approval of PFAS-free alternatives cannot be achieved within a five-year derogation.

In principle, the submitters of the dossier draw a distinction between the following levels of evidence:

- sufficiently strong evidence: good evidence from one or more lines of evidence, with the ability to explain and reconcile any contradictory information;
- weak evidence: the information identified or obtained from the consultation was insufficient to draw a clear conclusion;
- inconclusive evidence: contradictory evidence from one or more lines of evidence where the conflicts cannot be explained and reconciled; and
- no evidence.

The following assessments are made with regard to medical technology:

1. The evidence is [sufficiently strong][59] that technically and economically feasible alternatives are [not generally available] and that the substitution potential is [low] for the following applications of medical devices:
   - implantable medical devices (excluding meshes and wound treatment products),
   - tubes and catheters,
   - coatings of metered dose inhalers, and
   - diagnostic laboratory testing.

2. There is [weak] evidence that technically and economically feasible alternatives are [not generally available] and that the substitution potential is [uncertain] for the following applications of medical devices:
   - hernia meshes,
   - wound treatment products,
   - coatings (other than metered dose inhalers),

[59]ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs), E.2.9.2.1.; square brackets taken from the original.

- engineered fluids,
- membranes used for venting of medical devices, and
- Contact lenses, ophthalmic lenses

3. There is [sufficiently strong] evidence that technically and economically feasible alternatives are [generally available] and that the substitution potential is [high] for propellants in metered dose inhalers.

4. There is [weak] evidence that technically and economically feasible alternatives are [generally available] and that the substitution potential is [high] for sterilization gases.

If medical devices are significantly modified – as would be the case if the PFASs were replaced – they must undergo a new approval procedure. The dossier acknowledges that this may take more than two years under the MDR. If the initial applications are rejected, a new development period of two to five years may also be necessary. It is assumed that the entire process from identifying an alternative to having an approved product can take at least five years, and even up to ten. The assessment also considers the (socioeconomic) costs of a full ban, as well as further PFAS emissions during transitional periods; fluorinated gases are considered to be the largest component, followed by fluoropolymers and non-polymer PFASs (including precursors of perfluoroalkyl acids, PFAAs).

The dossier therefore recommends a derogation of 12 years after the end of the transitional period for

- implantable medical devices (not including meshes, wound treatment products, tubes and catheters),
- tubes and catheters,
- coatings of metered dose inhalers,
- diagnostic laboratory testing

A derogation of 12 years after the end of the transitional period will be reviewed for the following products after consultation on the Annex XV report:

- hernia meshes,
- wound treatment products,
- coatings (other than metered dose inhalers),
- engineered fluids,
- membranes used for venting of medical devices, and
- Contact lenses, ophthalmic lenses
- PCTFE-based packaging for medical preparations, medical devices and molecular diagnostics,
- PTFE in the packaging of ophthalmic solutions,
- final packaging of sterilized medical devices

7. Ban

The ban will take effect after the expiry of the transitional period (RO1) or the derogations (RO2). This includes

- the manufacture, use and import of PFASs, and
- the marketing and use of PFASs as part of a(nother) substance or in mixtures or products if certain limit values are exceeded.

The specified limit values are listed in the dossier[60]:

- 25 ppb for all PFASs with targeted PFAS analysis (excluding polymer PFASs),
- 250 ppb for the total amount of PFASs with a targeted PFAS analysis, with degradation of the precursors if applicable,
- 50 ppm for PFASs including polymer PFASs. If the total fluorine content exceeds 50 mg/kg, the manufacturer, importer or downstream user must provide the enforcement authorities with evidence of fluorine measured as PFAS or non-PFAS content.

[60] ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs), section 2.3.2

Appendix I: Compilation of various areas in which PFASs are used

Glüge et al.[61] have investigated for various industrial sectors where and why PFASs are or were used. The blanks and question marks are taken from the original. The list supplements the areas mentioned in the position paper.

Use category/subcategory	Function of PFAS	Properties of the PFAS employed
Aerospace		
Phosphate ester-based brake and hydraulic fluids	Corrosion protection	Altering the electrical potential at the metal surface
Gyroscopes	Flotation fluids in gyroscopes	?
Wire and cable	High-temperature endurance, fire resistance, and high-stress crack resistance	Non-flammable polymers, stable
Turbine-engine	Use as lubricant	Corrosion resistant, stable, non-reactive, operate at a wide temperature range
Turbine-engine	Use as elastomeric seals	Operate at a wide temperature range
Thermal control and radiator surfaces	Reject waste heat	Survival over a wide operating temperature range, low solar absorbance, high thermal emittance, and freedom from contamination by outgassing
Coating	Protect underlying polymers from atomic oxygen attack	Non-reactive, very stable
Propellant system	Elastomers compatible to aggressive fuels and oxidizers	Non-reactive, very stable
Jet engine/satellite instrumentation	Use as lubricant	Long-term retention of viscosity, low volatility in vacuum and their fluidity at extremely low temperatures

Biotechnology		
Cell cultivation	Supply of oxygen and other gases to microbial cells	Great capacity to dissolve gases
Ultrafiltration and microporous membranes	Prevent bacterial growth	?

[61] Glüge et al. (2020), An overview of the uses of per- and polyfluoroalkyl substances (PFAS), Environ. Sci.: Processes Impacts, 22,2345 [the blanks and question marks are taken from the original] https://pubs.rsc.org/en/content/articlehtml/2020/em/d0em00291g

Building and construction		
Architectural membranes *e.g.* in roofs	Resistance to weathering, dirt repellent, light	Oleophobic and hydrophobic, low surface tension, beneficial weight-to-surface ratio
Greenhouse	Transparent to both UV and visible light, resistant to weathering, dirt repellent	Oleophobic and hydrophobic, low surface tension
Cement additive	Reduce the shrinkage of cement	?
Cable and wire insulation, gaskets & hoses	High-temperature endurance, fire resistance, and high-stress crack resistance	Non-flammable polymers, stable

Chemical industry		
Fluoropolymer processing aid	Emulsify the monomers, increase the rate of polymerization, stabilize fluoropolymers	Fluorinated part is able to dissolve monomers, non-fluorinated part is able to dissolve in water
Production of chlorine and caustic soda (with asbestos diaphragms cells)	Binder for the asbestos-fibre-based diaphragms	?
Production of chlorine and caustic soda (with fluorinated membranes)	Stable membrane in strong oxidizing conditions and at high temperatures	Stable, non-reactive
Processing aids in the extrusion of high- and liner low-density polyethylene film	Eliminate melt fracture and other flow-induced imperfections	Low surface tension
Tantalum, molybdenum, and niobium processing	Cutting or drawing oil	Non-reactive, stable
Chemical reactions	Inert reaction media (especially for gaseous reactants)	Non-reactive, stable
Polymer curing	Medium for crosslinking of resins, elastomers and adhesives	?
Ionic liquids	Raw materials for ionic liquids	?
Solvents	Dissolve other substances	Bipolar character of some of the PFAS

Electroless plating	Disperses the pitch fluoride in the plating solution	Low surface tension

Electroplating (metal plating)		
Chrome plating	Prevent the evaporation of chromium(VI) vapour	Lower the surface tension of the electrolyte solution, very stable in strongly acidic and oxidizing conditions
Nickel plating	Non-foaming surfactant	Low surface tension
Nickel plating	Increase the strength of the nickel electroplate by eliminating pinholes, cracks, and peeling	Low surface tension

Copper plating	Prevent haze by regulating foam and improving stability	Low surface tension
Tin plating	Help to produce a plate of uniform thickness	Low surface tension
Alkaline zinc and zinc alloy plating		
Deposition of fluoropolymer particles onto steel	Supported by fluorinated surfactants	Cationic and amphoteric fluorinated surfactants impart a positive charge to fluoropolymer particles which facilitates the electroplating of the fluoropolymer

Electronic industry		
Testing of electronic devices and equipment	Inert fluids for electronics testing	Non-reactive
Heat transfer fluids	Cooling of electrical equipment	Good heat conductivity
Solvent systems and cleaning	Form the basis of cleaning solutions disk drives	Non-flammable, low surface tension
Carrier fluid/lubricant deposition	Dissolve and deposit lubricants on a range of substrates during the manufacturing of hard	?
Etching of piezoelectric ceramic filters	Etching solution	Acidic

Energy sector		
Solar collectors and photovoltaic cells	High vapour barrier, high transparency, great weatherability and dirt repellency	Oleophobic and hydrophobic, low surface tension
Photovoltaic cells	Adhesives with PFAS hold mesh cathode in place	Lower the surface tension of the adhesive
Windmill blades	Coating	High weatherability
Coal-based power plants	Polymeric PFAS filter remove fly ash from the hot smoky discharge	Stable, non-reactive
Coal-based power plants	Separation of carbon dioxide in flue gases	Lower the surface tension of the aqueous solution
Lithium batteries	Binder for electrodes	Almost no reactivity with the electrodes and electrolyte
Lithium batteries	Prevent thermal runaway reaction	Good heat absorption of first layer and good heat conductivity of second layer
Lithium batteries	Improve the oxygen transport of lithium-air batteries	Great capacity to dissolve gases
Lithium batteries	Electrolyte solvents for lithium–sulfur batteries	Bipolar character of some of the PFAS
Ion exchange membrane in vanadium redox batteries	Polymeric PFAS are used as membranes	Resistance to acidic environments and highly oxidizing species

Zinc batteries	Prevent formation of dendrites, hydrogen evolution and electrode corrosion due to adsorption onto the electrode surface	Low surface tension, non-reactive
Alkaline manganese batteries	MnO_2 cathodes containing carbon black are treated with a fluorinated surfactant	?
Polymer electrolyte fuel cells	Polymeric PFAS are used as membranes	Ion conductance
Power transformers	Cooling liquid	Good heat conductivity
Conversion of heat to mechanical energy	Heat transfer fluids	Good heat conductivity

Food production		
Wineries and dairies	Final filtration before bottling with polymeric PFAS	Resist degradation

Machinery and equipment	?	?

Manufacture of metal products		
Manufacture of basic metals	Inhibit the formation of acid mist during the electrowinning of copper	Lower the surface tension of the aqueous solution
Manufacture of fabricated metal products	?	?
Pickling of steel wires	Acid-pickling promoter	?
Treatment of coating of metal surfaces	Promote the flow of metal coatings, prevent cracks in the coating during drying	Lower the surface tension of the coating
Treatment of coating of metal surfaces	Corrosion inhibitor on steel	Non-reactive
Etching of aluminium in alkali baths	Improving the efficient life of the alkali baths	?
Phosphating process for aluminium	Fluoride-containing phosphating solutions help to dissolve the oxide layer of the aluminum	?
Cleaning of metal surfaces	Disperse scum, speed runoff of acid when metal is removed from the bath, increase the bath life	?
Water removal from processed parts	Solvent displacement	Low surface tension

Mining		
Ore leaching in copper and gold mines	Increase wetting of the sulfuric acid or cyanide that leaches the ore	Low surface tension

Ore leaching in copper and gold mines	Acid mist suppressing agents	Low surface tension
Ore floating	Create stable aqueous foams to separate the metal salts from soil	Low surface tension
Separation of uranium contained in sodium carbonate and/or sodium bicarbonate solutions by nitrogen floatation	Improve the separation	?
Concentration of vanadium compounds	Destruction of the mineral structure, increases the specific surface area and pore channel thus facilitating vanadium leaching	Acidity

Nuclear industry		
Lubricants for valves and ultracentrifuge bearings in UF6 enrichment plants	PFAS are used as the lubricants	Stable to aggressive gases

Oil & gas industry		
Drilling fluid	Foaming agent	Low surface tension
Drilling – insulating material for cable and wire	Polymeric PFAS are used as insulating material	Withstand high temperatures
Chemical driven oil production	Increase the effective permeability of the formation	Low surface tension
Chemical driven oil production	Foaming agent for fracturing subterranean formations	Low surface tension
Chemical driven oil production	Heavy crude oil well polymer blocking remover	?
Chemical driven gas production	Change low-permeability sandstone gas reservoir from strong hydrophilic to weak hydrophilic	Hydrophobic and oleophobic properties
Chemical driven gas production	Eliminate reservoir capillary forces, dissolve partial solid, dis-assemble clogging, increase efficiency of displacing water with gas	Lower surface tension of the material
Oil and gas transport	Lining of the pipes is made out of polymeric PFAS	Non-reactive (corrosion resistant)
Oil and gas transport	Reduce the viscosity of crude oil for pumping from the borehole through crude oil-in-water emulsions	Hydrophobic and oleophobic properties
Oil and gas storage	Aqueous layer with PFAS prevents evaporation loss	Lower the surface tension of the aqueous solution

Oil and gas storage	Floating layer of cereal treated with PFAS prevents evaporation loss	Low surface tension
Oil containment (injection a chemical barrier into water)	Prevents spreading of oils or gasoline on water	?
Oil and fuel filtration	Polymeric PFAS are used as membranes	Non-reactive (corrosion resistant)

Pharmaceutical industry		
Reaction vessels, stirrers, and other components	Use of polymeric PFAS instead of stainless steel	?
Ultrapure water systems	Polymeric PFAS are used as filter	Low surface tension
Packaging	Polymeric PFAS form moisture barrier film	Hydrophobic
Manufacture of “microporous” particles	Processing aid	?

Photographic industry		
Processing solutions	Antifoaming agent	Lower the surface tension of the solution
Processing solutions	Prevent formation of air bubbles in the solution	Lower the surface tension of the solution
Photographic materials, such as films and papers	Wetting agents, emulsion additives, stabilizers and antistatic agent	Low surface tension, low dielectric constant
Photographic materials, such as films and papers	Prevent spot formation and control edge uniformity in multilayer coatings	Low surface tension
Paper and plates	uniformity in multilayer coatings Anti-reflective agents	Low refractive index

Production of plastic and rubber		
Separation of mould and moulded material	Mould release agent	Hydrophobic and oleophobic properties
Separation of mould and moulded material	Reduce imperfections in the moulded surface	Low surface tension
Foam blowing	Foam blowing agent	Low surface tension
Polyol foams	Foam regulator	Lower the surface tension of the foam
Polymer processing aid	Increase processing efficiency and quality of polymeric compounds	Lower the surface tension of the polymeric products
Etching of plastic	Wetting agent	Low surface tension
Production of rubber	Antiblocking agent	Low surface tension
Fluoroelastomer formulation	Additive in curatives	?

Semiconductor industry		
Photoresist (itself)	Photoresist matrix, changes solubility when exposed to light	?
Photoresist (photosensitizer)	Increase the photosensitivity of the photoresist	?
Photoresist (photo-acid generator)	Generate strong acids by light irradiation	Able to generate strong acids
Photoresist (quencher)	Controlling the diffusion of the acid to unexposed region	?
Antireflective coating	Provide low reflectivity	Low refractive index
Developer	Facilitate the control of the development process	?
Rinsing solution	Rinsing the photoresist to remove the developer	Low surface tension
Etching	Wetting agent	Low surface tension
Etching	Reduce the reflection of the etching solution	Low refractive index
Etching	Etching agent in dry etching	Strong acids
Cleaning of silicon wafers	Etch cleaning	Strong acids
Cleaning of integrated circuit modules	Remove cured epoxy resins	?
Ceaning vapour deposition chamber	Remove dielectric film build up	Generation of reactive oxygen species
Wafer thinning	Non-stick coating composition on carrier wafer	Low surface tension
Vacuum pumps	Working fluid	Stable, non-reactive
Technical equipment in contact with process chemical or reactive plasma	Polymeric PFAS are used in inert moulds, pipes and elastomers	Stable, non-reactive
Multilayer circuit board	Bonding ply composition	Low dielectric constant, low dissipation factor

Textile production		
Dyeing and bleaching of textiles	Wetting agent	Low surface tension
Dyeing process using sulphur dyes	Antifoaming agent	Low surface tension
Dye transfer material	Release agent	Low surface tension
Textile treatment baths	Antifoaming agent	Low surface tension
Fibre finishes	Emulsifying agent	Hydrophobic and oleophobic properties

Watchmaking industry		
Lubricants	Form an oil layer and reduced wear	Non-reactive (do not oxidize, resistant to corrosion)
Drying as production step after aqueous cleaning	Solvents in solvent displacement drying	Low surface tension

Wood industry		
Drum filtration during bleaching	The used coarse fabric is made out of polymeric PFAS	Stable
Coating for wood substrate	Clear coating is made out of polymeric PFAS	Stable, non-reactive
Wood particleboard	Part of adhesive resin	Low surface tension

Other use areas		
Aerosol propellant	Aerosol propellant	Non-flammable, stable, non-reactive

Air conditioning	Working fluid	Non-flammable, stable, non-reactive

Antifoaming agent	Prevent foaming	Low surface tension

Ammunition	Make the final product rubbery and reduce the likelihood of an unplanned explosion due to shock; enable long-term storage without degradation of the polymer	Long-term stability without degradation

Apparel		
Breathable membranes	Polymeric PFAS are used as membranes	High permeability to water vapour, but resist passage of liquid water
Long-lasting durable water repellent finish	Provide water and oil repellence, stain resistance and soil release	Lower surface tension of the fabric, hydrophobic and oleophobic properties

Automotive		
Car body	Weather resistance paint, no-wax brilliant top coat	Low surface tension
Automotive waxes	Aid spreading, improve the resistance of the polish to water and oil	Lower the surface tension of the wax, oleophobic
Windshield wiper fluid	Prevent icing of the wind shield	?
Car body	Light, stable	Beneficial weight-to-surface ratio, stable
Engine and steering system	Polymeric PFAS are used as sealants and bearings	Operate at a wide temperature range, non-reactive
Engine oil coolers	Heat transfer fluid	Good heat conductivity
Cylinder head coatings and hoses	Increase the fuel efficiency	?
Cylinder head coatings and hoses	Reduce the fugitive gasoline vapour emissions	Low surface tension
Electronics	Cables and wires	High-temperature endurance, fire resistance

Fuel lines, steel hydraulic brake tubes	Corrosion protection	Non-reactive, stable
Interior	Dirt repellent in carpets and seats	Low surface tension, oleophobic
Brake pad additives	?	?

Cleaning compositions		
Cleaning compositions for hard surfaces	Enhance wettability	Lower the surface tension of the cleaning product
Carpet and upholstery cleaners	Provide stain resistance and repel soil	Low surface tension, oleophobic
Cleaning compositions for adhesives	?	?
Dry cleaning fluids	Stabilizer, improve the removal of hydrophilic soil	Hydrophobic and oleophobic, low surface tension
Cleaning of reverse osmosis membranes	Remove calcium sulphate	?

Coatings, paints and varnishes		
Paints	Emulsifier for the binder, dispersant for the pigments, wetting agent	Hydrophobic and oleophobic, low surface tension
Paints	Enhance the protective properties of anticorrosive paints	Non-reactive
Paints	Antifouling on ships	?
Paints and coatings	Anti-crater, improved surface appearance, better flow and levelling, reduced foaming, decreased block, open-time extension, oil-and water repellency, dirt pickup resistance	Low surface tension, oleophobic
Paints and coatings	Form second coat on a first coat	Low surface tension
Coatings	Antistick and anticorrosive coatings	Low surface tension, non-reactive
Coatings	Highly durable and weatherable	Stable, non-reactive

Conservation of books and manuscripts	Preserve historical manuscripts	Permeability to water vapour, but resist passage of liquid water

Cook- and bakingware	Prevent food from sticking to the pan/baking ware	Low surface tension, non-reactive, stable at high temperatures

Dispersions	Disperse solutions	Low surface tension

Electronical devices		
Printed circuit boards	Use fibre-reinforced fluoropolymer layer	Low dielectric constant

Capacitors	Separation of high voltage components (dielectric fluid)	High dielectric breakdown strength, non-flammable
Acoustical equipment	Provide an electrical signal in response to mechanical or thermal signals	Piezoelectric and pyroelectric properties
Liquid crystal displays (LCDs)	Provide the liquid crystal with a dipole moment	Dipoles
Liquid crystal displays (LCDs)	Polymeric PFAS provide moisture sensitive coating for displays	Hydrophobic
Light management films in flat panel display	Reduced static electricity build-up and dust attraction during fabrication	Low dielectric constant
Razors	Polymeric PFFAs is used on the razor	?
Electroluminescent lamps	Polymeric PFAS is used as coating	?

Fingerprint development	Solvent	?

Fire-fighting foam		
Fluoroprotein (FP) foams	Fuel repellents	Low surface tension
Film-forming fluoroprotein (FFFP) foam	Film formers, foam stabilizers	Lower the surface tension of water
Alcohol-resistant film forming fluoroprotein (AR-FFFP) foam	Film formers, foam stabilizers	Lower the surface tension of water
Aqueous film-forming foams (AFFF)	Film formers	Lower the surface tension of water
Alcohol-resistant aqueous film forming foam (AR-AFFF)	Foam stabilizers	Low surface tension

Flame retardants		
Polycarbonate resin	Flame retardants	Non-flammable
Other plastic	Flame retardants	Non-flammable

Floor covering including carpets and floor polish	Improve wetting and levelling	Low surface tension
Soil-release finishes for carpets	Provide water and oil repellence, stain resistance and soil release	Low surface tension, hydrophobic and oleophobic
Aftermarket carpet protection	Provide water and oil repellence, stain resistance and soil release	Low surface tension, hydrophobic and oleophobic
Resilient linoleum	?	?
Laminated flloor covering	?	?
Floor polish	Improve levelling and wetting	Low surface tension

Glass		
Surface treatment	Make glass surfaces hydrophobic and oleophobic	Hydrophobic and oleophobic
Surface treatment	Prevents misting of glass	Hydrophobic
Surface treatment	Dirt-repellent	Low surface tension
Surface treatment	Fire-or weather resistant	Non-flammable, stable
Etching and polishing	Increase the speed of etching, improve wetting	Low surface tension
Drying as production step in glass finishing	Solvents in solvent displacement drying	Low surface tension

Household applications		
Threads and joints	Polymeric PFAS is used for sealing	?

Laboratory supplies, equipment and instrumentation		
Consumable materials (vials, caps, tape)	Made out of polymeric PFAS	?
Personal protective equipment (gloves)	?	?
Particle filters	Minimize the sorption of compounds to the filter itself	Low surface tension
Solvents	Dissolve other substances	Hydrophobic and oleophobic
LC instruments	Polymeric PFAS are used in the solvent degasser	Non-reactive?
LC columns	Some columns are based on polymeric PFAS	?
Reverse phase LC-solvents	can contain PFAS	?
Seals and membranes in UPLCs, autoclaves and ovens	are made out of polymeric PFAS	Work over a wide temperature range
Oils and greases in pumps	Form a thick oil layer and reduced wear	Non-reactive, non-flammable
Sterilization of an insulated vessel	Sterilization medium	?
Electro plotting	Protein-sequencing membranes are made out of polymeric PFAS	?
Analysing the phosphoamino content in proteins	Protein-sequencing membranes are made out of polymeric PFAS	?

Leather		
Manufacturing of genuine leather	Improve the efficiency of hydrating, pickling, degreasing and tanning	?

Repellent treatment (genuine leather)	Provide water and oil repellence, stain resistance and soil release	Hydrophobic and oleophobic, low surface tension
Manufacturing of synthetic leather	Polymer melt additives that impart oil and water repellency to the finished fibres	Hydrophobic and oleophobic
Shoe brighteners	Improve the levelling of shoe brighteners	Low surface tension
Impregnation spray	Provide water and oil repellence, stain resistance and soil release	Low surface tension

Lubricants and greases	Form a thick oil layer and reduced wear	Non-reactive, non-flammable, operate also at high temperatures, do not form sludge or varnish

Medical utensils		
Electronic devices that rely on high frequency signals (defibrillators, pacemakers, cardiac resynchronization therapy (CRT), positron-emission tomography (PET) and magnetic resonance imaging (MRI) devices)	High dielectric insulators	High dielectric breakdown strength
Video endoscope	Use in charge-coupled device colour filters	?
Microbubble-based ultrasound contrast agents	Fluorinated gas inner core, which provides osmotic stabilization and contributes to interfacial tension reduction	Low solubility in aqueous media (dissolve more slowly)
X-ray imaging	Contrast enhancement agents	Radio-opaque
Magnetic resonance imaging	Contrast agent	Lack of a 19F endogenous background signal in vivo and high magnetic resonance sensitivity of 19F atoms
Proton and 19F NMR imaging	Contrast agents	Lack of fluorine in organs and tissue
Computed tomography and sonography	Contrast agents	Lack of fluorine in organs and tissue
Radio-opaque materials	Polymeric PFAS has been used	Radio-opaque
Surgical drapes and gowns	Improve water-, oil- and dirt-resistance	Hydrophobic and oleophobic, low surface tension
X-ray films	Wetting agents, emulsion additives, stabilizers and antistatic agent	Low surface tension, low dielectric constant
Dispersant	Facilitate the dispersion of cell aggregates	Low surface tension
Contact lenses	Raw material	

Retinal detachment surgery and Proliferative vitreoretinopathy	Endotamponade gases	High specific gravity, low surface tension, and low viscosity
Retinal detachment surgery and Proliferative vitreoretinopathy	Intraoperative tool during vitreoretinal surgery	High specific gravity, low surface tension, and low viscosity
Eye drops	Delivery agent	Unique combination of apolarity and amphiphility
Filters, tubing, O-rings, seals and gaskets in dialysis machines	Made out of polymeric PFAS	Low surface tension
Dialysis membranes	Made out of polymeric PFAS	Low surface tension
Catheter, stents, and needles	Provide low-friction and clot-resistant coatings	Low surface tension
Surgical patches and vascular catheter	Use of polymeric PFAS	?
Blood transfer and artificial blood	Oxygen carrier	Great capacity to dissolve gases
Organ perfusion	Oxygen carrier	Great capacity to dissolve gases
Percutaneous transluminal coronary angioplasty	Oxygen carrier	Great capacity to dissolve gases
Toothpaste	Enhances fluorapatite formation and inhibits caries	Low surface tension
Dental floss	Allows the narrow ribbon to slip easily between close-pressed teeth	Low surface tension
UV-hardened dental restorative materials	Improve the wetting of the set materials	Low surface tension
Ventilation of respiratory airway	?	?
Anaesthesia	Polymeric PFAS is used to dry or humidify breath	Hydrophobic
Artificial heart pump	Blood compatible and durable	Non-reactive, stable
Wound care	Cleaning burn residues	Dissolve hydrocarbon

Metallic and ceramic surfaces	Generates easily removable sludge	Hydrophobic and oleophobic

Music instruments		
Guitar strings	Prevent loss of vibration due to residue build up	?
Piano keys	Contain polymeric PFAS	?
Piano	Eliminate squeaks in piano key	?

Optical devices		
Glass fibre optics	Able to include rare earth in glass fibre optics	?

Optical lenses	Provide optical lenses with low refractive index and high transparency	Low refractive index

Paper and packaging		
Paper and cardboard	Provide water- and oil repellency	Hydrophobic and oleophobic
Manufacturing of paper	Release agent for paper-coating compositions	Low surface tension

Particle physics		
Particle accelerators	Part of the detection assemblies	Non-reactive, stable, high ionization charge density

Personal care products		
Cosmetics	Emulsifiers, lubricants, or oleophobic agents	Hydrophobic, low surface tension
Cosmetics	Make creams *etc.* penetrate the skin more easily	
Cosmetics	Make the skin brighter	
Cosmetics	Make the skin absorb more oxygen	Great capacity to dissolve gases
Cosmetics	Make the makeup more durable and weather resistant	Hydrophobic and oleophobic, stable, non-reactive
Hair-conditioning formulations	Enhance wet combing and render hair oleophobic	

Pesticides		
Insecticide against the common housefly and carmine mite	Suffocation of the insect by the adsorbed fluorinated surfactant	?
Insecticide against ants and cockroaches	?	?
Formulation additives	Anti-foaming agent	Low surface tension
Formulation additives	Dispersant, facilitate the spreading of plant protection agents on insects and plant leaves	Low surface tension
Formulation additives	Dispersant, increase uptake by insects and plants	Low surface tension
Formulation additive	Wetting agent for leaves	Low surface tension

Pharmaceuticals		
Active ingredient (fulvestrant)	Estrogen antagonists, inhibits the growth stimulus that the estrogen exert on cells	?
Active ingredient	Pharmaceutical combination of dabigatran and proton pump inhibitors	?

Formulation additives	Dispersant in self-propelling aerosol pharmaceuticals	Low surface tension
Formulation additives	Solvent	Hydrophobic and oleophobic

Pipes, pumps, fittings and liners		
Pipes, pipe plugs, seal glands, pump parts, fasteners, fittings and liners	Polymeric PFAS are used for these applications	Stable, non-reactive, low surface tension, hydrophobic and oleophobic
Working fluid for pumps in the electronics industry	Stable to reactive gases and aluminium chloride	Extremely stable, non-reactive

Plastic and rubber		
Plastic	Polymeric PFAS micropowder as additive?	?
Thermoplastic	Plasticizer	?
Bonding of rubber to steel	Allow adhesiveness bonding	Low surface tension
Rubber and plastic	Antistatic agent	Low dielectric constant
Resin	Improve weatherability and elasticity	Non-reactive, stable
Polycarbonate resins	Flame retardant for polycarbonate resins	Non-flammable

Printing (inks)		
Toner and printer ink	Enhance ink flow and levelling, improve wetting, aid pigment dispersion	Low surface tension
Toner and printer ink	Impart water resistance to water-based inks	Hydrophobic
Ink-yet recording heads	Make them ink repellent	Low surface tension
Recording and printing paper	?	?
Lithographic printing plates	?	?

Refrigerant systems		
Refrigerant fluid system	Heat transfer fluid	Good heat conductivity
Refrigerant compressor	Lubricants	Non-flammable

Sealants and adhesives		
Sealants	Can be made out of polymeric PFAS	Operate at a wide temperature range, non-reactive, stable
Silicone rubber seals	Prevents soiling	Low surface tension, hydrophobic and oleophobic

Adhesives	Improve levelling, spreading, and the penetration of the adhesive into the pore structure of the substrates	Low surface tension
Adhesives	Antistatic agent	Low dielectric constant

Soldering		
Vapour phase fluids in vapour phase soldering	Heat transfer medium	Good heat conductivity
Fluxing agent in solder paste	Low-foaming noncorrosive wetting agent	Non-reactive, stable, low surface tension

Soil remediation		
Vapour barrier material on top of contaminated soil	Evaporation retarder	?
Surfactants to mobilize pollutants	Surfactants to mobilize soil-bound contaminants in remediation	Stable, non-degradable (during photodegradation)

Sport article		
Ski wax	Highly water repellent	Low surface tension, hydrophobic
(Sailing) boat equipment	Weather protection of textiles; anti-fouling protection of ship hulls	Non-reactive, stable, hydrophobic and oleophobic
Tennis rackets	Used in coatings for tennis rackets	?
Bicycle	Lubricants	Hydrophobic
Climbing ropes	Provide water repellence, stain resistance and soil release	Low surface tension, hydrophobic
Fishing lines	No water absorption, invisible in water, high knot strength	Hydrophobic
Golf gloves	Antifouling protection for the natural sheep leather of the glove	?

Stone, concrete and tile	Impart oil and water repellency to the surface; delay oxidation and ageing of surface	Low surface tension, hydrophobic and oleophobic

Textile and upholstery		
Surface treatment	Provide water and oil repellence, stain resistance and soil release	Low surface tension, hydrophobic and oleophobic
Waving yarn	Facilitate waving	?

Tracing and tagging		
Tracking air-borne pollutants	Tracer in air	Non-radioactive, chemically and thermally stable, do not occur naturally, have very low atmospheric background concentrations

Testing ventilation systems	Tracer in air	〃
Mapping gas and petroleum reservoirs	Tracer in gas or petroleum	〃
Leak detection in cables, pipelines, landfill waste and underground storage tanks	Tracer in leaking material	〃
Tracking of marked items	Tracer in the marked item	〃

Water and effluent treatment		
Filter membranes	Polymeric PFAS minimize the sorption of compounds to the filter itself	Low surface tension

Wire and cable	Provide high-temperature endurance, fire resistance, and high-stress crack resistance	Non-flammable, operate at a wide temperature range