MedTech Europe PFAS Briefing
27 February 2023

Background

Per- and polyfluoroalkyl substances (PFASs) are a large class of thousands of synthetic chemicals that are used throughout society. PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS." (OECD, 2021). There are many groups of PFAS, for instance fluoropolymers, PFOA, PFHxS and its salts, to name a few.[1] They all contain carbon-fluorine bonds, which are one of the strongest chemical bonds in organic chemistry. PFASs have a wide range of different physical and chemical properties. They can be gases, liquids, or solid high-molecular weight polymers. PFASs are widely used as they have unique desirable properties. For instance, they are stable under intense heat. Many of them are also surfactants and are used, for example, as water and grease repellents.

PFAS has become a highly political and regulated family of chemicals in Europe, but also increasingly in other jurisdictions, e.g. the USA. In the EU, the biggest regulatory action will be the upcoming REACH Restriction Proposal on PFAS (the 5 Member States leading the file are expected to submit their dossier on 13 January 2023). The scope of this Restriction will be very broad, it will restrict the manufacture, placing on the market and use of PFAS (especially targeting consumer uses). Derogations will be provided, where the use of PFAS is deemed essential.

MedTech Europe has been working actively in preparation for the Restriction, to identify the uses of PFAS in medical technologies, what are the challenges with finding alternatives, how these technologies containing PFAS are handled at the end of life and how risks are managed. MedTech Europe surveyed its membership in the second half of 2022 to identify these points.

Objective

MedTech Europe would like to engage with the value chain to understand and address the potential emissions and end-of-life of medical technologies containing PFAS. As such, MedTech Europe is prepared to collaborate with its value chain to:

- **Understand more about what happens to PFAS used in medical technologies once they reach the end of their life, e.g.:**
  - How are PFAS-containing products treated at the end of life? (For example, are they disposed of as clinical waste, are they reused, incinerated, or end up as landfill?)
  - Are there arrangements for PFAS-containing technologies to be taken back by the manufacturer or recyclers?
  - What are the quantities or volume of PFAS that are collected in laboratories at the end of life of those technologies?
  - What measures are taken to dispose safely the PFAS-containing technologies?
  - What measures are taken to control or reduce the emissions of PFAS?

[1] For more information on PFAS, please review the pre-publication of the dossier, available at the link here: https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea

- How are workers protected from potential emissions of PFAS during their use phase?

Gathering this information is important, in order to prepare for the reporting requirements that are proposed in the PFAS pre-publication and can be used during the 6-month public consultation (starting 22 March 2023).

PFAS in the medical technologies sector

Why PFAS – properties & functions fulfilled by PFAS

- Properties such as chemical and heat resistance, lubrication and biocompatibility.
- PFAS is either a component of the final medical device or IVD, or a device part of an integral drug-device combination, or a processing aid used during upstream manufacturing.
- PFAS substances are often key to achieving the required high performance and durability of the products in the various uses/applications listed below.

Uses of PFAS (non-exhaustive)

1) Medical Devices
   - Blood contact invasive devices – e.g. grafts/covered stents, catheter tubings for infusion of medication and IV fluids and drug-eluting stent (DES) – blood flow within/between arteries and veins and for DES to control drug release to inhibit the vessel re-narrowing.
   - Medication contact components - minimise drug-device interactions.
   - Surgical sutures: pledgets made of PTFE serve as suture abutments when suturing soft tissue. They are essential in heart valve operations.
   - Fluoropolymers, like PTFE and PVDF, are used in several components for the treatment of serious acute and chronic diseases.
   - In hernia meshes for rapid healing of hernia.
   - Cleaning of medical devices as cleaning solvents in vapor degreasing applications.
   - Surgical drapes and gowns.
   - Ophthalmic products (endotamponades- in surgery to reposition a detached retina, eye drops, contact lenses).
   - Medical tapes and wound dressings.
   - Medical imaging devices, such as ultrasounds.

2) IVD reagents & instruments:
   - **IVD testing kits** for haemostasis products that detect blood coagulation.
   - Heat-transfer agent in IVD clinical **chemistry diagnostic testing instruments**, which is essential to the functioning of the instrument.
   - Surfactant properties in *in vitro* diagnostic **assays**, which allow measures of various parameters such as magnesium concentration in serum, plasma and urine.
   - Fluoropolymers like PTFE and PVDF are used in several components for **analytical instruments**.
   - Other: Coating on the **dispense tip**, **tubing and tubing connectors**, **distributors**, **seals** and **gaskets**, **syringe pump valves**, **O-rings** and **sealants**.

Types of PFAS/groups thereof used (non-exhaustive list)

1) IVD reagents & instruments:

PTFE ; FEP ; PCTFE ; ETFE ; PVDF ; FKM/FPM fluoroelastomers ; FFKM/FFPM perfluoroelastomers; Hexafluor propanol; Triflouracetic acid; Triflouracetic acid anhydride; Triflourmethane-sulfonic acid anhydride ; Triflourtoluene; Methyl trifluoromethanesulfonate.

2) Medical Devices

PTFE ; FEP ; Perfluoropolyether ; PVDF ; PVDF-HFP; Perfluorinated acrylates (C6 – C14); Hydrophobic surface treatments – surface bound or reacted fluoropolymers of undisclosed composition; PTFE coatings Specialty fluorinated lubricants; FKM/FPM fluoroelastomers; FFKM/FFPM perfluoroelastomers; PTFE and PVDF suture materials; Semifluorinated alkanes (for example 1-(Perfluorhexyl)octane and 1-(Perfluorobutyl)pentane).

Challenges with alternatives (assessment)

Without PFAS, these medical technologies would not be able to perform their intended purpose:

- Sometimes, the alternative is another type of PFAS: Apart from PFAS, it is unlikely that any alternative would have similar or superior functions.
- The functionalities of PFAS make them preferred over alternatives: At the same time, some of the intrinsic properties which render these substances the preferred choice are the very same that create a burden on the environment.
- As an example, a non-PFAS replacement would likely lead to:
  - increased incidence of puncture wounds, no deliverability of the guidewire or catheter to the target lesion or other adverse events.
  - increased incidence of device malfunction and inability of the surgeon to sufficiently visualize the surgical site.
- Where there is no alternative and the upcoming PFAS Restriction does not propose a derogation, this would likely lead to the lack of supply of these technologies and services. Many of the uses of PFAS in the above-mentioned medical technologies improve patients' lives and ultimately extend people's lives.

Medical technologies are invasive and/or come into contact with the human body and are strictly regulated by sectoral legislation requiring manufacturers to ensure a high level of: risk management, design, safety, quality, performance and alternatives assessment & validation requirements. Ensuring technologies comply with sectoral legislation takes years, and where alternatives need to be tested and validated, that extends that duration. Sufficient transitional periods would be needed to ensure alternative technologies (where technically feasible) can be made available to users.

Finally, even if medical technologies are allowed to continue to use PFAS because there are no suitable alternatives, the medical market is not sufficiently large for PFAS manufacturers to support. Any restriction will impact the medical industry regardless of timelines as manufacturers have already started to discontinue making the materials.

Summary

- MedTech Europe did a survey of PFAS uses in medical technologies since the summer of 2022.

- PFAS are used in a range of critical medical technologies, both IVD and medical devices and in device part of an integral drug device combination.
- Due to the expected broad impact of a future PFAS restriction, numerous technologies and services could be affected in parallel.
- PFAS often have no alternative, and where there is, it tends to be another PFAS.
- The multiple regulatory initiatives running in parallel (PVC, BPA, PFAS, etc.) lead to substitution requirements that are heavy on R&D and is taking away resources from innovation.
- When considering a transition to a potential non-PFAS alternative, it is important to consider patient well-being and the timeline and requirements under sectoral legislation.
- It is important to work with the value chain to demonstrate that the end-of-life and emissions of PFAS are monitored and addressed.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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