HCLTech | Supercharging Progress™

PFAS global regulations: Implications on MedTech industries

Table of contents

Abstract	3
Abbreviations	4
Introduction	5
PFAS background and restrictions	5
PFAS challenges and concerns	6
Next steps for PFAS restriction	9
Summary	11
How can HCLTech help?	11
Accelerators and ecosystem	12
Case study: PFAS elimination in Class II medical device	13
Current engagement of PFAS project accomplishments	14
References	14
Author information	16

Abstract

Per and Polyfluoroalkyl substances (PFAS) have attained significant attention from the public and global regulatory bodies due to their inherent persistence, bioaccumulation and toxicity. The European Chemical Agency (ECHA) recently published a proposal to restrict these PFAS if they exceed the minimum limit. On the one hand, the timeline for the restriction to come into force is very stringent and it isn't easy to adapt and comply. On the other hand, the disruption in the supply chain affects the MedTech industries, as most PFAS suppliers announced that they are not continuing to supply PFAS further. There is no potential alternative material available for PFAS.

This whitepaper briefly outlines the general considerations for the PFAS restriction proposal, regulations and timelines, implications, industrial challenges, concerns on the MedTech business and HCLTech' s approach for assessment and remediation [HCLTech PFAS framework].

Abbreviations

PFAS	Per and Poly Fluoro Alkyl substances
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
EPA	Environmental Protection Agency
ECHA	European Chemicals Agency
EU	European Union
Ppb	Parts Per billion
Ppm	Parts Per million
TSCA	Toxic Substances Control Act
POPs	Persistent Organic Pollutants
RAC	Risk Assessment Committee
SEAC	Socio-Economic Analysis Committee
PLC	Polymers of Low Concern
OECD	Organization for Economic Cooperation & Development
FP	Fluoro Polymers
TFA	Tri Fluoro Acetate
LCA	Life Cycle Assessment
PFAA	Per and Poly Fluoro Alkyl Acids
FPAs	Fluorinated Processing Aids
NFPAs	Non-Fluorinated Processing Aids
PFCAs	Perfluoro carboxylic acids
RBA	Risk-Benefit Analysis

Introduction

PFAS constitute a diverse group of highly fluorinated synthetic chemicals used in many industrial and consumer products since the 1950s. They have attracted much public attention since the late 1990s and early 2000s, when the hazards and ubiquitous occurrence in the environment of two PFASs, Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS), started to be reported and recognized. The PFAS family encompasses numerous compounds with carbon chains studded with fluorine atoms and categorized by their carbon chain length as short chains (less than six) and long chains (six or more).

PFAS can be released into the environment during manufacturing, processing and industrial and commercial use. In addition, products containing PFAS that are disposed of in landfills or by incineration lead to the release of toxic substances into the environment. These compounds are persistent in the environment, bio-accumulative and toxic to humans and other animals (Figure 1).

PFAS compounds play a pivotal role in the MedTech Industries, especially in medical devices, In-Vitro Diagnostics (IVDs), pharmaceuticals and consumer health care due to their remarkable resistance to chemical and heat, lubricity and biocompatibility.

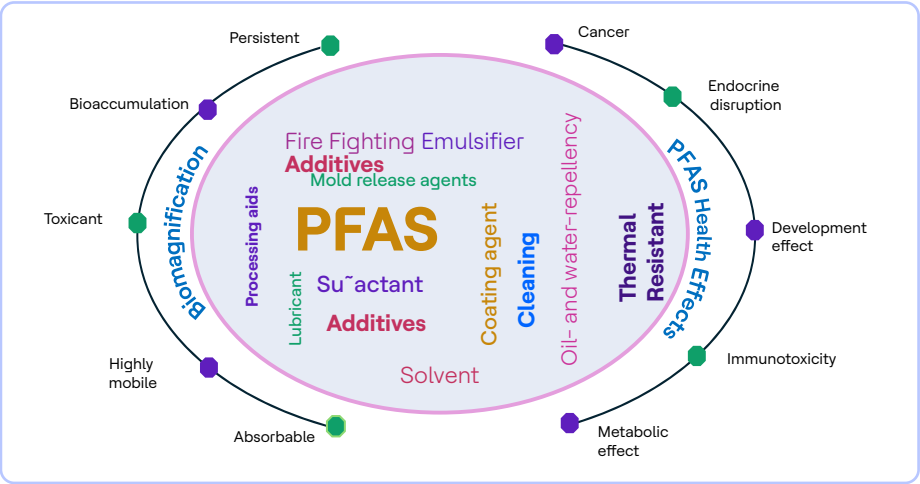


Figure 1: PFAS applications and their impact on environment and human health

PFAS – Background and restrictions

In recent years, European Union (EU) and United States (US) federal and state authorities have proposed several health-based regulatory values and evaluation criteria (Figure 2). In October 2021, the Environmental Protection Agency (EPA) released the PFAS Strategic Roadmap to lay out the approach to protecting public health and the environment from the impacts of PFAS. EPA sets a timeframe between 2021 and 2024 to take specific actions and policies to safeguard public health, protect the environment and hold polluters accountable.

In February 2023, the European Chemicals Agency (ECHA), backed by the national authorities of Germany, Denmark, the Netherlands, Norway and Sweden, published a restriction proposal on PFAS. The proposal is set to be one of the largest ever on chemical substance restrictions in the EU. It may significantly impact the use, manufacture and import of PFAS-containing products in the EU.

The proposed threshold limits of PFAS as constituents, in mixtures or in articles are ≤ 25 parts per billion (ppb) for any targeted PFAS analysis (excluding polymeric PFAS), ≤ 250 ppb for the sum of targeted PFAS analysis (excluding polymeric PFAS) and ≤ 50 parts per million (ppm) for PFAS (including polymeric PFAS). If total fluorine exceeds 50 mg F/kg, proof for the fluorine measured as the content of either PFASs or non-PFASs is required if requested by enforcement authorities.

The proposed restrictions would not apply to active substances in biocidal products (Regulation (EU) 528/2012), plant protection products (Regulation (EC) 1107/2009) or human and veterinary medicinal products (Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC).

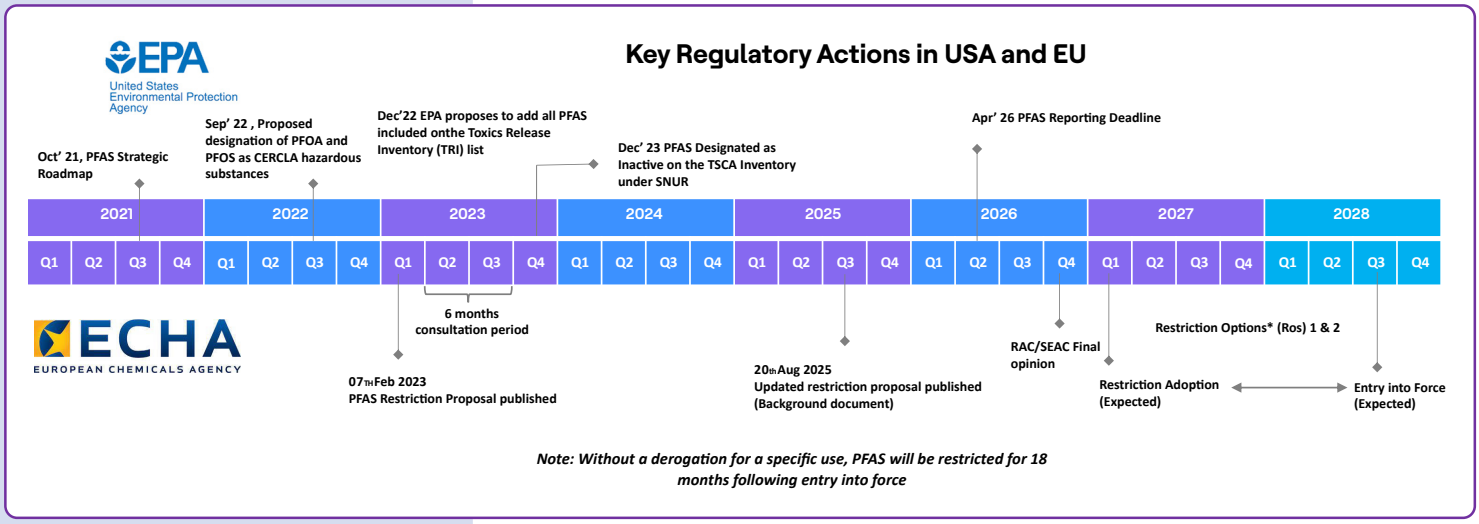


Figure 2: PFAS restriction timeframe

PFAS – Challenges and concerns

The ECHA recently concluded its public consultation on the restriction proposal and received 5,600 comments from more than 4,400 organizations, companies and individuals. Sweden had the highest number of comments at 1,369, followed by Germany, Japan and Belgium at 1,298, 938 and 303, respectively, while China ranked fifth with 262 comments. In terms of the source of comments, 58.7% (3,313) came from enterprises, 27.3% (1,543) from individuals and 9.8% (552) from industries or trade associations.

ECHA's two scientific committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) are presently evaluating the proposed restriction together with comments from different sectors. ECHA has received an unprecedented number of comments, many of which were

similar in nature and concerned common themes or uses (Figure 4). In tandem, the five national authorities who prepared the proposal are updating their initial report to address the consultation comments.

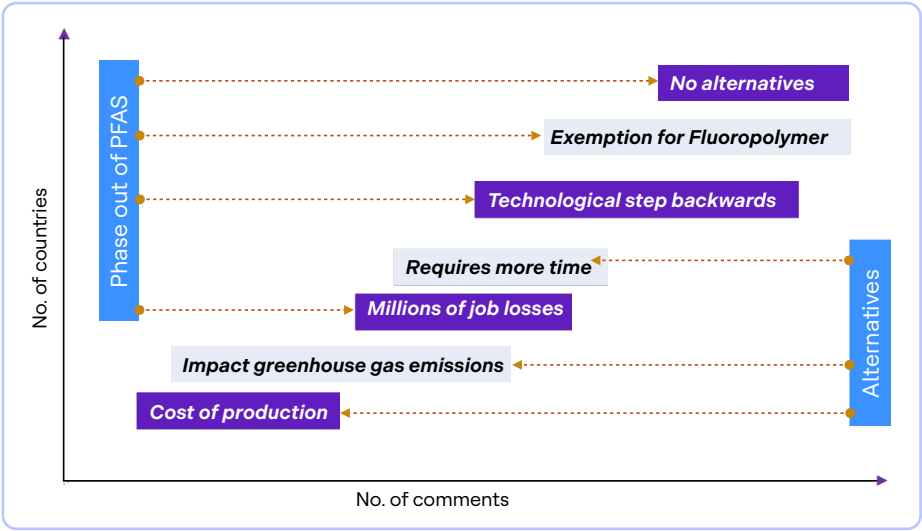


Figure 3: Challenges and concerns raised on the proposed PFAS restrictions

The proposed PFAS restriction has generated significant apprehensions across various industries and rendered the use of essential high-performance materials nearly impossible. Furthermore, the total ban on PFAS (10,000+ substances), identification of potential alternatives and time and cost have called for exemptions for many chemicals, including fluoropolymers.

Are fluoropolymers the polymers of low concern?

Fluoropolymers are a group of polymers within the PFAS class. Several research studies have shown that fluoropolymers are safe and do not pose a significant risk to humans or the environment. They are thermally, biologically and chemically stable, negligibly soluble in water, non-mobile, non-bioavailable, non-bioaccumulative and non-toxic.

Some fluoropolymers have been considered Polymers of Low Concern (PLC) according to the Organization for Economic Cooperation and Development (OECD) PLC criteria. Emissions related to fluoropolymers occur mainly during their production (PFAS as polymer processing aids) and end-of-life phases. Emissions may include non-polymeric PFAS such as FPAs, unreacted monomers, oligomers or other unintended byproducts formed during manufacturing.

OECD Polymer of Low Concern (PLC) Criteria

Polymer composition

MW, Mn, MWD

wt% oligomer

Electrical charge

Reactive Functional Groups (RFG)

Functional Group Equivalent Weight (FGEW)

Low MW Leachable

Water/liquid solubility/ octanol water partition

Particle size

Polymer stability

Thermal stability

Abiotic stability

Biotic stability

Not all fluoropolymer products meet the OECD PLC criteria (e.g., Nafion, due to the presence of reactive functional groups)

PLC assessment should be performed on a product-by-product (e.g., PTFE product made in China cannot be assumed to be same as produced from others)

Polymers are too large to penetrate cell membranes: Currently, no scientific evidence related to the bioavailability, thus blanket statement that polymers cannot enter cells is factually inaccurate.

- Inhaled spherical microparticles of Teflon were able to migrate into the surface lining layer of hamster alveoli, where interactions with lung cells could occur.
- Many fluoropolymer substances are marketed in the form of suspensions with submicron fluoropolymer particle sizes. Thus, release of bioavailable fluoropolymer particles is plausible.

Figure 4: Overview of PLC criteria

PLC mainly focuses on stability, which includes production, manufacturing and disposal processes. However, the risk posed by early and late aspects of the chemical lifecycle still warrants further study.

Several literature studies and theoretical evaluation studies have shown that thermal degradation or decomposition of fluoropolymers Table 1 (E.g.,

PTFE, FEP) can lead to the formation of Trifluoroacetate (TFA), Hydrogen Fluoride (HF), Carbon tetrafluoride (CF4), Tetrafluoro Ethylene (TFE) and some carbonaceous residues. While fluoropolymers, including PTFE, share similar structures characterized by carbon-fluorine bonds, the generation of Perfluoro carboxylic acids (PFCAs) is particularly associated with PTFE due to its unique polymerization and degradation pathways.

Table 1: Thermal degradation of fluoropolymers

Fluoropolymer	Thermal decomposition temp (°C)	Possible by products
PTFE	400°C	TFA, PFCAs, HF, Carbonaceous residues
ETFE	350-360°C	HF, CF4, TFE, Carbonaceous residues
FEP	450°C	HF, Fluorinated gases, residues of carbon

During thermolysis, the carbon-fluorine bonds in the PTFE structure break, forming free radicals or reactive intermediates. This can form a carboxylic acid group once it reacts with oxygen from the air. If the manufacturing process is happening in a controlled environment/inert atmosphere, it is not expected to result in the formation of PFCAs due to an insignificant amount of oxygen. If thermolysis of FPs occurs in the outside atmosphere/ in the presence of oxygen or moisture, it leads to longer chain per or PFCAs, which are found to be persistent. Furthermore, CFCs and other fluorocarbon degradants can destroy ozone layers and act as greenhouse gases. The continued use of fluoropolymers may exacerbate stratospheric ozone depletion and global warming.

Several FP manufacturers have been overcoming the great challenge of producing FPs free from FPAs and adopting sustainable technologies. A lot of progress has been observed in the few years after several FP manufacturers modified their production using NFPAs (3M, AGC, Arkema, Chemours, Daikin, Gujarat Fluorochemicals, Solvay and others).

Next steps for PFAS restrictions

Most companies have started to assess and prepare for these restrictions. Below are the steps we outlined to identify, comply with or replace PFAS with alternatives.

1. The manufacturers should familiarize themselves with various PFAS regulations across the globe
2. Conduct a product portfolio assessment and an impact analysis for the presence of PFAS.
3. Identifying PFAS in the supply chain
4. Prepare comprehensive plans to eliminate PFAS from raw materials and manufacturing processes

5. Collaborating with vendors or supply chains early and identifying suitable material to meet the reporting requirements
6. Conduct research to identify potential sustainable alternatives to PFAS

Since, regulatory bodies have already started a step-by-step phase out of these chemicals, it is imperative that industries move for a safer substitution anticipating possible regulatory changes. It will take time to completely phase out PFAS because of the challenges in identifying, developing and qualifying non-PFAS alternatives to meet the same function performance of existing products and applications. An accelerating pace of research and actions is needed to tackle the impact of PFAS and protect health and the environment.

Integration of PFAS into LCA

Researchers have started to analyze the environmental impact of PFAS substances by performing LCA. LCA has been carried out for PFAS substances by ISO 14040 and 14044 guidelines.

Holmquist et al. created a framework by defining the fractions of individual PFAS substances that transform into Perfluoroalkyl Acids (PFAAs), highly persistent terminal forms that can remain in the environment. The framework estimated human toxicity, marine, freshwater aquatic eco toxicity and other environmental impacts for three PFAAs, namely PFOA, Perfluoro Hexanoic Acid (PFHxA) and Perfluoro Butanesulfonic Acid (PFBS). The results demonstrate that even low emissions of PFASs can significantly affect LCA results. Conducting an LCA for PFAS-containing medical products helps understand the environmental impact of these substances. Analyzing the entire lifecycle, starting from raw material extraction, manufacturing, use phase and end of disposal, gives an idea of the product's environmental impact.

Lowering a product's environmental impact in medical devices can be accomplished in several ways, including reducing the number of materials used or choosing materials with a minimal environmental impact during manufacturing processes. A detailed framework for characterizing PFAS in LCA is below.

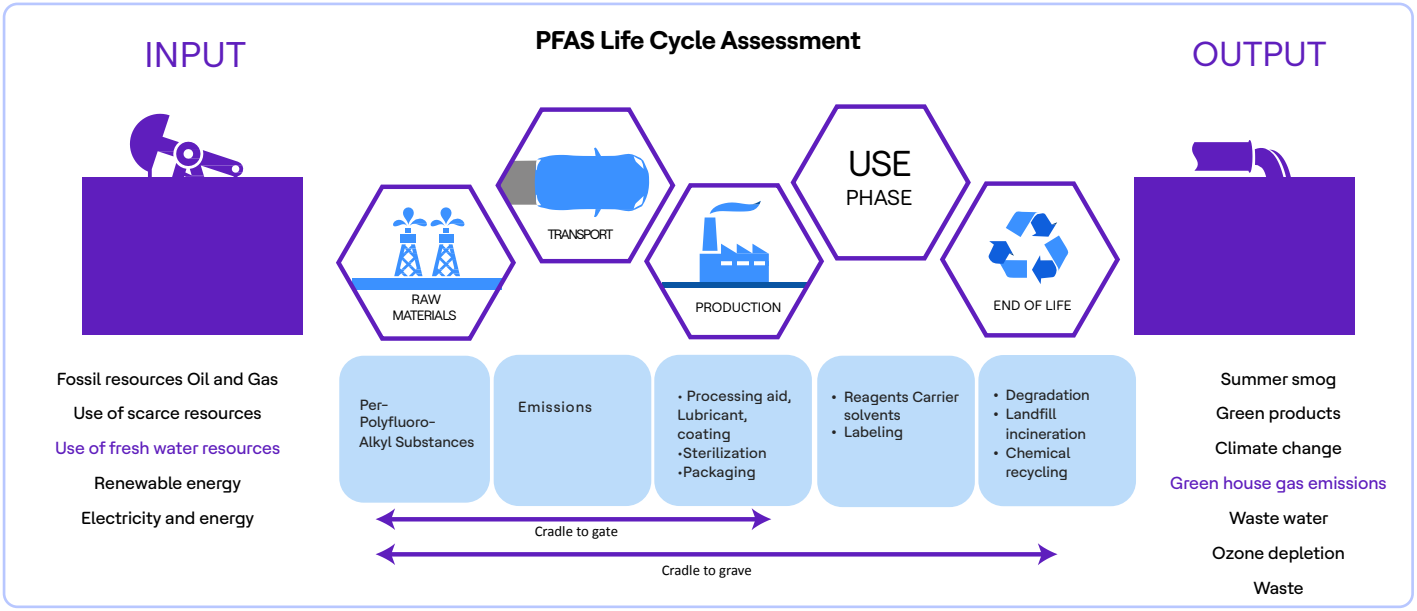


Figure 5: LCA process flow for PFAS

LCAs for PFAS chemicals provide insight into their effects on the environment, identify ways to make improvements and guide decisions that protect both human health and the planet.

Summary

PFAS have gained global public and regulatory attention for several years due to their inherent persistent, bio-accumulative and toxic properties. It is understood that PFAS compounds play a pivotal role in the medical industry, especially in medical devices, pharmaceuticals, consumer health care and IVD. The EU, the US and other global regulators are making significant inroads towards minimizing the manufacture, import, sale and use of PFAS. The recent regulatory action, "wide-use restriction" of PFAS under REACH, may impact multinational businesses based in other countries but doing business within the EU, inducing a ripple effect across the global economy. It also affects the quality and availability of treatments for patients in the EU, the US and other countries. Thus, demands an alternative for PFAS at the functional and performance level and mandates a significant investment of time, effort and cost.

How can HCLTech help?

At HCLTech, we have a long history of leading the removal of potentially harmful substances from MedTech products, which goes beyond what is required for regulatory compliance. We are supporting our customers in replacing PVC with non-PVC and DEHP-free polymers and eliminating BPA from hundreds of medical device products.

As part of this effort, we are currently engaging with all our customers to phase out PFAS by proactively identifying and developing PFAS-free sustainable alternatives without compromising the function and performance of the devices. Below are the steps we have outlined to identify, comply with and/or replace PFAS with alternatives.

Phases of activities		**Service offerings**
	Product portfolio assessment	Identification and assessment for PFAS, supply chain follow up, PFAS testing and quantification and preparation of rationale or justification
	Impact analysis	Operational risk assessment, business continuous strategy planning, risk mitigation plan, identification of alternative suppliers and competitive market analysis
	Derogation	Risk Benefit Analysis (RBA) and providing compelling evidence to support derogation proposals or application

Phases of activities		Service offerings
	Alternative materials identification	Sustainable alternative materials identification, materials testing and characterization, prototype manufacturing, functional and performance testing, LCA and product compliance assessment, ensure that the alternatives do not result in regrettable substitutions.

Accelerators and ecosystem

We are integrating GenAI with every stage of our PFAS remediation process. Our state-of-the-art technology can integrate with a wide range of PLM tools, break down products to their raw materials, analyze any potential PFAS compounds from the manufacturing to the raw material level, co-relate with PFAS regulations around the world and identify the potential components or products or compounds which are at risk due to the upcoming regulations. Furthermore, it helps us to provide a detailed view of when and what type of remediation must be taken at each level (product or component or raw material). We are also looking at integrating PFAS test reports and identifying potential alternatives.

Restricted substances and PFAS database

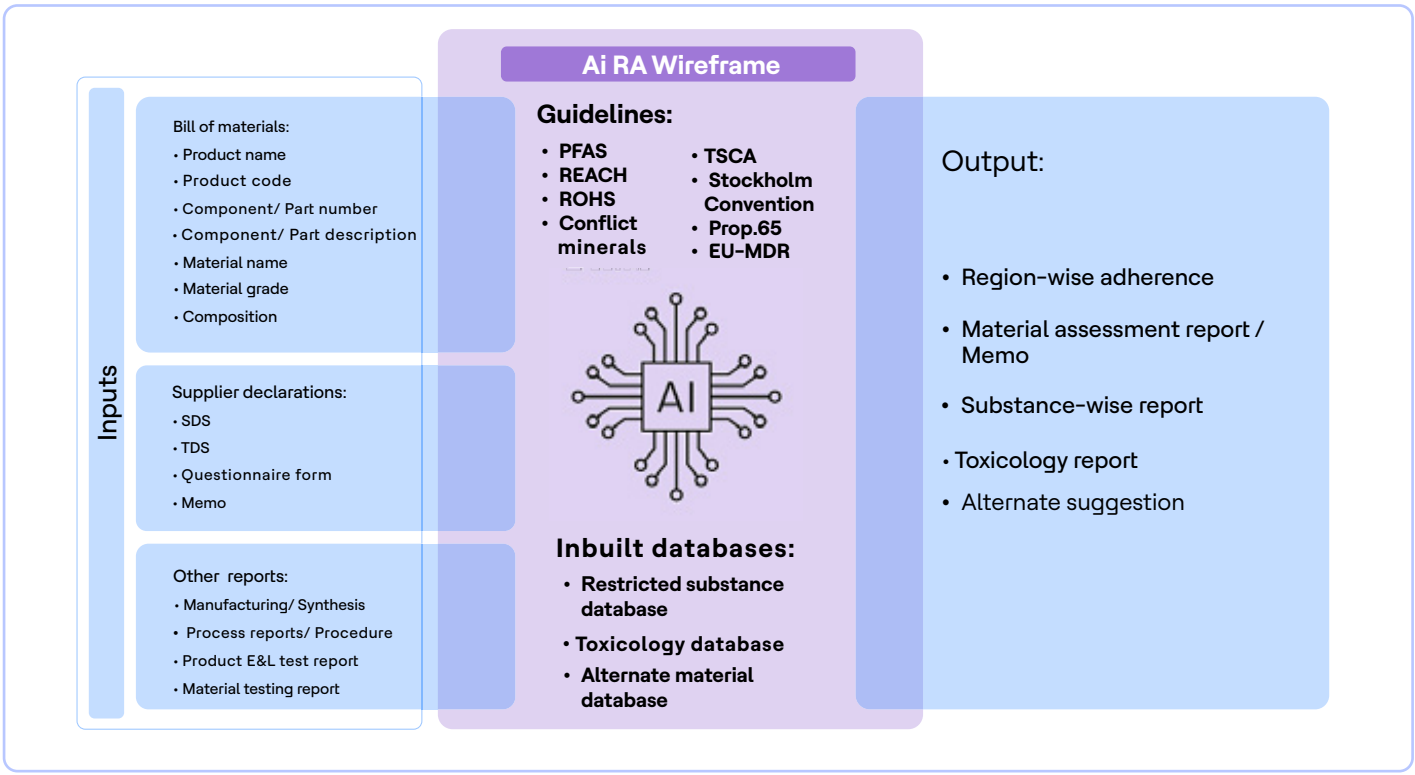
Automation (PFAS Assessment)

Analytical testing (Ecosystem)

Alternative materials (Database)

PoC – Protype/ testing (Ecosystem)

Cross functional domain expertise



Case study: PFAS elimination in Class II medical device

Problem

Manufacturers of a Class IIb medical device required support in addressing PFAS presence. The scope of work included product portfolio assessment, supplier out-reach, PFAS testing, identification of alternate materials/ suppliers.

HCLTech solution and approach

- Identification PFAS substances through performing product portfolio assessment
- Supplier reach-out and stakeholders connect
- PFAS testing/strategy plan for unresponsive suppliers
- Impact assessment/rationale and justification for presence of PFAS (if applicable)
- Identification PFAS free sustainable alternate materials and suppliers

Achievement

- Our team worked closely with all the stakeholders, suppliers and vendors to complete the scope of work on timely manner.
- Identified potential alternative without compromising the functional and performance of the product.
- Appreciation received from the customer for the support provided by HCLTech, for on time delivery and quality

Impact

- Implemented system to track supplier
- Reduced
- Assured

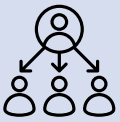
Current engagement of PFAS project accomplishments

10+

MedTech manufacturers

40k+

Components/ Assemblies



1500+

Suppliers reach out

References

1. Korzeniowski SH, Buck RC, Newkold RM, Kassmi AE, et al., A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag. 2023 Mar;19(2):326-354.
2. Brendel S, Fetter É, Staude C, Vierke L, Biegel-Engler A. Short-chain perfluoroalkyl acids: environmental concerns and a regulatory strategy under REACH. Environ Sci Eur. 2018;30(1):9.
3. https://echa.europa.eu/-/echa-publishes-pfas-restriction-proposal
4. tsca-8a7-reporting-instructions_may2024.pdf (epa.gov)
5. Henry BJ, Carlin JP, Hammerschmidt JA, Buck RC, et al., A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag. 2018 May;14(3):316-334.
6. Lohmann R, Cousins IT, DeWitt JC, Glüge J, et al., Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS? Environ Sci Technol. 2020 Oct 20;54(20):12820-12828.
7. David A. Ellis, Scott A. Mabury, Jonathan W. Martin and Derek C. G. Muir, Thermolysis of Fuoropolymers as a potential source of halogenated organic acids in the environment. Nature, Vol 412, 19 July 2001.

8. Holmquist H, Fantke P, Cousins IT, Owsianiak M, Liagkouridis I, Peters GM. An (Eco)Toxicity Life Cycle Impact Assessment Framework for Per- And Polyfluoroalkyl Substances. Environ Sci Technol. 2020 May 19;54(10):6224-6234.
9. Registry of restriction intentions until outcome - ECHA (europa.eu)
10. Cui J, Guo J, Zhai Z, Zhang J. The contribution of fluoropolymer thermolysis to trifluoroacetic acid (TFA) in environmental media. Chemosphere. 2019 May; 222:637-644.
11. Verma, S, T. Lee, Endalkac Sahle-Demessie, Mohamed Ateia Ibrahim and Mallikarjuna N. Nadagouda. Recent advances on PFAS degradation via thermal and nonthermal methods. Chemical Engineering Journal Advances. 2023; 13:100421.
12. Junli W, Zunhui L, Xuexiang H, Mingrui S, Paul W, Kyle D and David H. Critical Review of Thermal Decomposition of Per- and Polyfluoroalkyl Substances: Mechanisms and Implications for Thermal Treatment Processes. Environmental Science & Technology 2022 56 (9), 5355-5370
13. Tamoor, M.; Samak, N.A.; Yang, M.; Xing, J. The Cradle-to-Cradle Life Cycle Assessment of Polyethylene terephthalate: Environmental Perspective. Molecules 2022, 27, 1599.
14. ICRL – International Chemical Regulatory and Law Review: Global Regulations Around PFAS: The Past, the Present and the Future (lexxion.eu)

Author information

Bonda Chaitanya

Bonda holds a Master's in Polymer Science and Engineering from the Indian Institute of Technology (IIT), Roorkee. He has experience in medical device research and development, particularly in material assessment and drafting material of concern reports with respect to REACH, RoHS, California Prop 65 and PFAS regulations. He is also supporting the identification of alternative PFAS-free materials.

Kavya Vasudevan

Kavya is a materials expert with experience in polymers. She holds a Master of Technology in Materials Science and Engineering from IIT, Kharagpur and a Bachelor of Technology in Plastics Technology from CIPET, Chennai. She has adept experience in troubleshooting injection molds and validating them and is experienced in recycling of post-consumer and post-industrial resin. She has made functional prototypes that satisfy all medical device manufacturing requirements and she has successfully researched polymer toxicology and the extent and applicability of sustainability in the healthcare industry. She is also leading versatile teams on Nitrosamines and PFAS.

Malini Devi K

Malini is a materials specialist with experience in polymers and elastomers. She holds a Master of Technology in Polymer Science and Engineering. She started her work journey exploring Plasticizers and PFAS. Slowly, she rose in new product development for selecting greener materials for medical devices and expanded the growth in sustainability in medical device and product stewardship programs. She is currently engrossed in the field of material sustainability and has also kicked off in the manufacturing domain for mold qualification.

HCLTech | Supercharging Progress™

hcltech.com

HCLTech is a global technology company, home to more than 223,000 people across 60 countries, delivering industry-leading capabilities centered around digital, engineering, cloud and AI, powered by a broad portfolio of technology services and products. We work with clients across all major verticals, providing industry solutions for Financial Services, Manufacturing, Life Sciences and Healthcare, High Tech, Semiconductor, Telecom and Media, Retail and CPG and Public Services. Consolidated revenues as of 12 months ending June 2025 totaled $14 billion. To learn how we can supercharge progress for you, visit hcltech.com.