

Fluoropolymers and the PFAS REACH Restriction

Fluoropolymers Product Group (FPG)
of Plastics Europe

8 August 2023





The Fluoropolymers Product Group

The Fluoropolymers Product Group (FPG) represents Europe's leading fluoropolymer producers and experts.

As the voice of the industry across Europe, the Fluoropolymers Product Group advocates for a balanced regulatory environment based on scientific facts to ensure that European industries remain competitive and sustainable.

Part of Plastics Europe, the group's members are 3M, AGC, Arkema, Chemours, Daikin Chemicals, DuPont, Gujarat Fluorochemicals, Honeywell, W. L. Gore & Associates, and Solvay.

Irreplaceable fluoropolymers

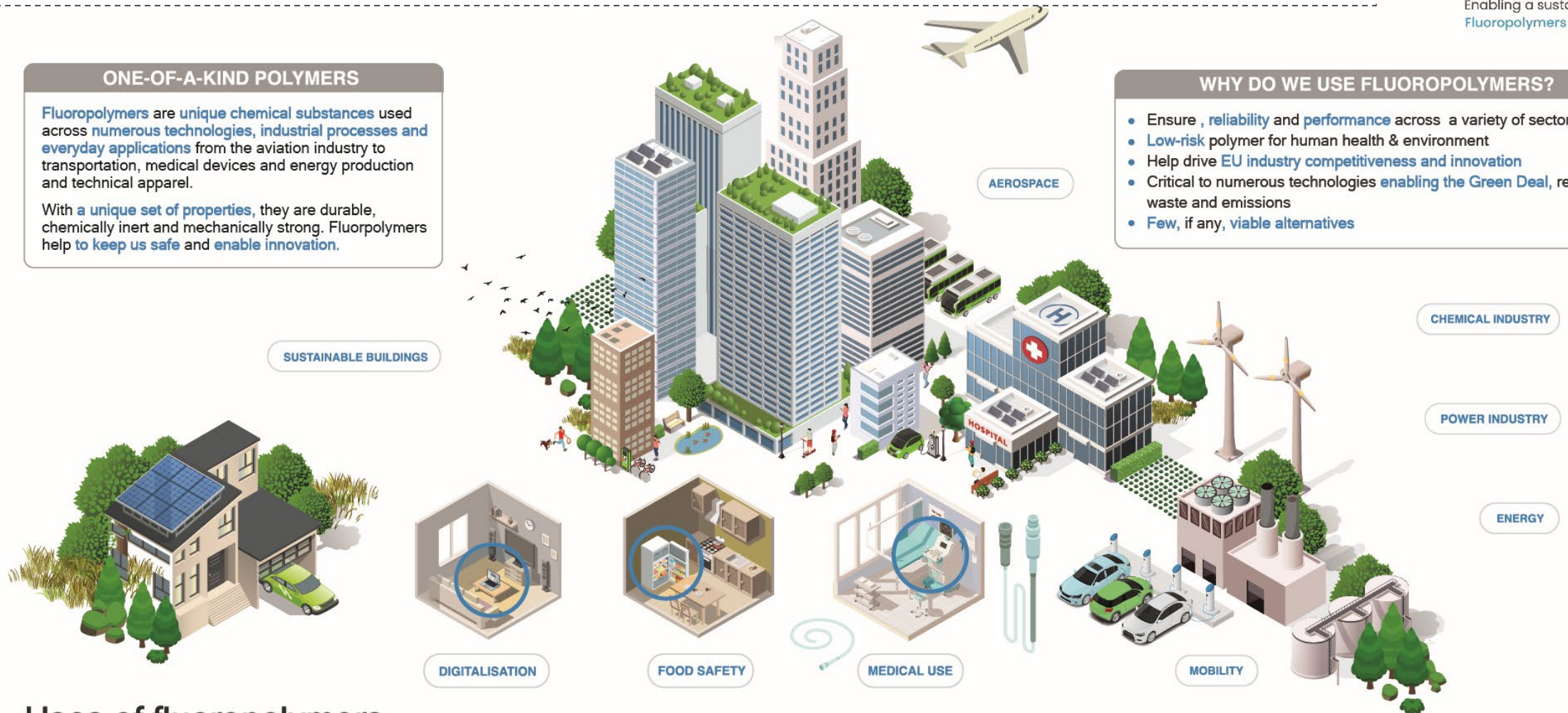
ONE-OF-A-KIND POLYMERS

Fluoropolymers are unique chemical substances used across numerous technologies, industrial processes and everyday applications from the aviation industry to transportation, medical devices and energy production and technical apparel.

With a unique set of properties, they are durable, chemically inert and mechanically strong. Fluoropolymers help to keep us safe and enable innovation.

WHY DO WE USE FLUOROPOLYMERS?

- Ensure , reliability and performance across a variety of sectors
- Low-risk polymer for human health & environment
- Help drive EU industry competitiveness and innovation
- Critical to numerous technologies enabling the Green Deal, reducing waste and emissions
- Few, if any, viable alternatives



Uses of fluoropolymers

- Promoting sustainable and smart mobility through electric vehicles.
- Extending the lifespan of medical equipment and devices, reducing the need for replacements, risk of failure and cross infections.
- Enabling a data driven economy through the manufacturing of microprocessors and semi-conductors.
- Facilitating the Renovation Wave and the construction of energy efficient buildings.

- Driving innovation and helping decarbonise the aviation industry.
- Assisting the chemicals industry in preventing corrosion in harsh environments.
- Ensuring food and pharmaceuticals remain fresh and uncontaminated.
- Protecting workers in professional protective and high-performance clothing.

The proposed “universal” PFAS REACH restriction

What is a REACH restriction?

REACH

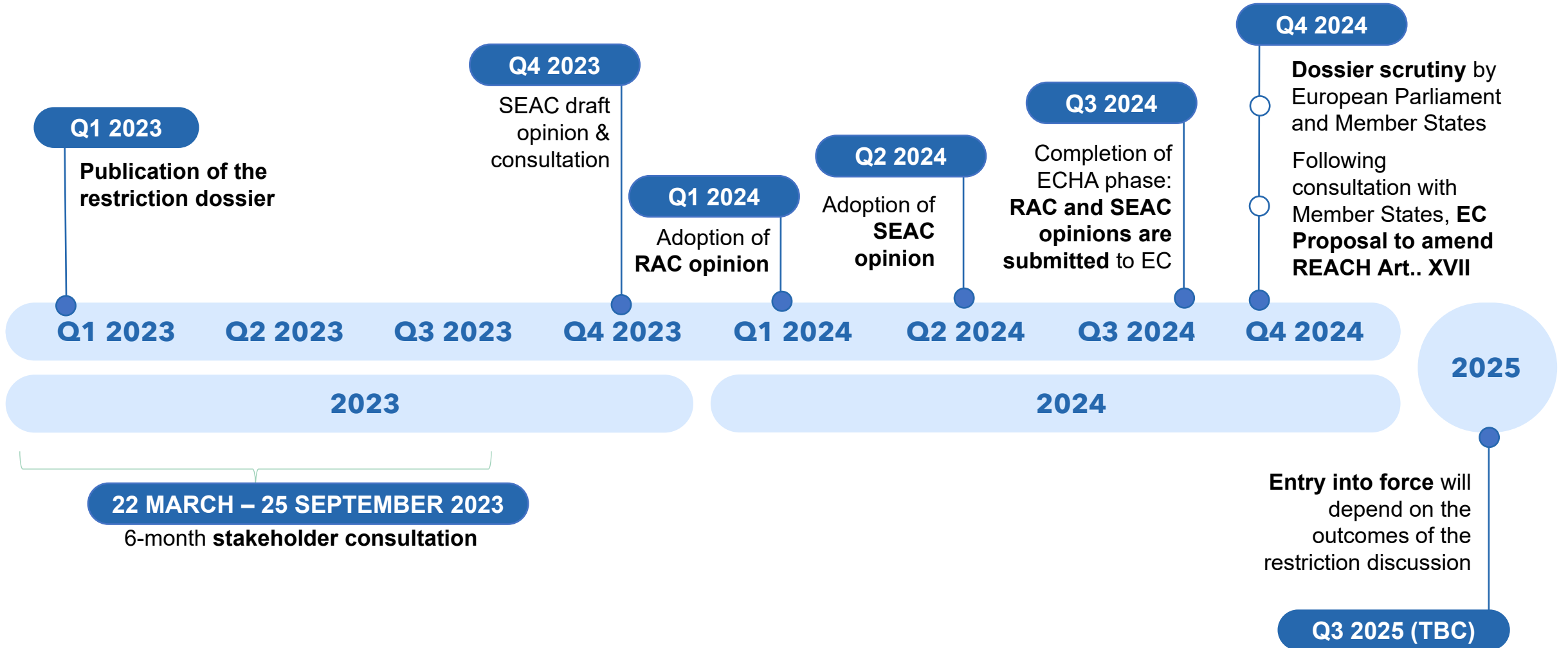
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is the European Union regulation dating from 18 December 2006, addressing the production and use of chemical substances and their potential impacts on both human health and the environment.
- The regulation established the European Chemicals Agency (ECHA), which manages the technical, scientific and administrative aspects of REACH.

REACH Restriction

- REACH restrictions limit, ban or set conditions on the manufacture, placing on the market (including imports) or use of a substance or group of substances.
- Restrictions are a measure for protecting human health and/or the environment from risks posed by chemicals on their own, in mixtures or in articles.



Tentative timeline of EU PFAS REACH Restriction: 2023-2025



PFAS REACH restriction proposal



PFAS definition (in the restriction proposal). Any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it).



The dossier submitters believe that all PFAS have the same hazard profiles and behave the same. Therefore, they should be grouped and regulated together.



The proposal does not provide for derogation of key PFAS monomers used in fluoropolymer manufacture.



The dossier submitters propose a total ban over time on the use of all fluoropolymers in all applications.

FPG views on the proposed “universal” PFAS REACH restriction

All PFAS are not the same

A segmentation of the PFAS family according to known properties rather than a structure-based classification alone is needed for a risk-based regulatory approach and is a scientifically based approach.

Fluoropolymers should not group together with other PFAS, which may be of concern.

01

The proposal makes limited reference of the fact that fluoropolymers have very different hazard profiles to other PFAS substances.

02

Differentiation should be made between the broad family of PFAS according to their intrinsic properties, toxicological profiles and critical uses.

03

Fluoropolymers present different toxicologic and ecotoxicologic profiles from PFAS that can be considered of concern

04

Fluoropolymers do not pose a risk to human health or the environment as they are non-toxic, not bioavailable, non-water soluble, non-mobile and do not bio-accumulate.

Fluoropolymers and EU strategic objectives

Fluoropolymers are used in critical applications which help to deliver strategic European and industrial objectives and are an enabler of the European Green Deal, E-mobility and digital transition of the European economy and society.

01

Fluoropolymers are used in critical applications including smart mobility, clean energy and sustainable industry, semi-conductors/electronics...

02

Many critical applications where fluoropolymers are used are not even proposed for derogation and will be banned 18 months after entry in to force.

✓ e.g. chemical process industry, pharmaceutical manufacturing, aerospace, military and defense, semiconductor manufacturing, water and wastewater treatment...

03

Periods for time limited derogations are not substantiated by a strong evidence base and are in many cases inadequate.

04

The proposed restriction creates general uncertainty that would undermine investment decisions and innovation in critical applications that help deliver strategic EU ambitions (fight against climate change, European Green Deal, the Chips Act, Hydrogen Strategy, and Sustainable and Smart Mobility Strategy).

Alternatives

The dossier submitters state that a move away from using fluoropolymers to alternative materials in many applications can be made.

The evidence base to support this opinion is limited and does not reflect the reality of the stringent performance and safety requirements that are the reason fluoropolymers are used in so many critical applications.

01

Inadequate information on alternatives could open the door for regrettable substitution.

02

Alternatives that do not perform at the same specification as a fluoropolymer, may be potentially hazardous, less durable and as such would mean applications are unable to meet stringent safety standards.

03

During the REACH restriction process, alternative must be assessed for their risks to human health and the environment, their availability, but also their technical and economic feasibility.

FPG views on the PFAS REACH restriction proposal

FPG believes that a total ban on fluoropolymers is not proportionate and by way of derogation, fluoropolymers and applications containing a fluoropolymer shall not be restricted.

The concerns of persistence raised in the restriction proposal can be appropriately managed through the implementation of different regulatory frameworks together with responsible manufacturing and End-of-Life (EoL) risk-management practices.

Regulatory frameworks as the Industrial Emissions Directive (IED), the Waste Framework Directive (WFD), and the Occupational Health Safety Directive can address the concerns related to fluoropolymers effectively and in an expeditiously manner compared to the REACH restriction.

Get involved

PFAS REACH restriction public consultation

22.03.2023 - 25.09.2023

- To date, ECHA has received more than 2500 submissions (both confidential and non-confidential) from stakeholders including individuals, companies, trade associations, Member States and NGOs.
- From the total 329 submissions analysed so far (comments submitted by individuals or anonymous are not included), 202 are referring to fluoropolymers with 90% of them proposing a derogation or an exemption of fluoropolymers from the PFAS REACH restriction.
- 45 Trade Associations have already responded to the consultation including, among other, the European Association of the Advanced Rechargeable & Lithium Batteries Value Chain (RECHARGE), the European Association of Motorcycle Manufacturers (ACEM), Hydrogen Europe, the European Automobile Manufacturers' Association (ACEA), the Electronics Industry Association (SEMI Europe), the Semiconductor Industry Association (ESIA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).
- At least 30 of the trade associations' submissions are requesting a derogation of (some) fluoropolymers.
- Only 1 Member state, Belgium, has submitted its comments to ECHA without, however, referring to fluoropolymers.
- The NGO Health and Environment Alliance (HEAL) also responded to the consultation supporting the inclusion of fluoropolymers under the OECD definition of 2021 and their restriction due to unacceptable risks to human health and the environment.

Important things to remember when drafting your response



In your submission, recognise the importance of the PFAS restriction issue and the concerns of the regulators.



You should present scientific and socio-economic data that can help prevent possible unjustified restriction of fluoropolymers.

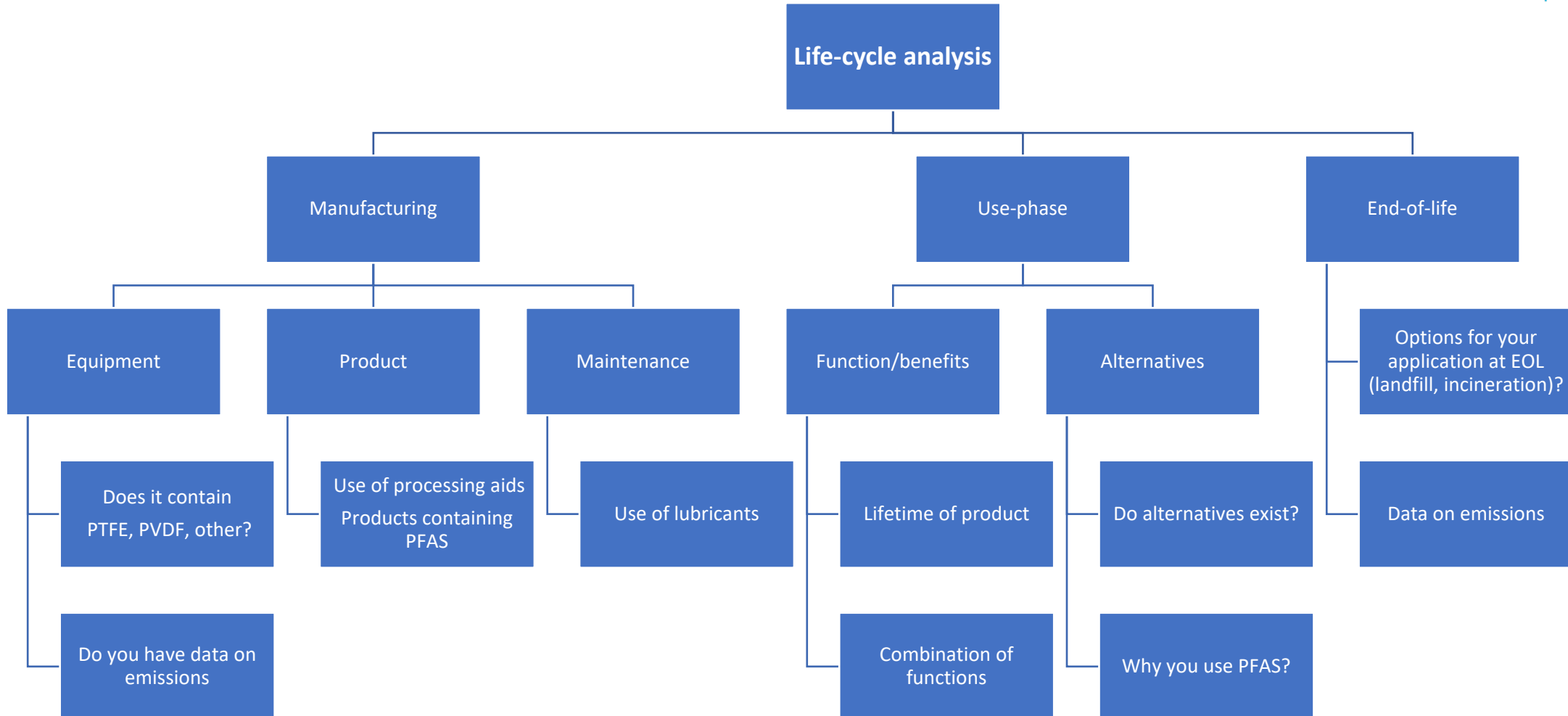


Only submit objective data in support of your response, avoid to draft a position paper that only makes statements.



If you submitted data during the calls for evidence of the dossier submitters in 2020 and 2021 you are encouraged to submit the data again.

Overview of the area to provide information on



- What emissions are there at the manufacturing stage?
 - Are these well-controlled?
- What risks or hazards are there from working with PFAS? E.g. worker safety/health

- Have you made testing on your product e.g. degradation (losses to environment)?
 - What were the results?
- Do your products need to meet any EU / international standards?
 - If yes, which standards? Do you have any information on the testing process required to meet the standards?

- Do you know the end of life of the product your manufactured?
- Do you provide guidance to your customers on correct disposal?

What to submit to the public consultation

Ensure your submission is visually easy to read and well-laid out on the page.

Introduce your sector and provide detail on the type of fluoropolymer that you use, and for which uses/application.

If your application is restricted as proposed, explain the impact you expect on your business and that of your customers.

If available, submit with your response scientific and/or socio-economic data (this can include studies or testing you may have carried out)

Submit data related to volumes, why you use FP, the performance criteria, function, and benefits of the use of fluoropolymers in your applications.

Submit information on alternatives (e.g., their availability and performance trade-offs vis-a-vis fluoropolymers).

Highlight standards & specifications needed to be met by your customer's requirements and the importance of fluoropolymers to reach those standards.

Submit any information related to releases and exposure and worker handling.

Do you use FP during maintenance? E.g. lubricants, greases or other products. Give information on these uses.

In submitting your data, also clearly state why you need a derogation.

Key information should be clearly labelled, and any statements you make should be supported by factual scientific/socio-economic data that can help prevent possible unjustified restriction of fluoropolymers.

Getting involved with FPG or by ourself

- Raise awareness of the impact of the PFAS restriction on your national economy and our industry in term of investment, employment and innovation.
- Inform the value chain of the impact of the restriction and encourage them to contact their national authorities to share views and concerns on fluoropolymers industry impacts
- Respond to ECHA public consultation and carry out a socio-economical analysis (SEA) on fluoropolymers applications.
- Participate to join outreach program organized by the fluoropolymer industry.
- Provide us with case studies of vital uses of fluoropolymers in your sector for publication on the FPG website/LinkedIn



Talk and share with us

- Visit our website <https://fluoropolymers.eu> to know all the fact and figures and use them for your own advocacy
- Join us on LinkedIn <https://www.linkedin.com/company/fluoropolymers-product-group> and follow us on Twitter https://twitter.com/FPG_EU
- Read our regular newsletter to keep abreast of the latest developments at EU level. To subscribe visit our website or send an email to brusselsbcwfluoropolymers@bcw-global.com
- Nicolas Robin - Director Fluoropolymers Product Group - Plastics Europe
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Annexes

- Regulatory management option analysis (RMOA)
<https://fluoropolymers.plasticseurope.org/index.php/fluoropolymers/irreplaceable-uses-1/reports-policy-documents/rmoa>
- Socio-economic analysis
<https://fluoropolymers.plasticseurope.org/index.php/fluoropolymers/irreplaceable-uses-1/reports-policy-documents/socio-economy-analisis>
- A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers
<https://doi.org/10.1002/ieam.4646>
- ECHA website to reply to the public consultation
<https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term>