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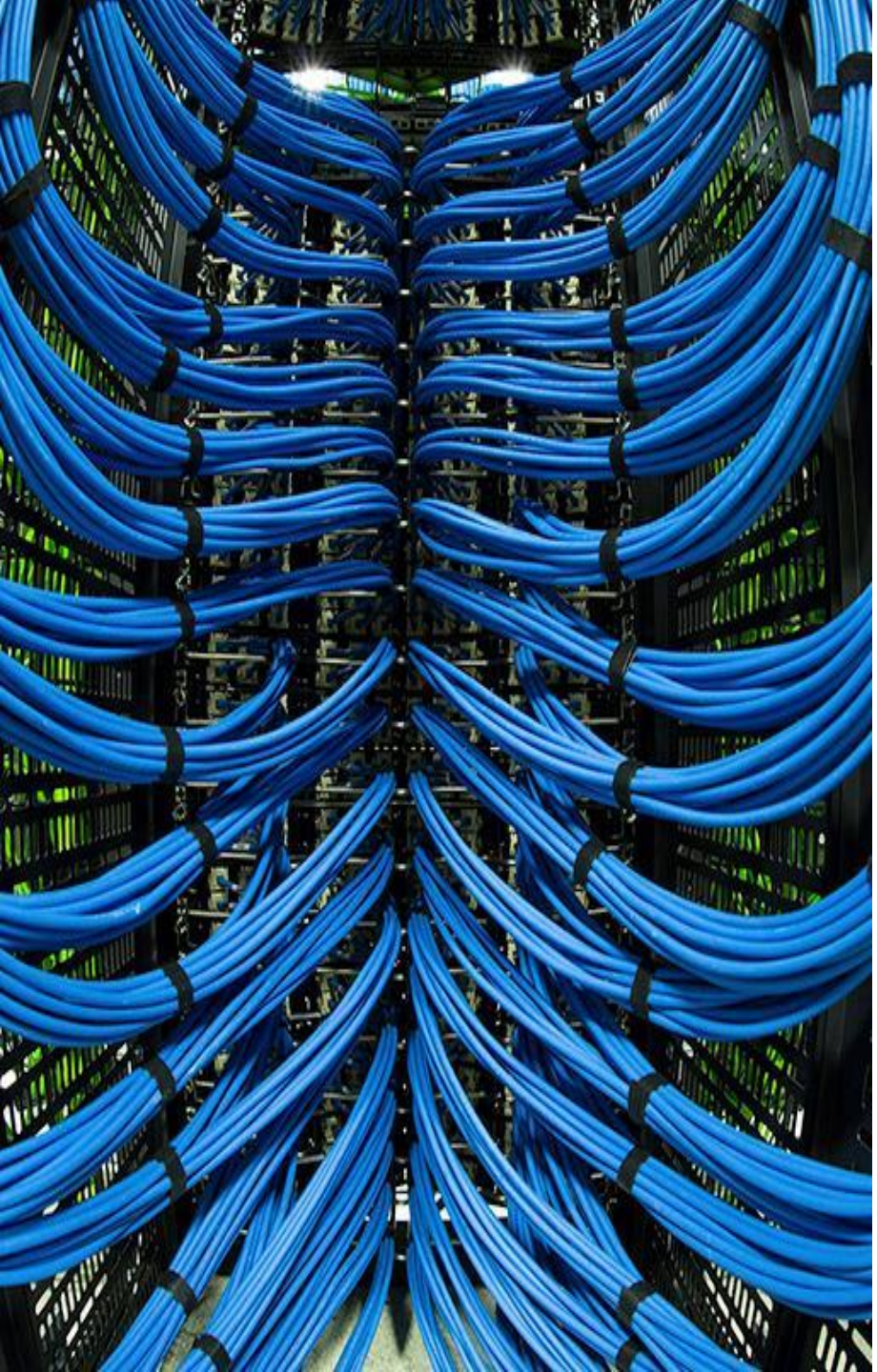
Fluoropolymers and the PFAS REACH Restriction

Fluoropolymers Product Group (FPG)
of Plastics Europe

13 April 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.

Impact of the restriction

What is the PFAS REACH restriction?

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Since 2020, the competent authorities of the five countries (Denmark, Germany, Netherlands, Norway, Sweden) have been preparing a REACH restriction dossier for all PFAS. For them ,REACH restriction “is considered to be the most effective and efficient way to manage such a large and complex group of substances that are used in numerous applications.” The restriction would cover PFAS manufacturing, use, and placement on the EU market.

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.

PFAS REACH restriction proposal

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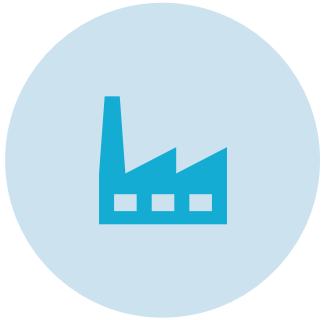
PFAS definition (in the restriction proposal): Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).

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



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

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

PFAS REACH restriction proposal - Sectors

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The following sectors and applications are considered in the PFAS REACH restriction proposal.

PFAS manufacture	Textile, upholstery, leather, apparel and carpets (TULAC)	Food contact materials and packaging	Metal plating and manufacture of metal products
Consumer mixtures	Cosmetics	Ski wax	Applications of fluorinated gases Energy sector
Medical devices	Transport	Construction products Lubricants	Electronics and semiconductors
Petroleum and mining			

Irreplaceable fluoropolymers

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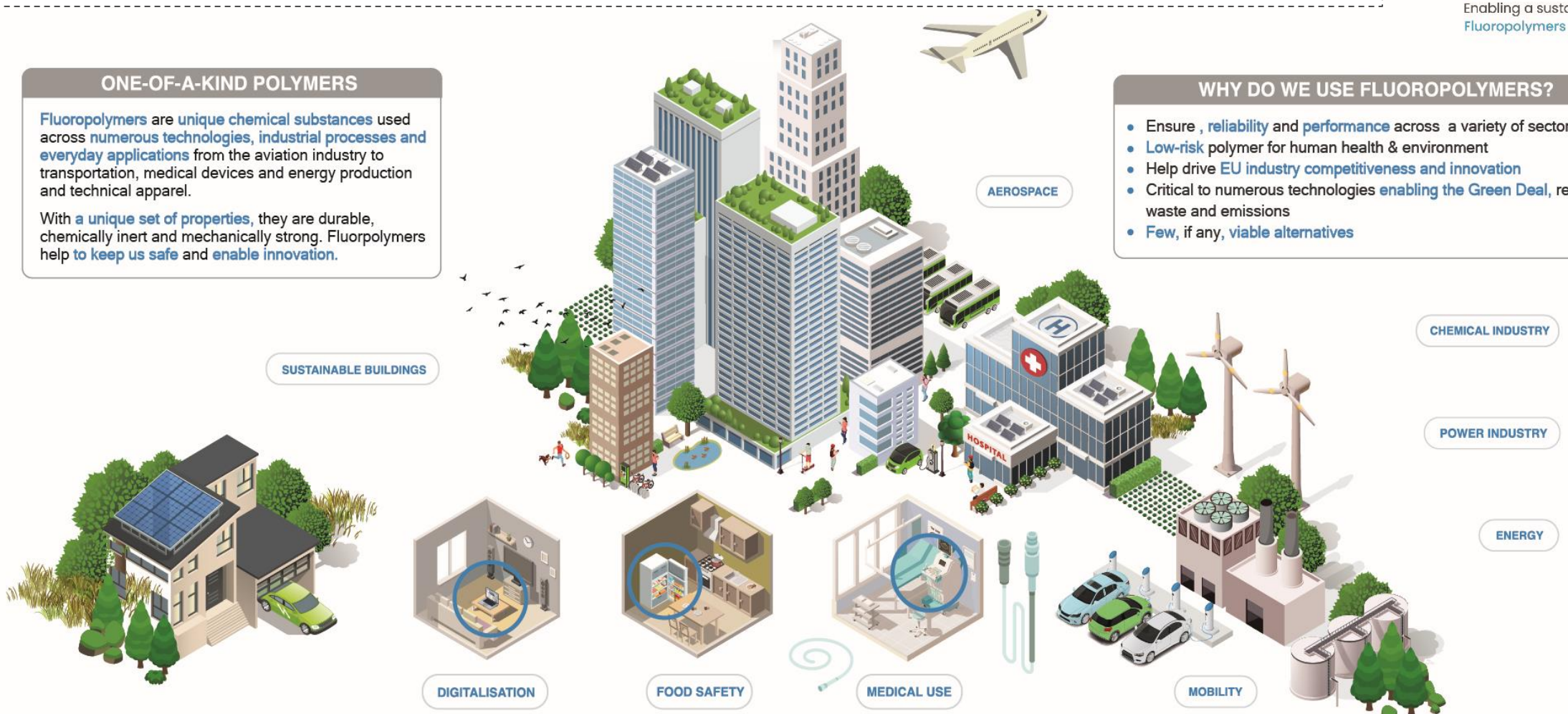
ONE-OF-A-KIND POLYMERS

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. Fluorpolymers 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 though 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.

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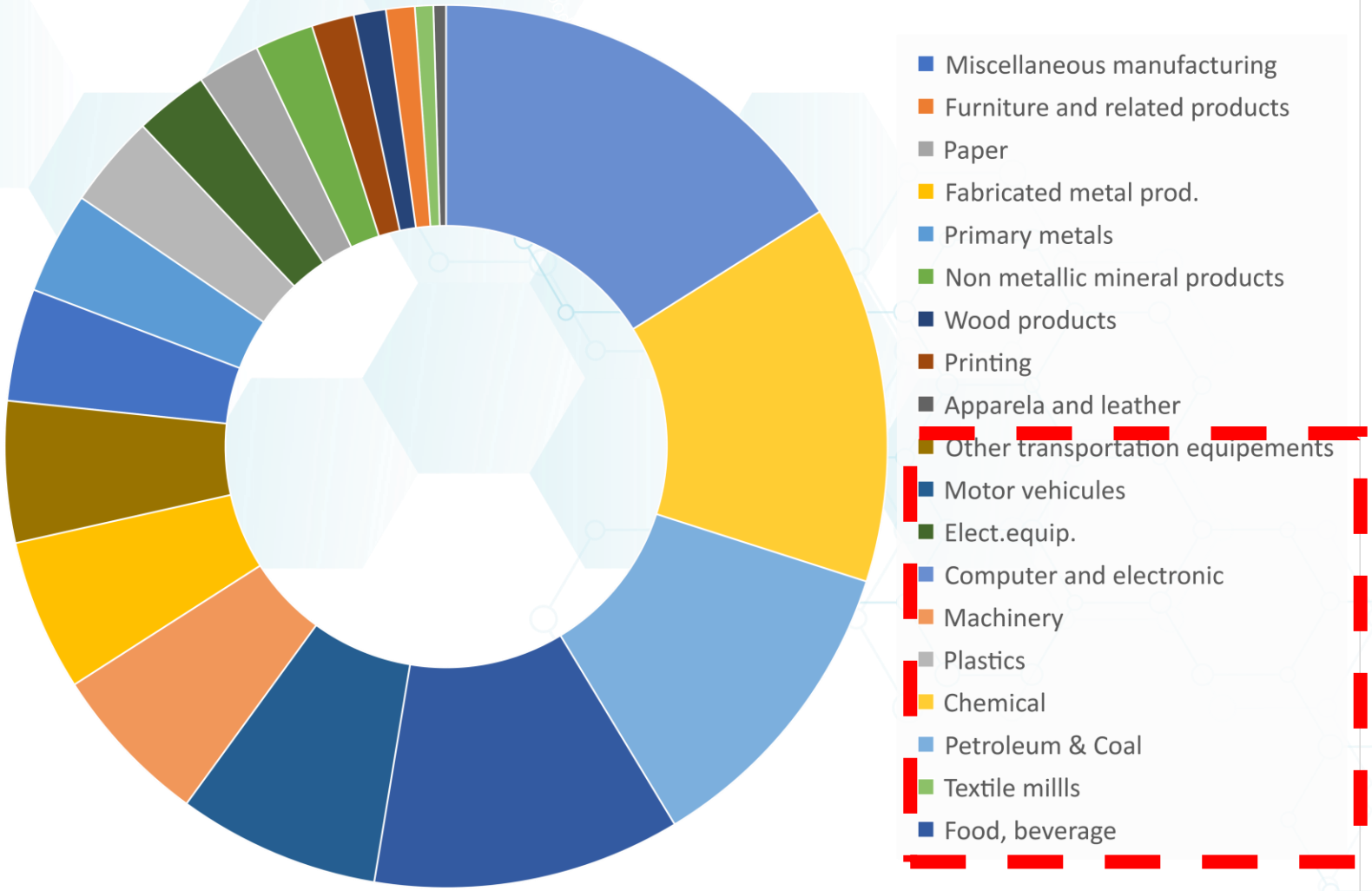
78 % of the US industries rely on fluoropolymers and will be impacted by the proposed restriction



Source: Manufacturing Industry Statistics – 2021 - NIST

FPG position on the PFAS REACH restriction

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All PFAS are not the same

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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.

They present a different toxicologic and eco-toxicologic profile from PFAS that can be considered a 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 profile and critical uses.

03 FPG member companies continue investigating and developing R&D programs for the advancement of fluoropolymer production technologies allowing for a transition away from using PFAS-based polymerization aids with reduced fluorinated residue levels and meeting all performance requirements.

04 However, during this transition, it may be necessary to continue using fluorinated polymerization aids until non-PFAS polymerization aids are developed. Therefore, relevant derogations for fluoropolymers should be provided.

Fluoropolymers and EU strategic objectives

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Fluoropolymers are used in critical applications that help deliver strategic European climate and industrial objectives. They are an indispensable driver of the European Green Deal and Digital transition

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

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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.

Life-cycle concerns

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A total ban on fluoropolymers is not proportionate. Given their benign hazard profile, a general derogation for fluoropolymers should be provided in the proposal.

01 FPG acknowledges regulatory concern related to emissions during manufacturing and at End of Life (EoL).

02 All FPG members have committed to responsible manufacturing principles and already implement them.

03 A total ban on fluoropolymers is not proportionate. The concerns of persistence raised in the restriction proposal can be appropriately managed through the implementation of responsible manufacturing and EoL risk-management practices.

FPG view on the PFAS REACH restriction

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> *By way of derogation, fluoropolymers and applications containing a fluoropolymer shall not be restricted*

- Fluoropolymers are Polymers of Low Concern (PLC) and safe in use - OECD criteria – They are chemically stable, non-toxic, non-bioavailable, non-water soluble and non-mobile materials.

- Significant benefits are generated along the value chain via the use of fluoropolymers. Their stability in combination with these properties, translates to unique, durable, lasting performance enables the development of innovative technologies.

- The fluoropolymer industry is committed to the responsible manufacturing. They are constantly improving and/or developing state-of-art technologies in their manufacturing process and management of environmental emissions.

Tentative timeline of EU PFAS REACH Restriction: 2023-2025

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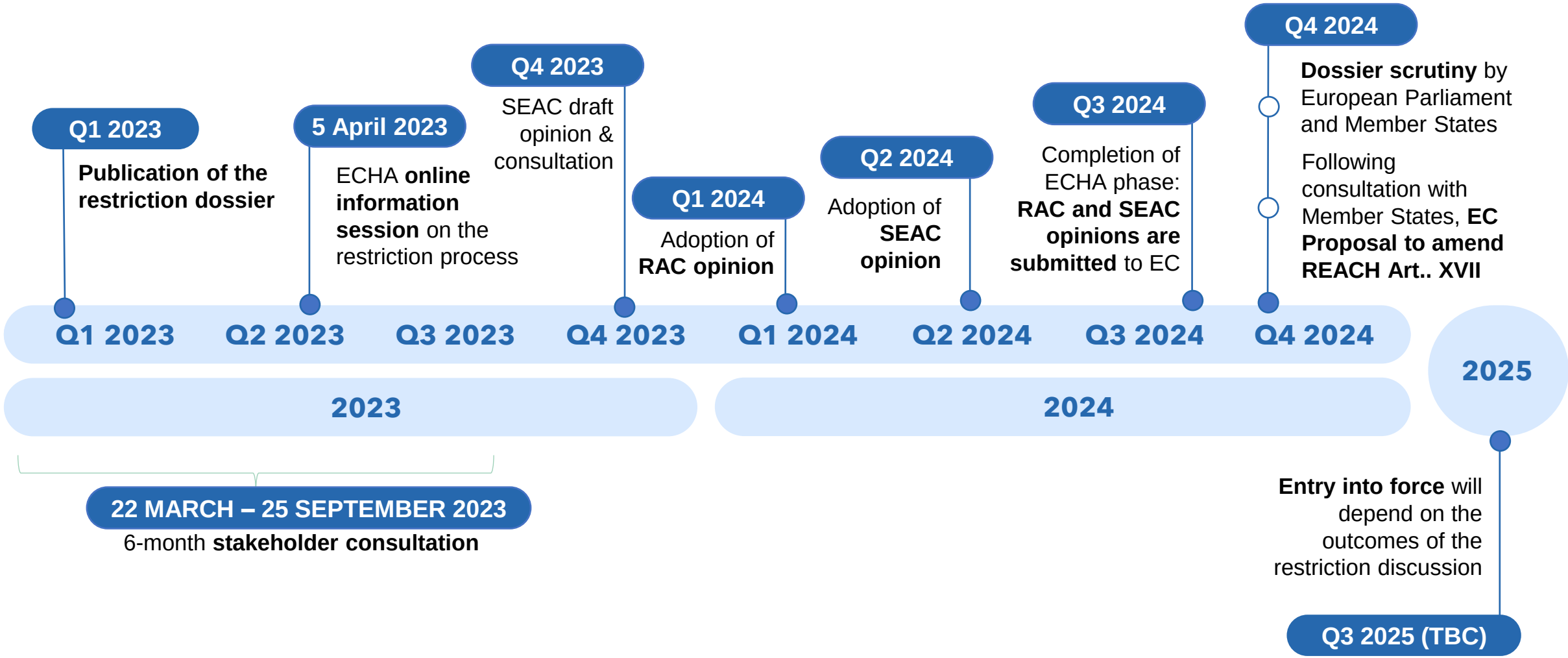

Guidance to the PFAS Public Consultation Response

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Important things to remember when drafting your response

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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.

No first deadline for comments to be submitted to ECHA. However, you are encouraged to submit comments early (e.g. by mid-May) which will give ECHA more time to consider you input. If you have further data to submit you have until 25 September to do so.

What to submit to the public consultation

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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.

Overview of areas to provide information on

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Life-cycle analysis

Manufacturing

Manufacturing Equipment

Does it contain…
- PTFE
- PVDF
- Other?

What product is being manufactured

- Use of FP* processing aids?
- What product are you manufacturing containing FP?

Maintenance

In maintaining your equipment & facility, do you use a FP? e.g.
- Lubricants
- Other? …

Use-phase

Function/ Benefits

- What function does the product containing FP have? Why is the function important?
- What is the lifetime of your product?

Alternatives

- Why are you using FP & not alternative? E.g. there is no alternative, FP delivers best performance, etc.
- Have you tried work with an alternative substance? What was the result?

End-of-life

Fate

- What are the options for your application at EoL?
- Do you have data on emissions that are generated if e.g. landfilled or incinerated

Some things to think about…
- ✓ What emissions are there at the manufacturing stage?
  - Are these well-controlled?
- ✓ What risks or hazards are there from working with FP? E.g. worker safety/health

Some things to think about…
- ✓ 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 standard? If yes, which standards? Do you have any information on the testing process required to meet the standard?

Some things to think about…
- ✓ Do you know the end of life of the product your manufactured?
- ✓ Do you receive from your supplier, or do you provide guidance to your customers on correct disposal?
- ✓ Do you know if your product can be recycled?

Finally, talk and share with us

- Visit our **website** https://fluoropolymers.plasticseurope.org/ to know all the fact and figures

- 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

- Provide us with case studies of vital uses of fluoropolymers in your sector – for publication on the FPG website/LinkedIn