

Fluoropolymers and the PFAS REACH Restriction

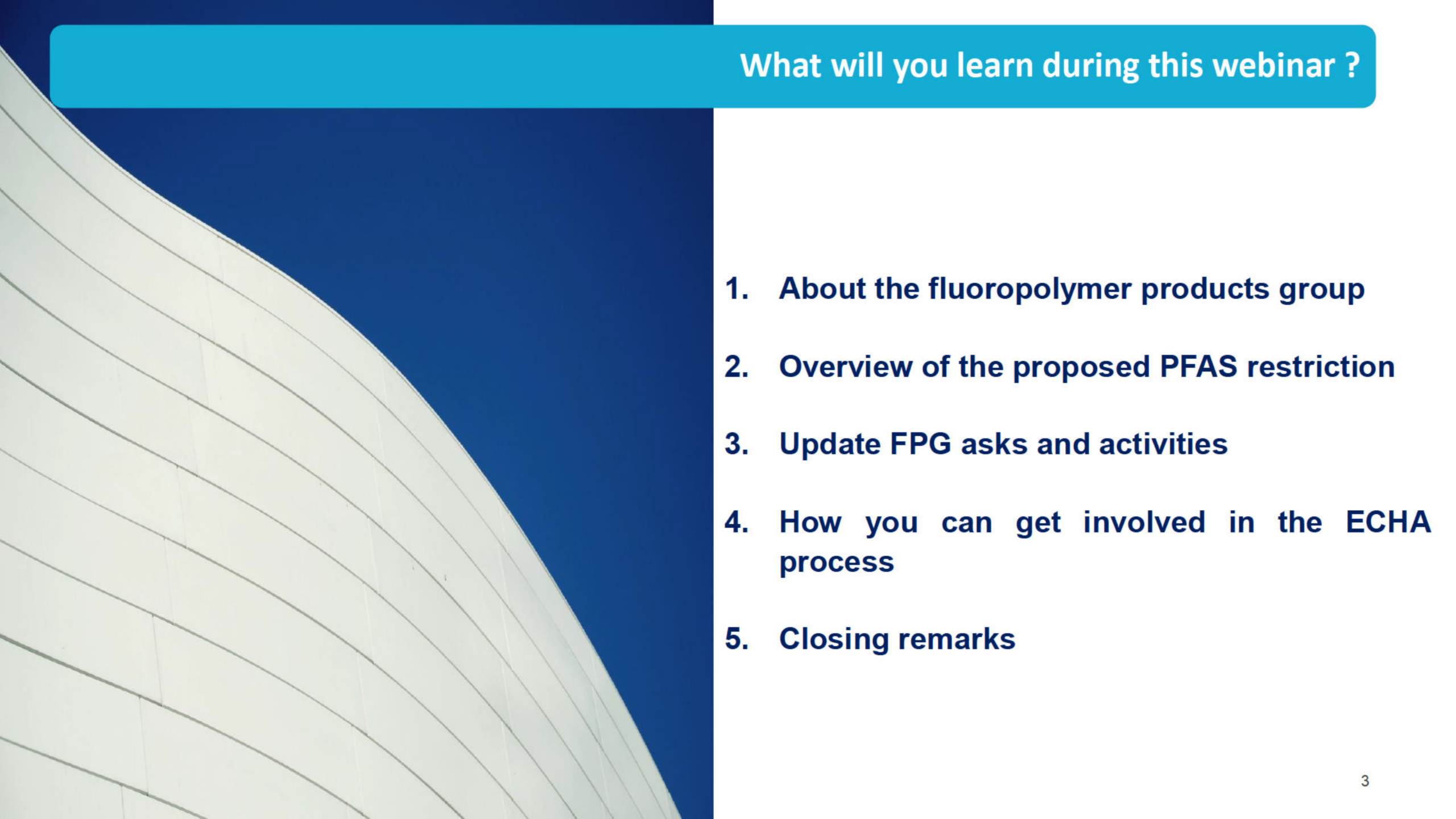
Fluoropolymers Product Group (FPG)
of Plastics Europe

Webinar 13 February 2023



ANNOUNCEMENTS

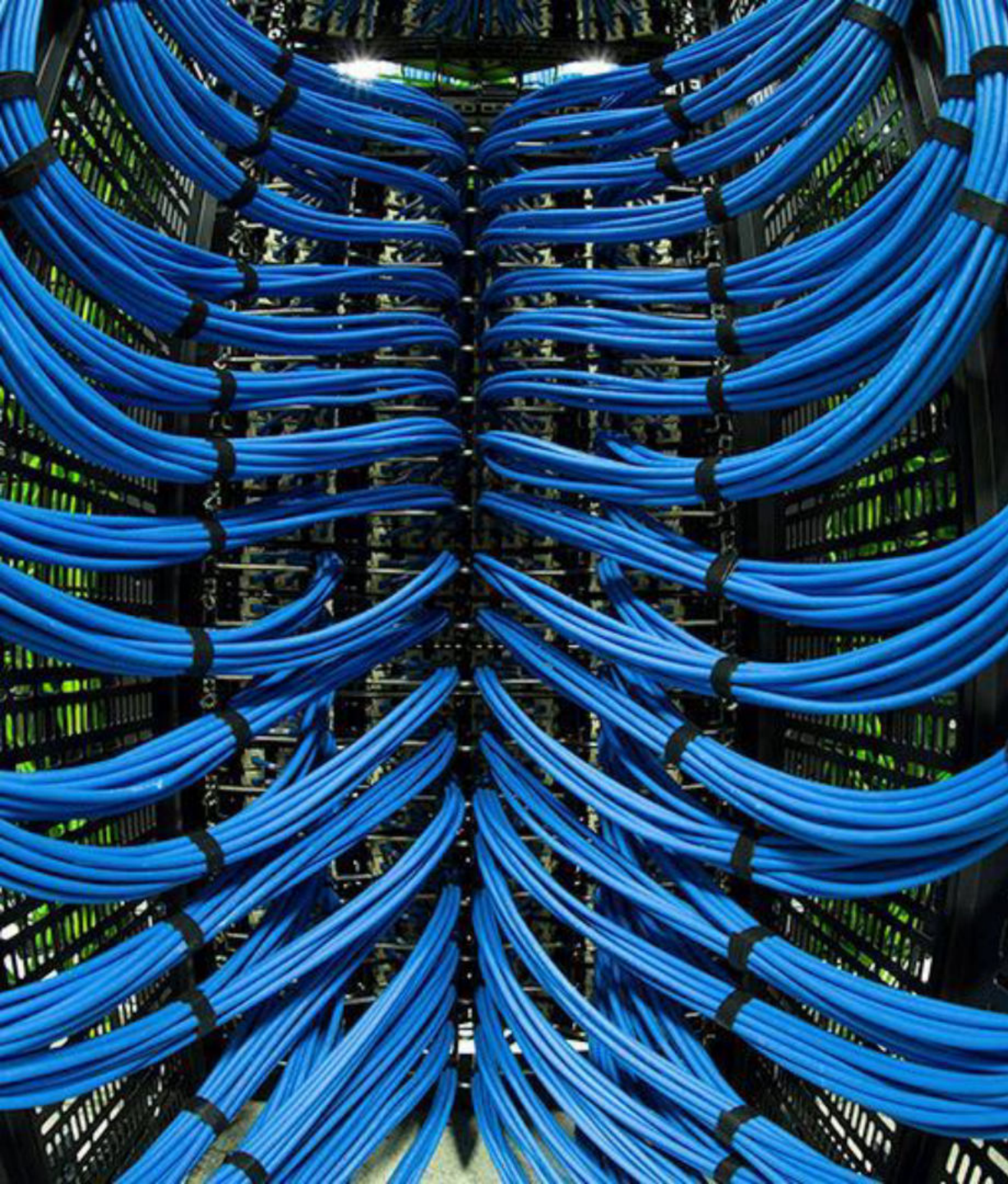
- More than 1800 people from around the world registered for this webinar
- This webinar is being recorded
- Due to the high number of participants all microphones and videos are switched off
- The webinar chat function is open to all participants, you are encouraged to share any questions or comments in the chat
- Please do not post any commercially sensitive information in the chat
- Following the conclusion of the webinar we will share the presentation and a link to the video
- We will also compile all question/comments and look to respond to them in the coming weeks
- Finally, thank you to complete a short survey which will appear on your screen at the end of this webinar!



What will you learn during this webinar ?

1. **About the fluoropolymer products group**
2. **Overview of the proposed PFAS restriction**
3. **Update FPG asks and activities**
4. **How you can get involved in the ECHA process**
5. **Closing remarks**

About the Fluoropolymers Product Group



The Fluoropolymers Product Group (FPG)

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

Overview of the proposed PFAS restriction

What is REACH, 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.

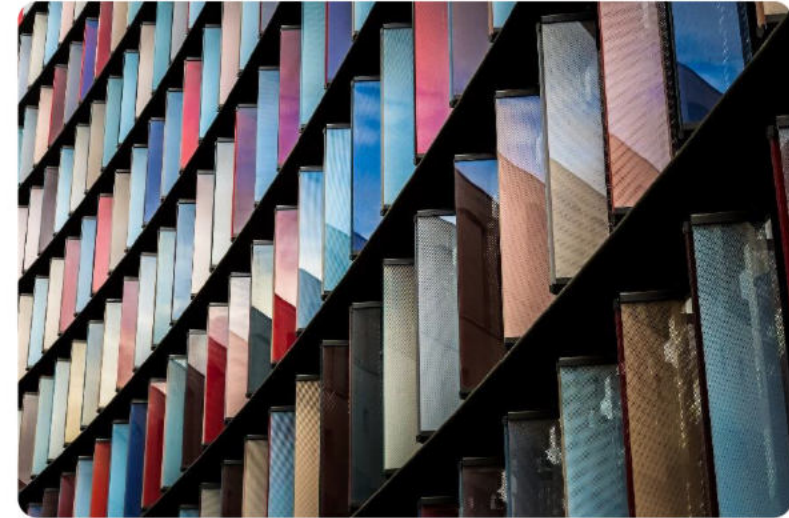
REACH Restriction

- 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.



What is the PFAS REACH restriction?

- Since 2020, the competent authorities of the five countries (Germany, Netherlands, Sweden, Norway, Denmark) have been preparing a REACH restriction dossier for all PFAS. The restriction proposal was submitted to ECHA on 13 January, 2023;
- 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;
- They argue that high persistence is the main concern for all PFAS along with concerns resulting from a specific combination of properties;
- They are also saying that releases of PFAS are considered a risk to the environment that it is not adequately controlled;



- **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 monomers used in fluoropolymer manufacture.
- The dossier submitters propose **a total ban over time on the use of all fluoropolymers** in all applications.



Fluoropolymers should be exempted from any regulatory action under the REACH restriction

- Fluoropolymers can be categorized as PFAS based on their molecular structure. However, their **environmental and toxicological profiles are distinctly different to the majority of other PFAS;**
- Fluoropolymers that meet the OECD Polymer of Low Concern (PLC) criteria are **non-toxic, not bioavailable, non-water soluble and non-mobile molecules** and are deemed as such to have **no significant environmental and human health impacts;**
- Fluoropolymer stability translates to **unique, durable, lasting performance** in many uses and applications. Additionally, the unique durability of fluoropolymers makes them ideal materials that enable innovation.

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

PFAS sectors/applications			
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
Medical devices	Transport	Electronics and semiconductors	Energy sector
Construction products	Lubricants	Petroleum and mining	

Pre-published PFAS restriction proposal – Restriction & Derogations

Sectors proposed for NO DEROGATION	
Applications in cookware, cosmetics, textiles packaging, chrome plating, ski wax, consumer mixtures, MDI propellants, electronics, coatings, films, tapes, etc This is a non-exhaustive list, please refer to the proposal for the full list	The pre-publication version of the proposal states that given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives, there are a broad range of uses where no derogation from restriction is proposed.

Pre-published PFAS restriction proposal – Restriction & Derogations

Sectors proposed for TIME-LIMITED DEROGATION

Polymerisation aids in the production of polymeric PFASs (the proposal however, excludes from such a derogation the use of polymerisation aids in the manufacturing of PTFE, PVDF and FKM). Some technical textiles; food contact materials, fire suppressing agents, insulating gases, some implantable medical devices, tubes and catheters, additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry; refrigerants in mobile air conditioning (MAC)-systems, refrigerants in some transport refrigeration, proton-exchange membrane (PEM) fuel cells, some lubricants, fluoropolymer applications in the mining and petroleum sector, etc

This is a non-exhaustive list, please refer to the proposal for the full list

The proposal states that given the sufficiently strong evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, a time-limited derogation is proposed.

Pre-published PFAS restriction proposal – Restriction & Derogations

Sectors proposed for POSSIBLE DEROGATION

Inconclusive evidence: *Conflicting evidence from one or different lines of evidence, where conflicts cannot be explained and reconciled*

Examples include: Textiles for the use in engine bays for noise and vibration insulation used in the automotive industry; non-stick coatings in industrial and professional bakeware; hard chrome plating; foam blowing agents in expanded foam sprayed on site for building insulation; industrial and professional use of solvent-based debinding systems in 3D printing; propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required, hernia meshes; wound treatment products, cleaning and heat transfer: engineered fluids for medical devices, rigid gas permeable (RGP) contact lenses and ophthalmic lenses; membranes used for venting of medical devices; etc

This is a non-exhaustive list, please refer to the proposal for the full list

There are proposals for potential derogations that require further investigation/presentation of evidence before making a decision on whether to grant them.

Sectors proposed for TIME-UNLIMITED DEROGATION

There are also a number of time un-limited derogations from restriction: PFAS used as active substances in Plant Protection Products (PPP), Biocidal Products (BP) and human and veterinary Medicinal Products (MP), as these are addressed under their respective regulations.

Update FPG tasks and activities

What is FPG doing?

- FPG is analysing the proposal, and preparing for the start of the public consultation. In particular, we are looking at the proposed regulatory action for fluoropolymers and their uses
 - For example, learning which fluoropolymers uses are proposed for a time-limited derogation, or not proposed for derogation at all
- We are also interested to know how the proposal meets the legal requirements of a REACH restriction
 - The proposal must establish that the manufacture, placing on the market or use of a substance "poses a risk to human health or the environment that is not adequately controlled and needs to be addressed"
- FPG is actively engaging with downstream users to raise awareness on the restriction proposal through webinars and stakeholder meetings and via communication (papers, social-media posts, newsletter etc)
- We are carrying out a socio-economical analysis (SEA) on fluoropolymers applications – you will shortly receive a questionnaire (*more information later in the presentation*)



We coordinated an industry letter to regulatory authorities

- In January 2023, an open letter to the five national competent authorities (DE, DK, NL, NO, SE) - submitters of the restriction dossier & the Commissioner Virginijus Sinkevičius (Environment, Oceans and Fisheries) and Commissioner Thierry Breton (Internal Market).
- The letter was co-signed by 21 association and stakeholders.

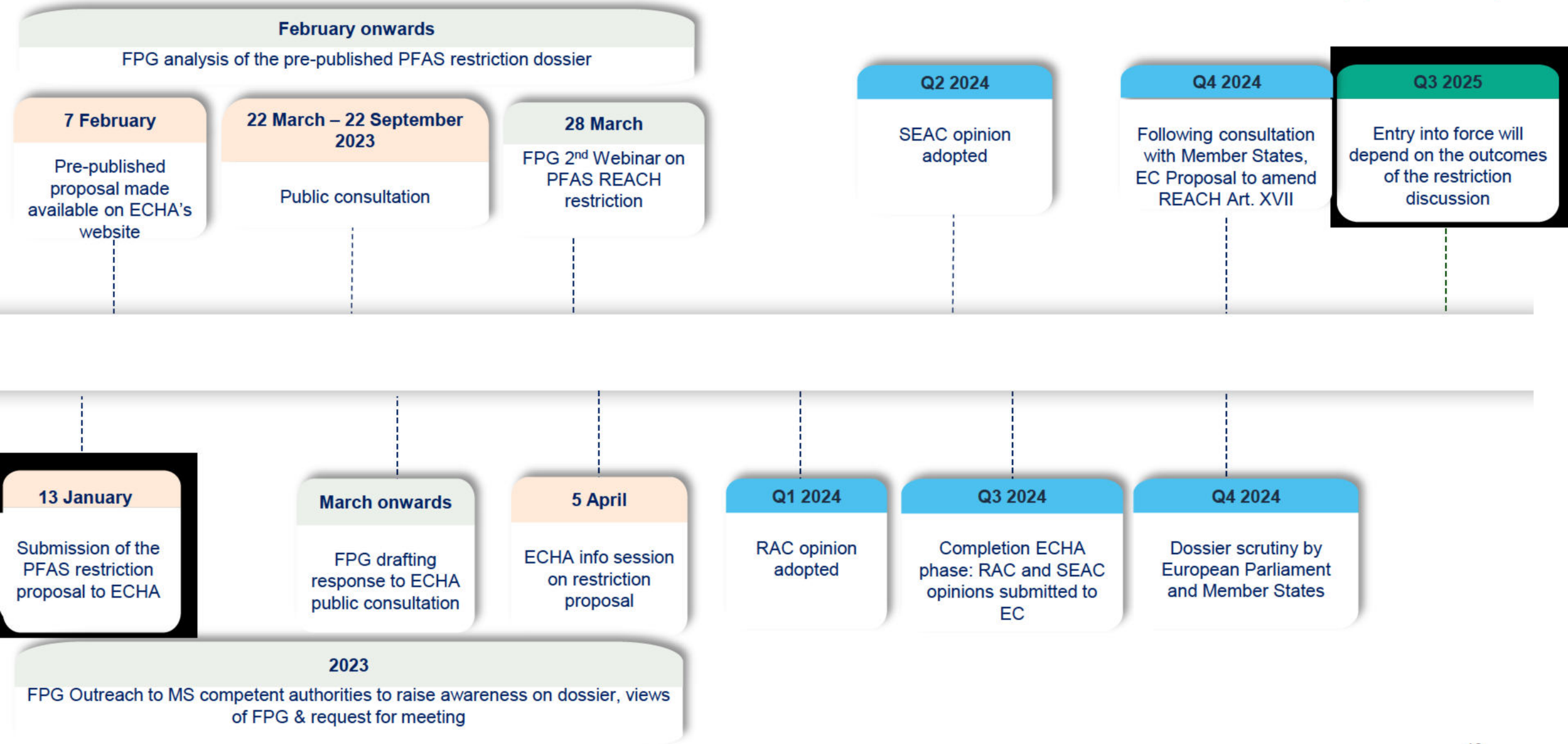
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A PFAS REACH restriction proposal that differentiates between fluoropolymers and other PFAS, and acknowledges their safe use and importance to applications should result in an exemption from any regulatory action under the REACH restriction.

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The PFAS REACH restriction timeline



How you can get involved in the ECHA process

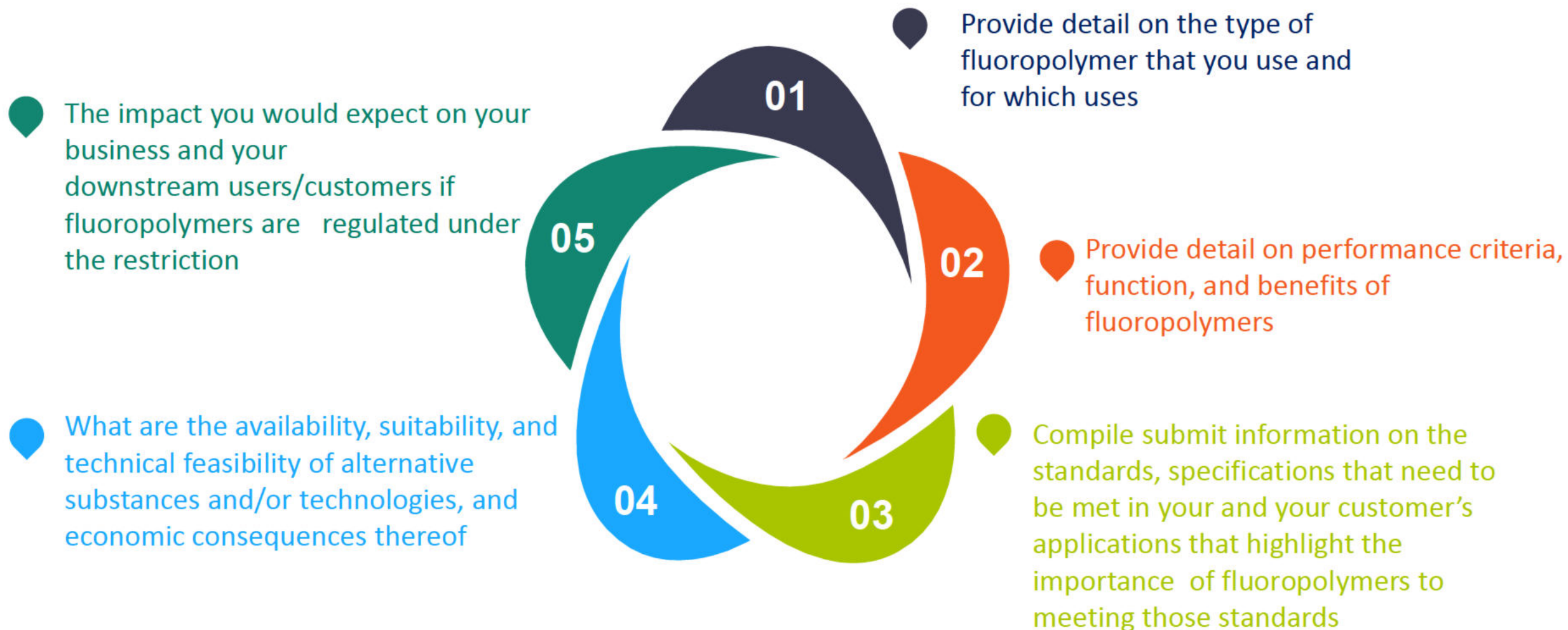


- **Take your time to read the proposal**, note where your products are mentioned and what regulatory action is proposed (derogation, no-derogation?):
 - Look especially at the table on pages 4-8 which is the proposed restriction;
 - You can also refer to Table 9 (starting on page 115) which presents a summary of proposed derogations;
 - Do you see statements related to fluoropolymers or their use that seem incorrect? Note these down too
 - What alternatives are stated can replace fluoropolymers in your product, do you agree?
 - Did you expect to see your application in the proposal but it is not there? Please flag this to FPG!
- **Engage with your relevant trade association** (at national, European, state or federal level – depending where you are located) to understand if they will be actively engaged in responding to the public consultation
 - Continue to follow the FPG through our media channels and webinars
- Contact your fluoropolymers supplier to understand how they are working to defend fluoropolymers against restriction

- **Prepare for the public consultation starting on 22 March**
 - In Table 9, if your use is marked 'for reconsideration' during the public consultation ECHA will require further evidence from stakeholders in order to make an informed opinion – you will need to consider sending supplementary evidence to defend your use
 - Even if your use is proposed for derogation, you should still comment. These derogations are time limited and there may be evidence not known to the dossier submitter that could influence the length of the derogation
 - If your use is not proposed a derogation, you need to submit scientific and socio-economic evidence to persuade RAC & SEAC that support your use should be derogated
- **You are kindly requested not to contact the Commission.**
 - They have no part to play in the current stage of the restriction process. Only when ECHA has completed their work will the Commission take charge of the dossier

Our advice to you 3/3

Information you should submit during the public consultation



FPG socio-economic impact assessment (SEIA)

- In anticipation of this public consultation, and of subsequent advocacy activities communicating the positions of fluoropolymer manufacturers and users, we have engaged an external consultant (ERM) to prepare a socioeconomic impact assessment (SEIA) on the importance of fluoropolymers to the EU economy and society. This SEIA will be used to support FPG's members' arguments for continued use of fluoropolymers in products and applications critical for the EU economy and society.
- To prepare the SEIA, a questionnaire was developed to provide information on the substances, uses and products, as well as on the suitability of potential alternatives.
- If you are interested to this questionnaire, let's know or/and encourage your trade association to reply to this questionnaire.



Upcoming FPG Webinar



FPG upcoming webinar – 28 March (invite to be sent shortly)

At our next webinar (taking place shortly after the start of the public consultation) we will:

- Provide you with an indepth feedback on the PFAS REACH restriction and how it impacts on fluoropolymers
- Will take you through in detail how to respond to the public consultation
- Update you on the PFAS REACH restriction work of FPG

Closing Remarks



Talk and share with us

- Visit our **website** <https://fluoropolymers.plasticseurope.org/> 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
- Provide us with case studies of vital uses of fluoropolymers in your sector – for publication on the FPG website/LinkedIn





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