

Fluoropolymers and a Universal PFAS REACH Restriction

Webinar organized by the Fluoropolymers Product
Group (FPG) of Plastics Europe

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1. About the Fluoropolymers Product Group (FPG)



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.**

2. PFAS REACH Restriction 2023

What is REACH? and 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.

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.
- 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 the persistence of all PFAS poses an unacceptable risk to the environment and humans.
- The competent authorities intend to make no differentiation between different types of PFAS and their toxicological profiles.

PFAS REACH restriction – FPG's position

FPG's position

- Fluoropolymers **should be exempted from any regulatory action under the REACH restriction**
 - Fluoropolymers can be categorized as PFAS based on their 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' criteria are **non-toxic, not bioavailable, non-soluble and immobile 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.

Who are the key actors in the PFAS REACH restriction process? 1/2

Dossier Submitter

- The 5 competent authorities will propose the restriction

ECHA

- Once formally accepted by ECHA, the restriction proposal will be worked on by **ECHA's Committee for Risk Assessment (RAC)** which will give its opinion on whether the suggested restriction is appropriate in reducing the risk to human health or the environment
- The **Committee for Socio-economic Analysis (SEAC)** prepares an opinion about the socio-economic impacts of the suggested restrictions, taking into account the comments and socio-economic analyses submitted by interested parties.

European Commission

- Once completed, the two opinions of ECHA's committees are submitted to the Commission which will then take a balanced view of the identified risks and of the benefits and costs of the proposed restriction.

Who are the key actors in the PFAS REACH restriction process? 2/2

Member State authorities for REACH

- Following the drafting of the restriction proposal by the Commission the draft is shared with Member States sitting in the REACH Committee for their feedback.

European Parliament

- Once the Member States and Commission have an agreed text, this is sent to the Parliament for scrutiny. The Parliament does not have the right to amend the proposal, only reject or accept it.

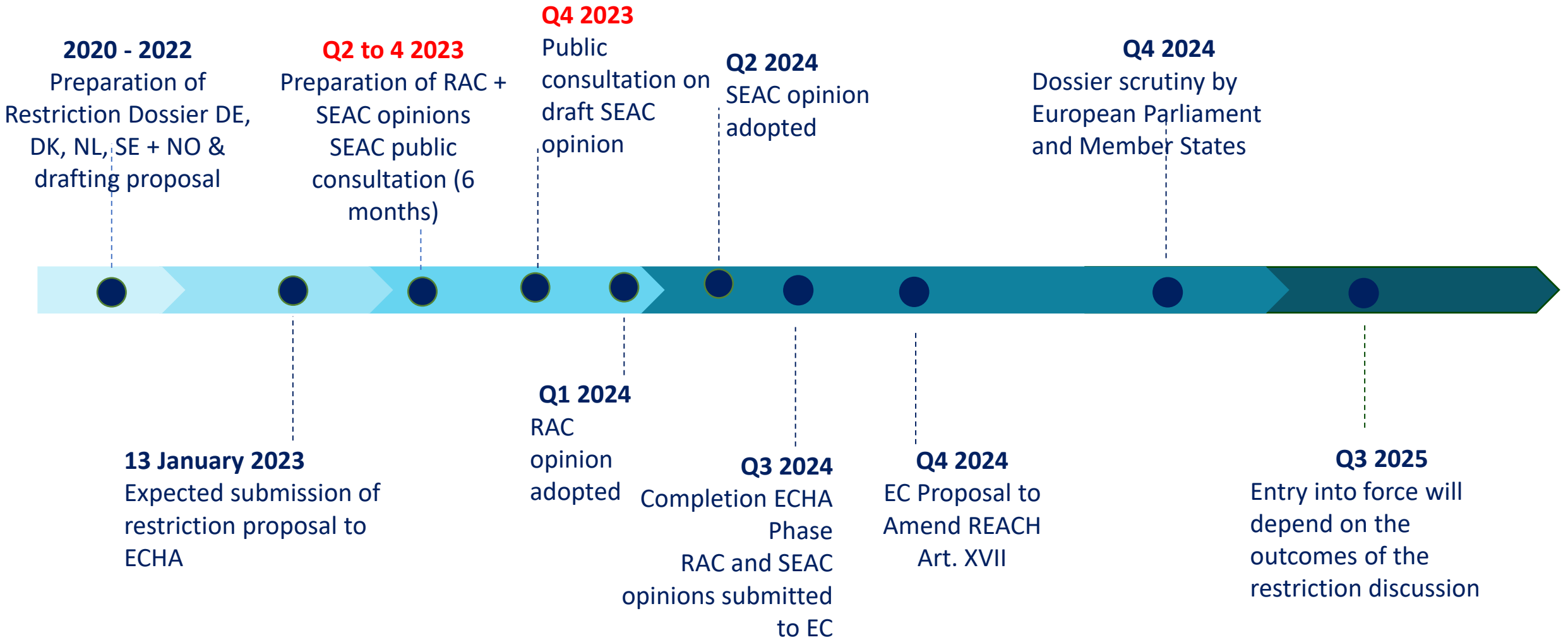
Stakeholders/Interested Parties

- Stakeholders include manufacturers, users, associations, importers, EU Member States, 3rd countries, citizens, NGOs etc. All stakeholders have the right to submit comments during the formal public consultations in the restriction process.

FPG regulatory-focused actions – up to now & in the future

- Development of a **Regulatory Management Option Analysis (RMOA)** – 2020
 - Showing various options how fluoropolymers might be regulated or other
 - Publicly available on FPG website
- **Socio-Economic Assessment**
 - 2017 and updated in 2022
 - Information available on FPG website
- **Responses to 5 CA calls for evidence** in 2020 and 2021
- Outreach to **Member State Competent Authorities, ECHA and the Commission**
 - To share the views of FPG on fluoropolymers and the PFAS regulatory work
- FPG **Responsible Manufacturing** commitment
 - FPG Members have committed voluntarily to responsible manufacturing principles
- **Socio-Economic Analysis (SEA)**
 - Related to topics mentioned on slide 14
 - For submission to ECHA (and the Commission) in 2023

What is the PFAS REACH restriction timeline



Text in red = action by stakeholders

Public consultations under REACH – How stakeholders can get involved & what to say 1/2

How you can get involved to share your views

- The PFAS REACH restriction proposal, and the SEAC draft opinion are both subject to public consultation. The consultations can be accessed via the ECHA website.
- Once the dossier is formally published by ECHA, interested parties have a 6-month window to comment on the restriction proposal.
- Following this 6-month consultation, the SEAC will make public its draft opinion which will also be open to consultation from interested parties (for 60 calendar days).
- **We highlight recommend you begin preparing your submission to the consultation by gathering the following data...see next slide...**

Public consultations under REACH – How stakeholders can get involved & what to say 2/2

What you should submit to ECHA 6-month consultation

In particular, we believe you are well-placed to provide Information related to:

- provide detail on the type of fluoropolymer that you use and for which uses;
- performance criteria, function, and benefits of fluoropolymers;
- submitting information on the standards/specifications that need to be met in your/your customer's applications that highlight the importance of fluoropolymers to meeting those standards;
- the impact you would expect to your business and your downstream users/customers if fluoropolymers are regulated under the restriction;
- what the availability, suitability, and technical feasibility of alternative substances and/or technologies, and economic consequences thereof.

3. Getting involved

Summary – get involved in defending fluoropolymers

- **A restriction on PFAS has the potential to inflict substantial negative impact on the fluoropolymers industry and downstream uses.**
- In 2023, the Fluoropolymers Product Group encourages you to **respond to the ECHA public consultation** to present scientific and socio-economic data that can help prevent possible unjustified restriction of fluoropolymers.
- We would also like to continue to **work with you in reaching out to Member State Competent Authorities** to share the views of industry on fluoropolymers and the PFAS REACH restriction.
 - Can you help facilitate the **exchange of information with you national authorities?**
 - You are welcome to contact us directly if you have any questions or can propose assisting us in the advocacy work during 2023
- We will continue to **organise webinars and events during 2023**, raising the visibility of the importance of fluoropolymers.

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 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



Questions and Answers

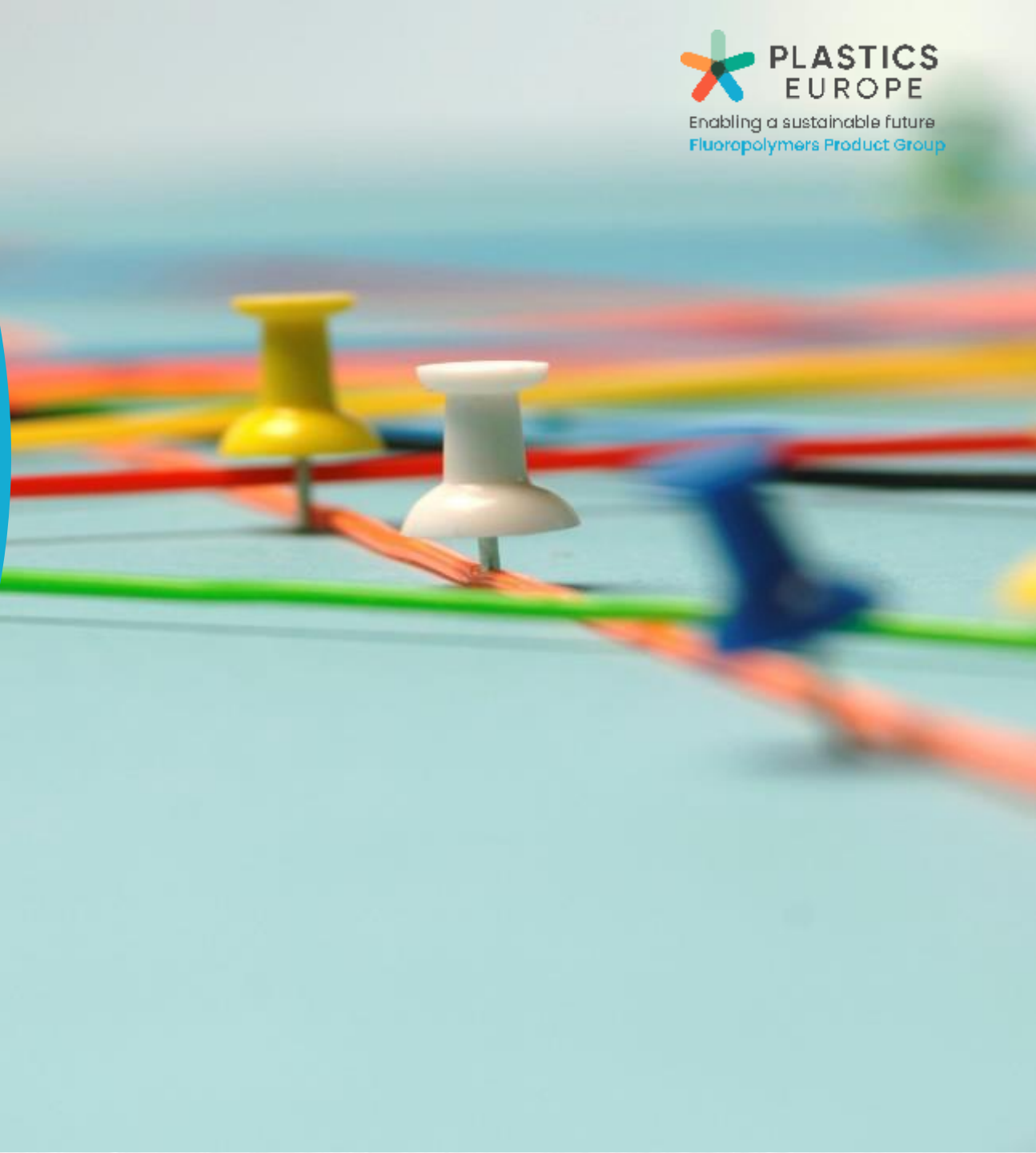
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Back up slides



Fluoropolymers: Uses in Cutting-Edge Economic Sectors



Chemicals and power

Corrosion prevention saves hundreds of millions of € each year in the EU.



Transport

Fluoropolymer fuel hoses enable fuel savings and reduce damage from emissions, worth ~ €140m per year in EU.



Renewable energy

PV module production efficiency increases which saves €40m – €90m each year in the EU.



Electronics

Critical in semiconductor manufacturing, enabling progress in IT that has generated trillions of € globally in the last 20 years.



Medical applications

Reduces the risks of failure, cross-infections and clogging of medical equipment.



Food and Pharma

Safer and cheaper food and pharma by preventing contamination and material failure

How are Fluoropolymers different to other PFAS

- Per- and polyfluoroalkyl substances (PFAS) are a **huge and diverse group** of chemical compounds.
- **Despite their chemical structure, fluoropolymers are different to other PFAS** and have specific toxicological and environmental profiles.
- **A panel of leading PFAS scientific experts concluded in 2022, that the lack of knowledge** about exposure, dose/body-burden-response relationships, relevant health effects, mode(s) of action, and potential interactions, **does not allow for a science-based grouping of PFAS for the purposes of human health risk assessment**

* “Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts” JK Anderson et al. October 2022.
<https://www.sciencedirect.com/science/article/pii/S0273230022001131>



How are Fluoropolymers different to other PFAS

- A 2022 [study](#)* shows that **96% of the global commercially available fluoropolymers** meet the **OECD polymers of low concern (PLC) criteria**. They possess distinct physical, chemical and biological properties and **should not be grouped with other PFAS for hazard assessment or regulatory purposes**.
- **Fluoropolymers that meet the OECD PLC criteria** are non-toxic, bio-compatible, non-soluble and immobile molecules.
- These studies demonstrate the **insignificant risk** fluoropolymers have on human health and the environment during the intended use phase, according to internationally recognized criteria.

* "A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and Fluoroelastomers" Stephen H. Korzeniowski et al. 9 June, 2022 <https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4646>

