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Fluoropolymers Product Group

Fluoropolymers and the proposed PFAS REACH Restriction

Fluoropolymers Product Group of Plastics Europe

September 2022

Per- and polyfluoroalkyl Substances (PFAS) REACH Restriction Timeline

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2020 - 2022
Preparation of Restriction Dossier DE, DK, NL, SE + NO & drafting proposal

Q1 2023
Deadline to submit restriction proposal to ECHA and ECHA dossier conformity check

Q2 to 4 2023
Preparation of RAC + SEAC opinions
SEAC public consultation (6 months)

Q1 2024
SEAC and RAC opinion adopted

Q2 2024
Completion ECHA Phase RAC and SEAC opinions submitted to EC

Q4 2024
Dossier scrutiny by European Parliament and Member States

Q4 2024
EC Proposal to Amend REACH Art. XVII

Q3 2025
Entry into force will depend on the outcomes of the restriction discussion

★ We are here

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.
- **96% of the global commercially 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 and they are deemed as such to have **insignificant environmental and human health impacts**.

FPG View on Grouping all PFAS in a PFAS REACH Restriction

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> *The Fluoropolymers Product Group believes that regulating all PFAS as one homogenous group may result non-replaceable fluoropolymer substances being unjustly banned from critical applications with high societal value.*

- Although fluoropolymers can be categorized as PFAS based on their structure, their properties are distinctly different from other PFAS substances and as such, this broad and diverse family of substances should not be grouped all together.
- It is not scientifically justified to classify inert solids, salts, liquids and gases in a single class, where properties like vapor pressure, environmental partitioning, hydrophobicity / lipophilicity, aqueous solubility and hazard itself, as well as surface and material properties vary greatly.
- Grouping based on well-established criteria such as long-chain vs short-chains, polymeric vs. non-polymeric substances is necessary for regulatory measures to be scientifically sound.

Grouping of PFAS – A View from the Scientific Community

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A panel of leading PFAS scientific experts convened to provide insight and guidance on PFAS grouping for the purposes of protecting human health. Most of them agreed that "all PFAS" should not be grouped together for risk assessment purposes, that persistence" is not sufficient for grouping PFAS for the purposes of assessing human health risk, agreed that it is inappropriate to assume equal toxicity/potency for PFAS without confirmatory information.

Challenges on grouping

- No global harmonized definition of PFAS exists, which is problematic for risk assessment purposes.
- Toxicity, bioaccumulation, toxicokinetics, and exposure profiles could vary among PFAS. Those characteristics should be considered when assessing human health risk. Similarly, grouping all PFAS together as "persistent" is not supported as practical nor appropriate for assessing human health.
- Most PFAS risk assessments will need to employ substantial assumptions and defaults. These assumptions are often multiplicative and can lead to overestimates of both potency and exposure, and therefore, over-regulation.

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THE FLUOROPOLYMER PRODUCTS GROUP COMMITS TO RESPONSIBLE MANUFACTURING PRINCIPLES

The fluoropolymer industry, represented by the **PlasticsEurope Fluoropolymer Products Group**, is committed to develop and implement innovative solutions to minimize the environmental footprint associated to fluoropolymer production and to reduce their potential emissions, based on the Best Available Techniques (BATs).

The fluoropolymer industry has adopted and will continue to develop new technologies and to invest in R&D to reach this goal. Therefore, the Fluoropolymer Products Group member companies commit voluntarily to the following **responsible manufacturing principles.**

FPG'S PRINCIPLES

1 BEST AVAILABLE TECHNIQUES

Continue to maintain, improve and/or develop Best Available Techniques in the manufacturing processes and management of environmental emissions related to fluoropolymers.

2 CONTAINMENT, CAPTURE & RECYCLE TECHNOLOGIES

Maintain and continuously improve and develop containment, capture, and recycle technologies to minimize emissions into the environment from PFAS substances intentionally and non-intentionally occurring during fluoropolymer manufacturing processes including fluorinated raw materials, fluorosurfactants, monomers, solvents, intermediates, and process chemicals as well as by-products.

3 SAFE SUBSTITUTION OF PFAS-BASED POLYMERIZATION AIDS

Intensify our efforts to investigate and develop R&D programs for the advancement of technologies for the replacement of PFAS-based polymerization aids during fluoropolymer production. Where proven technically feasible, environmentally sound, and viable at an industrial and commercial scale, FPG commits to replace the use of PFAS as polymerization aids.

4 ENHANCED RECYCLABILITY AND REUSABILITY

Continue to proactively work with its downstream users to increase recyclability and reuse of its products and develop R&D programs in line with the objectives of a circular economy.

5 ENSURE WORKERS MINIMAL EXPOSURE TO CHEMICALS

Continue to minimize the exposure levels for workers to chemicals used in the fluoropolymers manufacturing process.

6 MONITOR COMMITMENTS THROUGH THIRD-PARTY ASSESSMENT SYSTEMS

Introduce or expand already existing third-party assessment programs to help verify progress in members' commitments.

FPG COMMITMENTS

Each member company takes actions to implement these responsible manufacturing principles. In addition, the Fluoropolymer Products Group members aim to demonstrate progress on these actions by reporting on their achievements. As a first step, the Fluoropolymer Products Group is currently working on a review of wastewater related monitoring activities. The objective is the identification of best practices and possibly recommendations for procedural changes.

7 OPEN AND TRANSPARENT DIALOGUE WITH KEY STAKEHOLDERS

Continue to engage in an open and transparent dialogue with policymakers, employees, NGOs and other key stakeholders.

Socio-Economic Assessment under REACH SEAC will be looking at…

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Impact of…a proposed restriction on...industry (e.g. manufacturers and importers)
…impact on all other actors in the supply chain, e.g. commercial consequences e.g. impact on investment, research and development, innovation, one-off and operating costs (such as compliance, transitional arrangements, changes to existing processes, reporting and monitoring systems, installation of new technology)
Impacts … **on consumers**. E.g. product prices, changes in composition or quality or performance of products, availability of products, consumer choice, as well as effects on human health and the environment to the extent that these affect consumers
Social implications … e.g. job security and employment
Availability, suitability, and technical feasibility of alternative substances and/or technologies, and economic consequences thereof, and information on the rates of, and potential for, technological change in the sector(s) concerned.
Wider implications on trade, competition and economic development (in particular for SMEs and in relation to third countries) … This may include consideration of local, regional, national or international aspects
…**proposals for other regulatory or non-regulatory measures that could meet the aim of the proposed restriction** (this shall take account of existing legislation). This should include an assessment of the effectiveness and the costs linked to alternative risk management measures
…the **benefits for human health and the environment as well as the social and economic benefits** … e.g., worker health, environmental performance and the distribution of these benefits, for example, geographically, population groups

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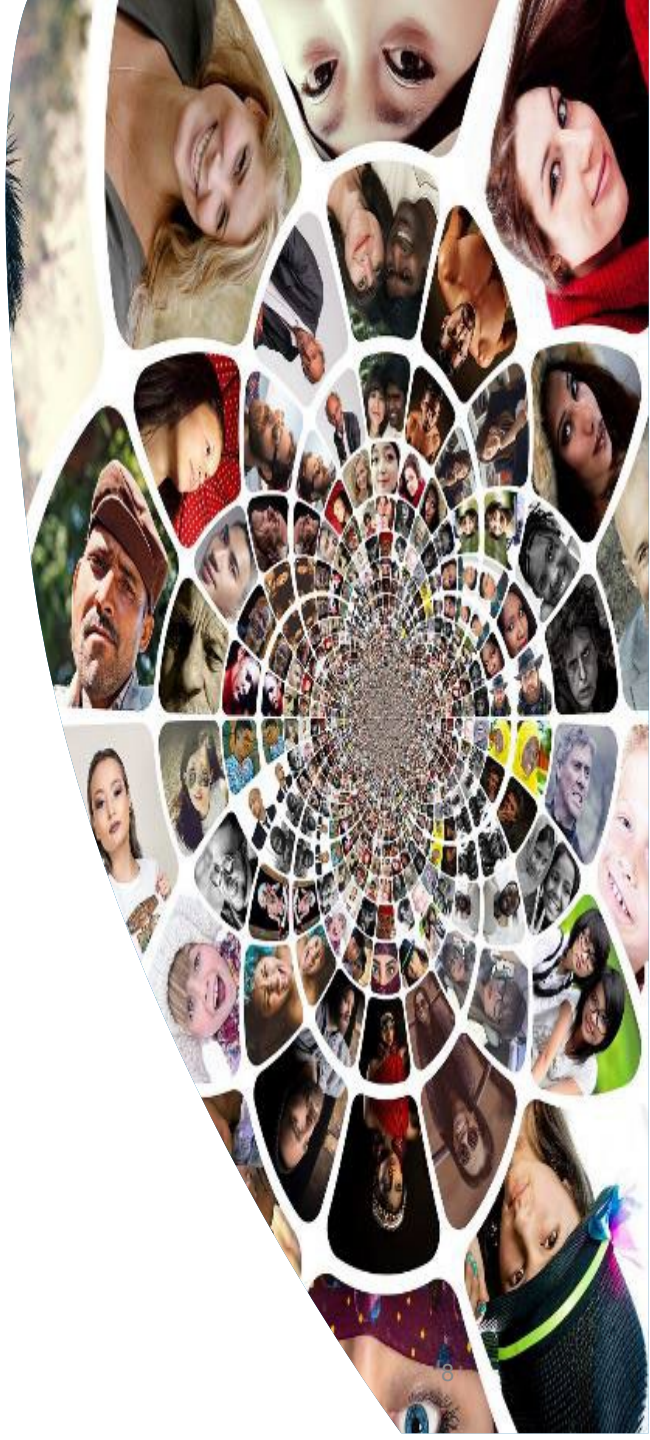

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A Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers - Society of Environmental Toxiology and Chemistry, 9 June 2022

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