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# Regulatory Management Option Analysis

# (RMOA)

# Fluoropolymers Product Group of Plastics Europe

**FPP4EU**

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# What is a Regulatory Management Option Analysis (RMOA)?

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The purpose of an RMOA is to evaluate all the possible Regulatory Management Options (RMOs) that could be selected to address concerns related to a chemical substance or group of substances, and to identify the most appropriate RMO in terms of ***effectiveness*** and ***proportionality***.

The methodology used to develop this RMOA is based on a variety of sources such as a tailored RMOA questionnaire delivered to manufacturers, importers, and downstream users (DUs) within the European supply chain, one-on-one calls with FPG Members, scientific literature review related to PFAS and FPs, and a Socio-Economic Analysis (SEA) on fluoropolymers (FPs), amongst others.

# Consideration of the Possible Regulatory Management Options

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| RMO | Screening result | Considered for further evaluation? |
|---|---|---|
| Voluntary Industry Initiatives to reduce risks at manufacture | Relevant, it could help in addressing concerns | YES |
| Harmonised Classification (CLH) under CLP | Not relevant, FPs themselves have a low toxicological profile | NO |
| Substance Evaluation under REACH | Not relevant, not applicable to polymers | NO |
| Substance Registration under REACH | Not relevant, not applicable to polymers | NO |
| Restriction under REACH | Relevant, due to the potential inclusion of FPs in the REACH PFAS restriction | YES |
| SVHC selection and Candidate Listing | Not relevant, SVHC identification would not address potential concerns | NO |
| Authorisation under REACH | Not relevant, particularly when restriction is already under discussion | NO |
| Other EU legislation on specific sectors of use | Not relevant, particularly if other RMOs on manufacture are implemented | NO |
| Other EU legislation dealing with waste and end-of-life | Relevant, this could help to address concerns out of scope of other RMOs | YES |

# Regulatory Management Options Considered by ChemService

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**RMO 1**: full restriction leading to a practical ban or elimination of FP manufacture and use across the EU.

**RMO 2**: partial restriction including a derogation of FP manufacture and uses but a ban on the use of PFAS polymerization aids for the manufacture of FPs.

**RMO 3**: restriction including a broad derogation to allow continued manufacture and use of FPs in the EU, linked to a Voluntary Industry Initiative which guarantees that industry will address the situations of concern related to manufacture and use of FPs.

**RMO 4**: update of existing EU regulations on waste that would impact the end-of-life treatment of FP products and articles.

# Outcome of the RMOA

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> *The result of the RMOA concluded that **the best regulatory option** to deal with concerns from FPs would be a combination of RMOs 3 and 4*

- **A derogation of FPs** and relevant **monomers** from the PFAS REACH restriction **should be granted.**
- The **use of PFAS-based polymerization aids** for the manufacture of FPs **should be allowed** by the regulators. Industry, however, would need to commit to efficiently address the concerns related to the manufacture and purity of FPs placed on the EU market
- EU legislation dealing with industrial emissions and waste should be reviewed and updated **to address any risk derived from the disposal of FPs** and from articles containing FPs.

# Key Takeaways of the RMOA 1/2

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> *Chemservice's RMOA concludes that **a full restriction of FPs is not the most effective tool** to meet these objectives set by the five competent authorities*

- A full restriction would **put at risk** key applications that are necessary to ensure **competitiveness** and achieving ambitious EU Green Deal goals.
- Regulatory actions that could lead to limiting the market access for a selected number of types of fluoropolymers could result in the manufacture of any type of these fluoropolymer products becoming **economically infeasible**.
- A full restriction could have **unpredictable consequences** for the critical sectors that rely heavily on fluoropolymers.

# Key Takeaways of the RMOA 2/2

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> *Fluoropolymers are **irreplaceable** in many uses without reliable alternatives*

- There are no alternatives that can replace the combined performance provided by fluoropolymers in "**virtually every critical application in which they are used**".
- Fluoropolymers **are indispensable** for applications in the chemical, electronics, semiconductors, healthcare and transport sectors and the deployment of 5G networks.
- The RMOA study confirms that fluoropolymers are **critical materials for innovation** and are deemed necessary **to achieve the EU goals** on areas like decarbonization, renewable energies or competitiveness in the digital transition.

# Safety of Fluoropolymers During the Use-phase

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> ***96%*** *of the global commercially available fluoropolymers meet or exceed the OECD polymers of low concern (PLC) criteria.*

- Fluoropolymers that meet the OECD PLC criteria are non-toxic, bio-compatible, non-soluble and non mobile molecules and they are deemed as such to have insignificant environmental and human health impacts.
- Fluoropolymers possess distinct physical, chemical and biological properties and should not be grouped with other PFAS for hazard assessment or regulatory purposes.

# End-of-life of Fluoropolymers

## Landfill

Fluoropolymers are chemically, thermally and biologically stable and are not expected to transform to dispersive non-polymeric PFAS when disposed of in a landfill.

## Incineration

Fluoropolymers are mineralized under commercial waste-to-energy incineration operating conditions.

## Recycling

- ✓ In primary and secondary recycling, solid fluoropolymer waste is ground and later fed back into the manufacturing cycle of some fluoropolymer products. In secondary recycling, waste is ground, followed by degradation to approximately 1 % of the original degree of polymerization by using electron beams, gamma rays or thermo-mechanical degradation.

- ✓ In tertiary recycling, solid fluoropolymer is ground, then decomposed into the starting monomers at temperatures above 600 °C to obtain the same chemical components from which the fluoropolymer was manufactured.

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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.

# Chemservice fluoropolymers RMAO key takeaways

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## 1 EU GREEN DEAL

A full PFAS REACH restriction would put at risk key applications that are necessary to ensure competitiveness of the EU industry, as well as the very ambitious goals set forward by the European Green Deal.

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## 2 PFAS REACH RESTRICTION

FPs, along with their relevant monomers, should be derogated from the PFAS REACH restriction. The use of polymerization aids should also be allowed by regulators to enable continued EU manufacture of FPs.

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## 3 INDUSTRY COMMITMENT

The industry should commit to efficiently address the concerns related to the manufacture and purity of FP products and pursue R&D programs for the advancement of technologies allowing for the replacement of PFAS-based polymerization aids and their implementation when proven technically feasible, environmentally sound and viable.

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## 4 EU LEGISLATION

EU legislation dealing with industrial emissions and waste should be reviewed and updated to ensure that adequate technical controls are put in place to minimise any risk

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## 5 COMPETITIVENESS

It is expected that any regulatory action that may lead to limiting the market access for fluoropolymers could result in the complete relocation of this industry outside the EU.

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