PlasticsEurope
Association of Plastics Manufacturers
Fluoropolymers Product Group

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FPG perspectives accompanying the Regulatory Management Option Analysis (RMOA) for fluoropolymers (FPs)

Dear Reader,

On 15 July 2021, five competent authorities confirmed their intentions initially expressed one year ago, to request the limitation of the manufacturing, placing on the market and use of PFAS to ensure a higher level of environmental and health protection in the EU.

PlasticsEurope's Fluoropolymers Product Group (FPG) commissioned the consulting firm ChemService to perform an independent Regulatory Management Option Analysis (RMOA) for fluoropolymers (FPs) to ensure decisions are taken based on scientific facts and evidence.

Chemservice's RMOA concludes that full restriction is not the most effective tool to meet these objectives set by the five competent authorities.

Instead, a combination of

1. restriction including a broad derogation for fluoropolymers supplemented by a Voluntary Industry Initiative which guarantees that industry will address the situations of concern related to manufacture and use of FPs (RMO3) and,

2. an update of existing EU regulations on waste that would impact the end-of-life treatment of FP products and articles (RMO4)

is the most appropriate approach to ensure adequate control of risks, while maintaining a proportionate balance in terms of use of necessary fluoropolymers on the European market.

Therefore, FPG continues to **advocate for the segmentation of the PFAS family of substances** before performing any grouping-based assessment, **placing environmentally stable compounds such as FPs in a separate category**.

1. Scope of the study and data collection

To develop the RMOA, Chemservice has developed a robust methodology, based on a combination of well-known guidance documents from ECHA and using 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 related to PFAS and FPs, and a Socio-Economic Analysis (SEA) on FPs, amongst others.

The analysis resulted in four potential regulatory management options (RMOs) with a detailed screening of each RMO performed. A final score was assigned to each RMO by comparing the expected outcomes of the corresponding regulatory actions.

2. Key takeaways

A. There is no indication in REACH that persistence alone justifies risk management measures.

FPs are not mobile in the environment given their negligible solubility and have been demonstrated to have no systemic toxicity and no bio accumulative. While FPs may meet the REACH definition to be considered persistent, they do not present a hazard to biota or the environment. A full restriction would put at risk key applications that are necessary to ensure competitiveness and achieving ambitious EU Green Deal goals, not to mention resulting risks by losing key functionalities that FPs play in ensuring safety and protection in industry and consumer applications.

B. 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. **A derogation of FPs and relevant monomers from the PFAS REACH restriction.** In addition, the use of PFAS-based polymerization aids to continue with the manufacture of FPs in the EU should be allowed by the regulators. However, this would be linked to **an industry commitment** to efficiently address the concerns related to the manufacture and purity of the FP products including their processing to products that are placed on the EU market (RMO 3).

b. In parallel, **EU legislation dealing with industrial emissions and waste should be reviewed and updated**, ensuring adequate technical controls are put in place to minimize to the furthest possible extent any risk derived from the disposal of FP products and from articles containing FPs (RMO 4).

C. Fluoropolymers are irreplaceable in many uses without reliable alternatives

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

D. Unpredictable consequences for the critical sectors relying on fluoropolymers

It is expected that any regulatory action that may 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** This could result in the **complete relocation of this industry outside the EU** with significant impacts for the whole fluoropolymer industry and unpredictable consequences for the critical sectors that rely heavily on these materials.

3. FPG position

A. A segmentation of the PFAS should be made

FPG believes that a segmentation of the PFAS family according to known properties rather than a structure-based classification alone is needed for a risk-based regulatory approach. Regulating all PFAS as one homogenous group will result in non-replaceable fluoropolymer substances being banned from critical applications. Therefore, **we advocate for the segmentation of the PFAS family of substances** before performing any grouping-based assessment, **placing environmentally stable compounds such as FPs in a separate category**.

B. An industry with responsible manufacturing at its core

There are environmental concerns derived from the manufacture, use and end-of-life treatment of fluoropolymers. As such, all **FPG Members have committed voluntarily to responsible manufacturing principles** in term of continuously improve and/or develop best available techniques in the manufacturing process, management of environmental emissions, development of R&D programs for the advancement of technologies allowing for the replacement of PFAS-based polymerization aids, and/or the increase recyclability and reuse of its products in line with the objectives of circular economy.

The implementation of the Voluntary Industry Initiative to address concerns related to FPs (RMO 3) will strengthen the already on-going efforts performed by fluoropolymer industry in ensuring responsible manufacturing practices. FPG Members are committed to working with EU authorities to establish and implement the technical actions that may be required to guarantee an adequate control of the risks derived from the manufacture and use of FPs, and remove such risks wherever possible, with a strong emphasis on R&D for a continued improvement of the polymerization process. This will be done with a clear schedule and following transparency principles and agreements to monitor progress.

Kind regards,

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