

Regulatory Management Option Analysis (RMOA) for Fluoropolymers

Fluoropolymers Product Group has commissioned a Regulatory Management Option Analysis (RMOA) for fluoropolymers (FPs) developed by the independent consulting firm Chemservice.

The objective of the study is to evaluate all the possible regulatory options that could be selected to address any concerns related to fluoropolymers, and to identify the most appropriate option to ensure adequate control of risks, while maintaining a proportionate balance in terms of use of FPs on the EU market.

Q&A

What is a Regulatory Management Option Analysis (RMOA)?

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. In this case, PlasticsEurope's Fluoropolymers Product Group (FPG) has commissioned the consulting firm Chemservice to perform an independent RMOA for fluoropolymers (FPs) to ensure scientific facts and evidence are taken into account in the decision-making process.

What was the methodology used by Chemservice?

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.

Which Regulatory Management Options (RMOs) have been analyzed in the report?

A screening of RMOs has been performed in the RMOA, leading to a first selection of the following RMOs that are further evaluated in more detail during the analysis:

- 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.

According to the results of the RMOA, what is the best regulatory option to deal with concerns about FPs?

The result of the RMOA has concluded that the best regulatory option to deal with concerns from FPs would be a combination of RMOs 3 and 4, the reason being that both RMOs are considered to be independent from each other and covering different risk situations.

FPs should be derogated from the PFAS REACH restriction, along with their relevant monomers. Furthermore, the use of polymerization aids should be allowed by regulators to continue with the manufacture of FPs in the EU. These conclusions would have to be linked, however, to an industry commitment to efficiently address the concerns related to the manufacture and purity of the FP products that are placed on the EU market (RMO 3). In parallel, EU legislation dealing with industrial emissions and waste should be reviewed and updated to ensure that 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).

According to the results of the RMOA, what would be the consequences of a full restriction (RMO 1)?

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 application. According to Chemservice, there are no alternatives that can replace the high performance provided by fluoropolymers in “virtually every critical application in which they are used”.

Moreover, 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.

What is the Fluoropolymers Product Group (FPG)'s position?

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.

An essential step to grant the full implementation of RMO 3 is the development of a Voluntary Industry Initiative to address concerns related to FPs. What are your commitments in this area?

All FPG Members have committed voluntarily to responsible manufacturing principles in terms of continuously improving and/or developing the 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 of 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 the 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.